Genius™ Review Station

Operator's Manual

MAN-11700-001 Rev. 002

Genius™
Review Station
Operator's Manual

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
Tel: 1-844-465-6442
1-508-263-2900
Fax: 1-508-229-2795
Web: www.hologic.com

EC REP
Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium

Australian Sponsor:
Hologic (Australia and
New Zealand) Pty Ltd
Suite 302, Level 3
2 Lyon Park Road
Macquarie Park
NSW 2113
Australia
Tel: 02 9888 8000

For Use With Version 1.2.x Software

MAN-11700-001

The Genius™ Digital Diagnostics System is a PC-based and automated imaging and review system for use with ThinPrep cervical cytology sample slides and other slide types. The Genius Digital Diagnostics System, when used with Genius Cervical AI, is intended to help a cytologist or pathologist highlight objects on a slide for further professional review. The Product is not a replacement for professional review. Determination of slide adequacy and patient diagnosis is at the sole discretion of the cytologists and pathologists trained by Hologic to evaluate ThinPrep-prepared slides and/or the pathologists reviewing other slide types as applicable.

Although this guide has been prepared with every precaution to ensure accuracy, Hologic assumes no liability for any errors or omissions, nor for any damages resulting from the application or use of this information.

This product may be covered by one or more U.S. patents identified at www.hologic.com/patent-information

Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

Document Number: AW-32334-001 Rev. 002

8-2025

IVD

Revision History

Revision	Date	Description
AW-32334-001 Rev. 001	7-2025	Reorganize the manual to separate the instructions for reviewing images with the Genius Cervical AI algorithm. Separate the intended use for reviewing with the Genius Cervical AI algorithm from the intended use for reviewing whole slide images. Describe custom case types, new tools for reviewing whole slide images, and related reports.
AW-32334-001 Rev. 002	8-2025	Administrative change

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Contents and Symbols

Contents

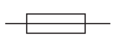
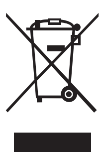
There are three parts to this operator's manual.

- Part 1 describes installation, general use, and care of the Genius Review Station.
- Part 2 contains information specific to the review of ThinPrep™ Pap tests with the Genius Cervical AI algorithm.
- Part 3 contains information specific to the review of digital whole slide images.

Your system configuration may not have all of the options described in this manual. Contact your Hologic representative for more information.

Symbols Used on the Instrument

The following symbols may appear on this instrument.

	Attention - refer to accompanying documents
 hologic.com/ifu	Consult the instructions for use
IVD	*In Vitro* diagnostic medical device
	Fuse (Not user-accessible)
	Waste Electrical and Electronic Equipment Do not dispose in municipal waste Contact Hologic for disposal of the instrument
SN	Serial number
	Manufacturer
	Date of manufacturer
EC REP	Authorized representative in the European Community

REF	Catalogue number
|	On (Power switch)
○	Off (Power switch)
⏻	On/Off, Standby mode
SS	USB 3 port (computer)
	Ethernet port (computer)
Made in USA	Made in USA
USA | CANADA	Information is applicable only in the USA and Canada
USA only	Information is applicable only in the USA
CE	Product meets the requirements for CE marking in accordance with EU-IVD Regulation 2017/746

Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician, or any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device and are trained and experienced in the use of the product.
UK CA	UK Conformity Assessed (Great Britain)
	Importer
	Country of manufacture

Refer to the documentation provided with the monitor for descriptions of other symbols used on the monitor.

Part 1

Part 1.

Installation, General Use and Care of the Genius™ Review Station

There are three parts to this operator’s manual.

- Part 1 describes installation, general use, and care of the Genius Review Station.
- Part 2 contains information specific to the review of ThinPrep™ Pap tests with the Genius Cervical AI algorithm.
- Part 3 contains information specific to the review of digital whole slide images.

Your system configuration may not have all of the options described in this manual. Contact your Hologic representative for more information.

Revision History

Revision	Date	Description
AW-32336-001 Rev. 001	7-2025	Initial release of instructions exclusive to the installation, general use and care of the Genius Review Station.

Document Number: AW-32336-001 Rev. 001

7-2025

Table of Contents

Table of Contents

1. Introduction

1. Introduction

Chapter One

Introduction

SECTION A OVERVIEW

The Genius Review Station is one component of the Genius Digital Diagnostics System. The Review Station is a computer with a specific monitor for diagnostic review of images. The computer runs a software application that is used to launch the Review Station software application in a captive browser window. The Review Station web application is hosted by the Genius Image Management Server (IMS). A Review Station is connected to an Image Management Server, which provides slide data for review and receives updates based on the review. One or more Review Stations can be associated with an Image Management Server.

The Review Station is to be used by a cytologist (CT) and a pathologist to screen digital images of microscope slides that have been imaged on the Genius Digital imager. Digital images are available for a CT or pathologist to review on the Review Station. Genius Cervical AI assists the CT or pathologist with review of ThinPrep Pap test images created on the Digital Imager.

Using a computer mouse and computer keyboard, the CT or pathologist is able to screen the case and mark objects of interest. The Review Station is networked to the Image Management Server and at review, slide data is retrieved from a slide database maintained by the Image Management Server. At the conclusion of a slide review, the slide data is stored in the database.

The Review Station consists of:

The **Monitor**, a medical-grade, high-resolution computer display screen provided by Hologic, with resolution sufficient to view the images at the images' full captured resolution.

The **Computer** that hosts the system application, a **keyboard** and a **mouse**. An optional barcode scanner can also be used with the computer.

Figure 1-1-1 Genius Review Station

Note: The computer shown in photos and illustrations in this operator's manual may differ from the appearance of the computer used in your laboratory.

SECTION B THE GENIUS DIGITAL DIAGNOSTICS SYSTEM PROCESS

Slides that have been prepared for screening are loaded into slide carriers which are placed into the Digital Imager. The operator uses a touch screen on the Digital Imager to interact with the instrument via a graphic, menu-driven interface.

A slide ID reader scans the slide's accession ID and locates the scan area. Then the Digital Imager scans a designated area of the microscope slide, creating a whole slide image.

The slide image data, the accession ID and its associated data record are transmitted to the Image Management Server, and the slide is returned to its slide carrier.

The Image Management Server acts as the central data manager for the Genius Digital Diagnostics System. As slides are imaged by the Digital Imager and reviewed at the Review Station, the server stores, retrieves and transmits information based on the case ID.

The cytologist (CT) or pathologist reviews cases at the Review Station. The Review Station is a computer running a Review Station software application, with a monitor suitable for diagnostic review of a whole slide image. The Review Station is connected to a keyboard and mouse. When a valid case accession ID has been identified at the Review Station, the server sends the whole slide image for that ID, and the CT or pathologist is presented with the whole slide image for review. If your product configuration includes an image analysis algorithm, the algorithm analyzes the images before the images display at the Review Station.

The CT or pathologist has the option to electronically annotate the image, mark objects of interest and include the annotations and comments in the case review. The reviewer always has the option to move and zoom through a view of the whole slide image, which provides complete freedom to move any portion of the specimen on the slide into the field of view for examination.

SECTION C SPECIMEN PREPARATION

The Review Station is used to review images and slide data from specimens that have been scanned on a Genius Digital Imager.

Refer to the operator's manual for the Digital Imager for information on using the Digital Imager.

SECTION D

REVIEW STATION TECHNICAL SPECIFICATIONS

Overview of Components

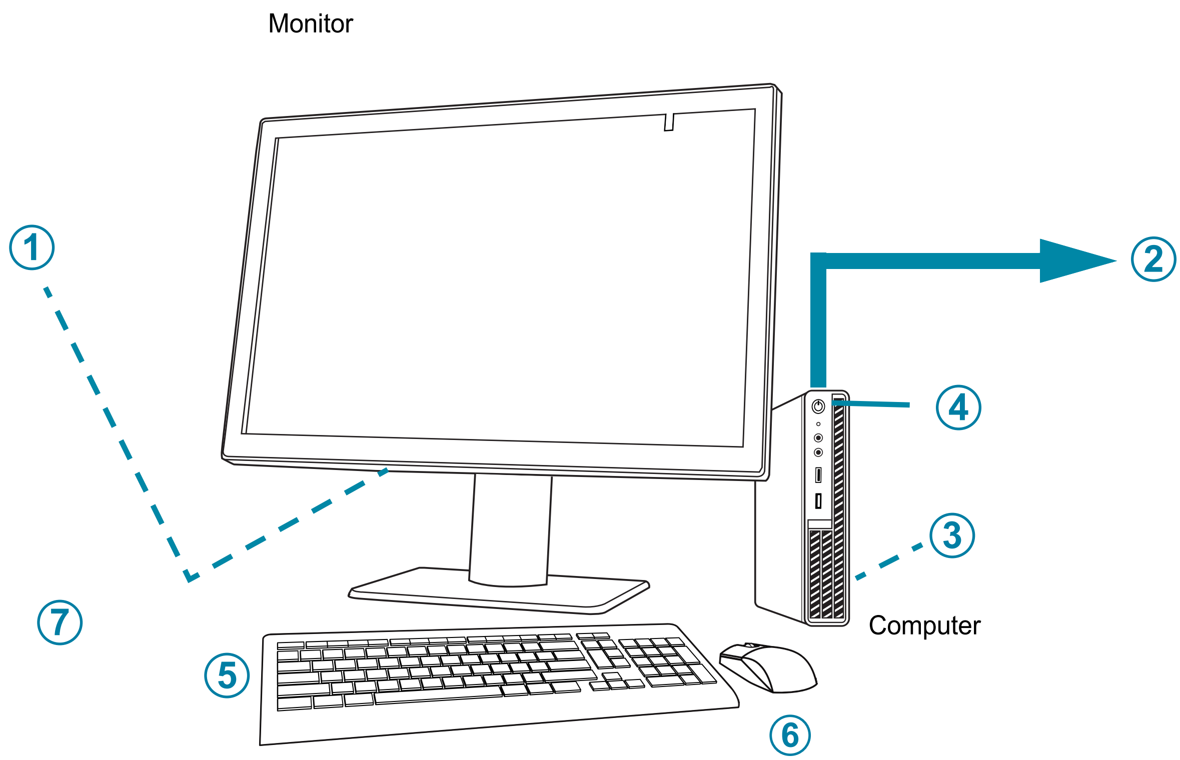


Figure 1-1-2 Review Station components

Key to Figure 1-1-2	
1	Monitor power button, under the connector compartment cover
2	Connection to the Image Management Server (depicted in concept in Figure 1-1-2)
3	Computer graphics processor unit (GPU) card, installed in the computer

Key to Figure 1-1-2	
4	Computer power button, location varies by computer model
5	Computer keyboard
6	Computer mouse
7	Barcode scanner (optional, not shown in Figure 1-1-2)

Review Station Monitor Dimensions

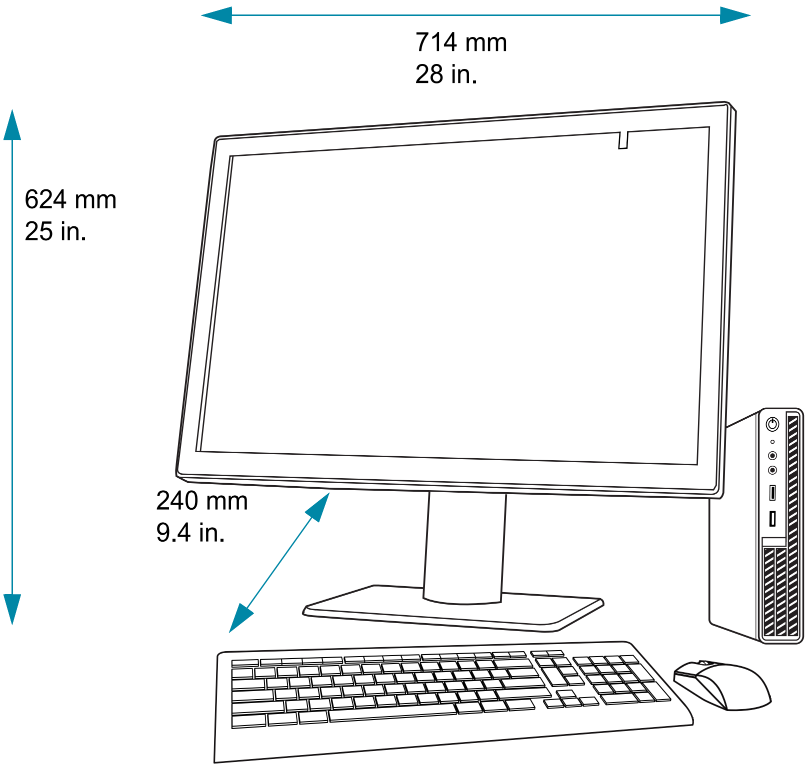


Figure 1-1-3 Review Station monitor dimensions

Weight

The Review Station monitor by itself weighs approximately 17.7 kg (39 lbs.).

Review Station Computer Specifications

Depending on the configuration in your laboratory, the computer may be supplied by Hologic with the graphics card already installed. The minimum specifications for the Review Station computer are:

Hardware:

- X86 processor, Intel™ Core™ i7 2.4GHz (4C, 8T), or faster
- 16GB DDR4 Memory or greater
- 256 GB Drive or greater
- 1Gb or faster network connection (recommended)
- An available PCIe Gen3 x16 slot in the PC for the Barco GPU card

- Keyboard and Mouse

Operating system:

- Window 10 – 64Bit

Operating temperature range
Refer to the documentation provided with the monitor and computer.

Non-operating temperature range
Refer to the documentation provided with the monitor and computer.

Operating humidity range
Refer to the documentation provided with the monitor and computer.

Non-operating humidity range
Refer to the documentation provided with the monitor and computer.

Pollution degree
Refer to the documentation provided with the monitor and computer.

Altitude
Refer to the documentation provided with the monitor and computer.

Atmospheric pressure
Refer to the documentation provided with the monitor and computer.

Sound levels
Refer to the documentation provided with the monitor and computer.

Power

Refer to the documentation provided with the monitor and computer for power specifications.

Fuses

Refer to the documentation provided with the monitor and computer for power specifications. Fuses are not user-accessible and are not intended to be changed by users. Contact Technical Support if the instrument does not operate. Do not remove any covers on the components other than the monitor's connector compartment cover.

Safety, EMI and EMC Standards

Refer to the documentation provided with the monitor and computer for safety, EMI and EMC standard information.

SECTION E INTERNAL QUALITY CONTROL

The Review Station functions as a viewer for data stored on the Image Management Server. The Review Station continuously checks for a proper connection to the server. If the connection to the server is broken, a message is shown on the Review Station. The Review Station cannot be used until the connection is reestablished.

The combination of the medical-grade monitor, the display controller (GPU), and system software provide consistent image quality. The monitor uses the front sensor to perform an automated color compliance test weekly and an automated calibration twice per year.

SECTION F GENIUS REVIEW STATION HAZARDS

The Review Station is intended to be operated in the manner specified in this manual. Be sure to review and understand the information listed below in order to avoid harm to operators and/or damage to the instrument.

If this equipment is used in a manner not specified by the manufacturer, then the protection provided by the equipment may be impaired.

The monitor and graphics card for the Review Station are those supplied by Hologic specifically for the Genius Digital Diagnostics System. They are required for proper performance of the system and cannot be substituted.

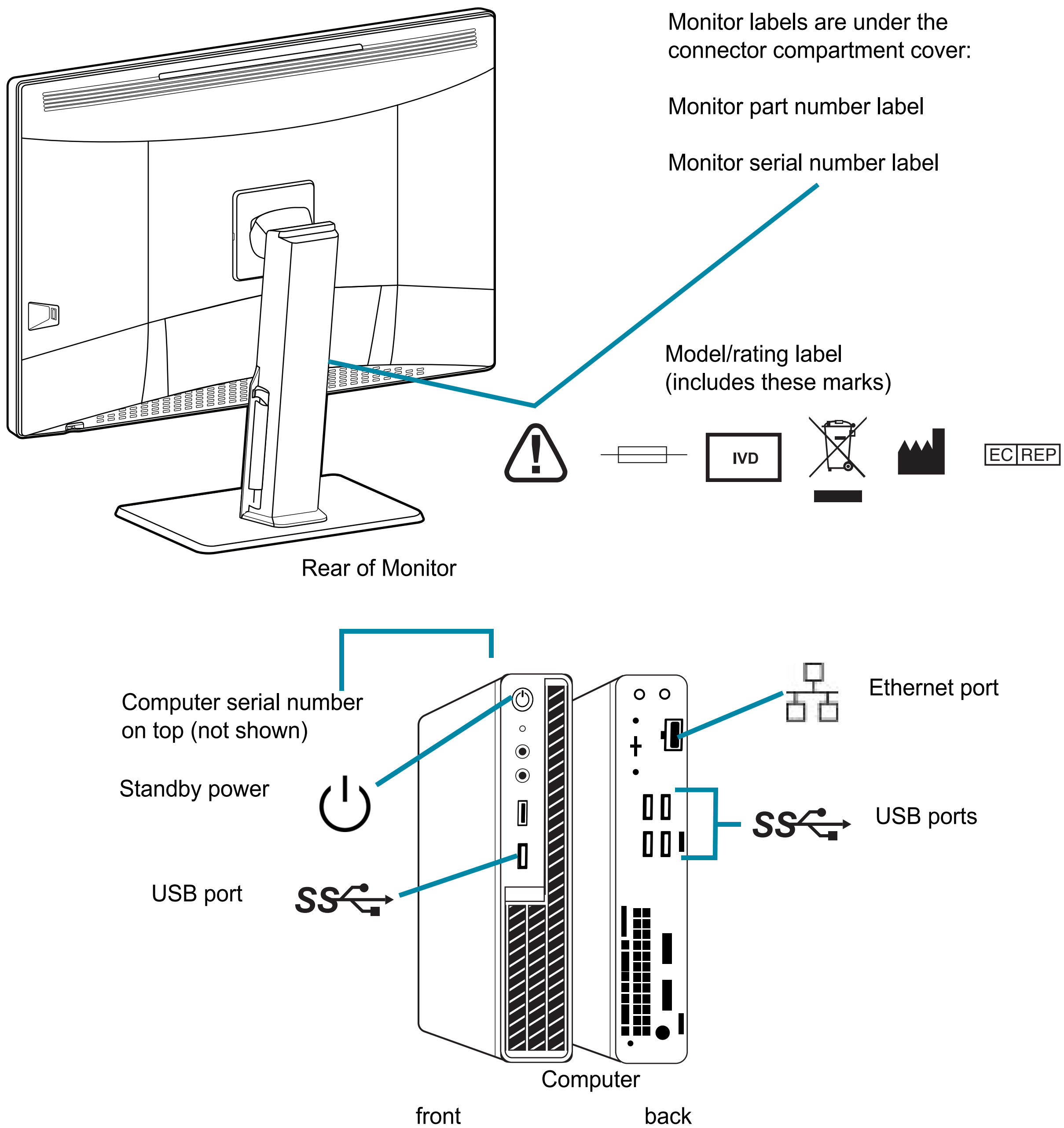
If any serious incident occurs related to this device or any components used with this device, report it to Hologic Technical Support and the competent authority local to the user and/or patient.

Warnings, Cautions and Notes

The terms **WARNING**, **CAUTION** and ***Note*** have specific meanings in this manual.

- A **WARNING** advises against certain actions or situations that could result in personal injury or death.
- A **CAUTION** advises against actions or situations that could damage equipment, produce inaccurate data or invalidate a procedure, although personal injury is unlikely.
- A ***Note*** provides useful information within the context of the instructions being provided.

Location of Labels



Note: The number and exact location of ports, labels and buttons may be different, depending on the computer model you have.
If the computer is not supplied by Hologic, the serial number may be in a different location.

Figure 1-1-4   Location of labels on the instrument

Warnings

WARNING: Service Installation Only. This instrument is to be installed by service personnel trained by Hologic.

WARNING: Grounded Outlet. To ensure safe operation of the instruments, use a three-wire grounded outlet.

Limitations

The monitor and graphics card for the Review Station are those supplied by Hologic specifically for the Genius Digital Diagnostics System. They are required for proper performance of the system and cannot be substituted.

SECTION G DISPOSAL

Disposal of the Device

Please contact Hologic Service. (Refer to Chapter 6, Service Information.)

Do not dispose in municipal waste.

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
1-508-263-2900
Fax: 1-508-229-2795
Web: www.hologic.com

EC REP

Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium

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2. Installation

Chapter Two

Installation

WARNING: Service Installation Only

SECTION A GENERAL

The Genius Review Station must be installed by qualified service personnel trained by Hologic. When installation is complete, the service personnel trains the operator(s), using the operator's manual as the training guide.

The Review Station should only be used by personnel who have been trained by Hologic or by organizations or individuals designated by Hologic.

SECTION B ACTION UPON DELIVERY

Inspect the packing cartons for damage. Report any damage immediately to the shipper and/or Hologic Technical Support as soon as possible. (Refer to Chapter 6, Service Information.)

Leave the instrument in the packing cartons for service personnel trained by Hologic.

Store the instrument in a suitable environment until installation (cool, dry area).

Note: The monitor manufacturer and the computer manufacturer provide documentation for those components. Refer to that for technical specifications. Do not discard.

SECTION C

PREPARATION PRIOR TO INSTALLATION

Pre-Installation Site Assessment

A pre-installation site assessment is performed by qualified service personnel trained by Hologic. The site assessment requires networking considerations with your laboratory's IT (Information Technologies) personnel. Be sure to have prepared any and all site configuration requirements as instructed by the qualified service personnel trained by Hologic.

The site must have a secure firewall and strong network security for devices connected to the Image Management Server and Review Station computer.

In addition to the networking requirements, the Review Station will require two outlets to power the instrument. Make sure there is adequate electrical supply within 2 meters of the instrument. The monitor and computer must be plugged into a three-prong grounded outlet. For the computer, disconnection from the power supply source is by removal of the power cord. For the monitor, disconnection from the power supply source is by unplugging the monitor from the wall outlet.

The keyboard, mouse, and optional barcode scanner each connect via USB to the Review Station computer.

Note: Do not position the instrument so that it is difficult to disconnect the power cords.

Computer Preparation

Depending on the configuration in your laboratory, the computer may be supplied by Hologic with the required graphics card already installed, or Field Service personnel trained by Hologic may install the required graphics card in a computer which meets the required specifications.

Field Service personnel trained by Hologic will need access to the computer to install the Review Station.

Location

The Review Station monitor 'foot print' is approximately 714 mm wide x 240 mm, and <624 mm high (28 in. x 9.4 in., and < 25 in. high). Make sure there is adequate desk space for using a keyboard and mouse. (See Figure 1-2-1.) The monitor is approximately 17.7 kg (39 pounds). Be sure the table or bench can support the weight of the monitor and computer.

CAUTION: Route connections carefully to avoid pinching the cables. To avoid tripping over, or disconnecting cabling, do not place cabling near foot traffic.

The Review Station should be placed on a flat, sturdy surface. Consider glare from other light sources. Do not restrict normal air flow around the instrument when it is powered on.

If the system is configured with the computer located separately from the monitor, be sure the computer is in a dust-free area, with easy access to the power switch.

Genius Event Bridge Messaging

As an option, depending on the configuration in your lab, Field Service personnel trained by Hologic may be involved in setting up Genius Event Bridge Messaging, to facilitate connectivity with applications such as a Laboratory Information System (LIS).

Figure 1-2-1 A Typical Review Station configuration

Security

Medical device security is a shared responsibility between stakeholders, including healthcare facilities, patients, providers, and manufacturers of medical devices. Overall, please keep in mind that all employees are responsible for the integrity, confidentiality, and availability of the data being processed, transmitted, and stored on the system. Hologic recommends that each laboratory works directly with your existing information systems and security staff to determine the most appropriate actions to take based on the information technology (IT) infrastructure at your site.

Cybersecurity safeguards

Hologic incorporates secure design principles into the product development life cycle to minimize cybersecurity risks.

Genius Review Station software may come preinstalled on hardware provided by Hologic or hardware provided by the customer.

Installation of third-party software beyond antivirus software is not officially supported by Hologic and may adversely affect system performance. Intrusion detection and/or system management software may be installed at customer's discretion.

The use of antivirus software is recommended on the Review Station.

Operating system patching

The Review Station software runs on Microsoft Windows (various editions). Customers may implement Windows updates as desired. Customers should schedule updates that do not conflict with clinical operations or predefined scheduled tasks. It is recommended to have a rollback strategy when applying patches.

Cybersecurity updates

Hologic continually evaluates software updates, security patches, and the effectiveness of the implemented security safeguards to determine if updates are needed to mitigate emerging threats. Hologic will provide validated software updates and patches throughout the lifecycle of the medical device to assure its continued safety and effectiveness.

SECTION D MOVING THE REVIEW STATION

CAUTION: Read and understand this section before moving the Review Station.

The Review Station should be handled with care. If the system must be moved, the monitor and computer must be disconnected from one another, moved separately and reconnected at the new location.

Before disconnecting any of the components, be sure to observe how they are originally connected. The connectors must go in the exact ports specified.

CAUTION: The instrument weighs 17 kg (39 lbs.) and should be moved by at least two people.

Figure 1-2-2 Moving the Review Station

SECTION E

CONNECTING REVIEW STATION COMPONENTS

The Genius Review Station components must be fully assembled before turning on the power and using the instrument. Service personnel trained by Hologic will assemble the instrument:

- Monitor
- Computer
- Computer graphics processing unit (GPU, graphics card)
- Computer mouse and keyboard
- Barcode scanner (optional)
- Connection to the Image Management Server

Monitor - a medical-grade, high-resolution, large-format computer display screen with a calibration sensor

Computer graphics processing unit (GPU, graphics card) - allows the computer to display slide images on the monitor

Computer - hosts the desktop application that is used to run the Review Station.

Connection to the Image Management Server - provides communication of slide image data from the Image Management Server to the Review Station computer. The server holds the database of slide image data, and the server hosts the communication between the components of the Genius Digital Diagnostics System.

CAUTION: Only use Hologic-supplied monitor and GPU.

CAUTION: Do not change any of the screen display settings on the monitor. The Review Station is designed to present images on the monitor as installed by service personnel trained by Hologic.

The computer may be supplied by Hologic, or a laboratory may supply its own computer. Field Service personnel trained by Hologic install the computer graphics card as part of the Review Station installation. Laboratory-supplied computers must meet or exceed minimum specifications for the Review Station. (Refer to "Review Station Computer Specifications" on page 1.6).

A network connection using a minimum of cat 6 cabling connects the Review Station to a networking device. (See Figure 1-1-4.) The networking device enables communication to the Genius Image Management Server.

Note: It is the responsibility of the customer to purchase and install the necessary quantities and lengths of Ethernet cable required for networking the Review Station to the system. Installation configuration should be planned prior to instrument installation.

Adjusting Monitor Height and Tilt

The Review Station monitor can be raised and lowered to suit the reviewer's preference. The monitor can be tilted to suit the reviewer's preference. Refer to the instructions provided by the monitor manufacturer for more information.

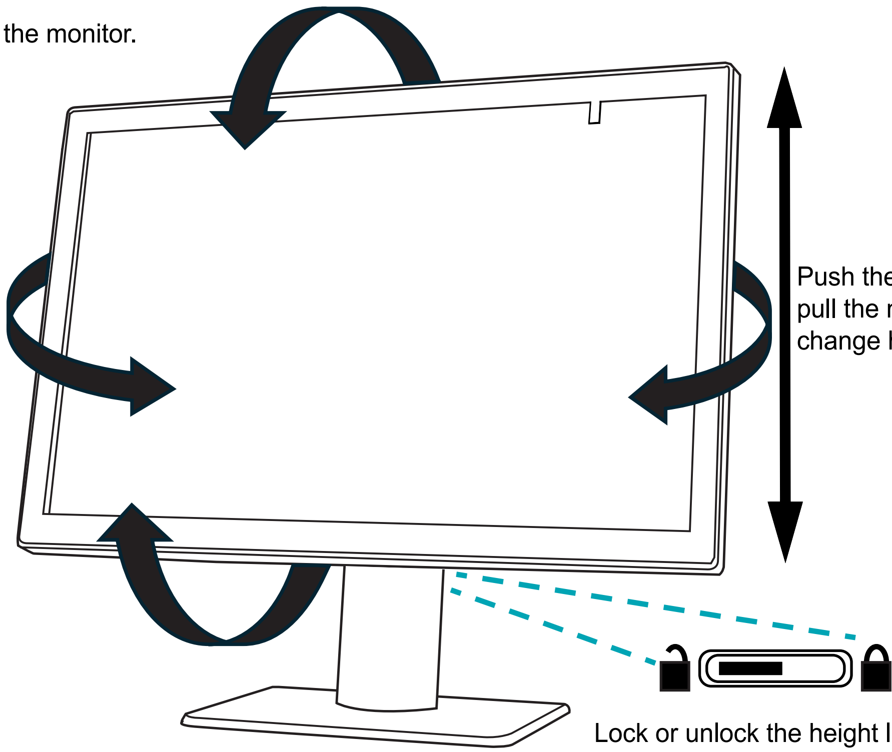


Figure 1-2-3 Adjust height or tilt

SECTION F POWER ON THE REVIEW STATION

WARNING: Grounded Outlet

To ensure safe operation of the instrument, use a three-wire grounded outlet.

Note: All power cords must be plugged into a grounded outlet. Disconnection from the power supply source is by removal of the power cord.

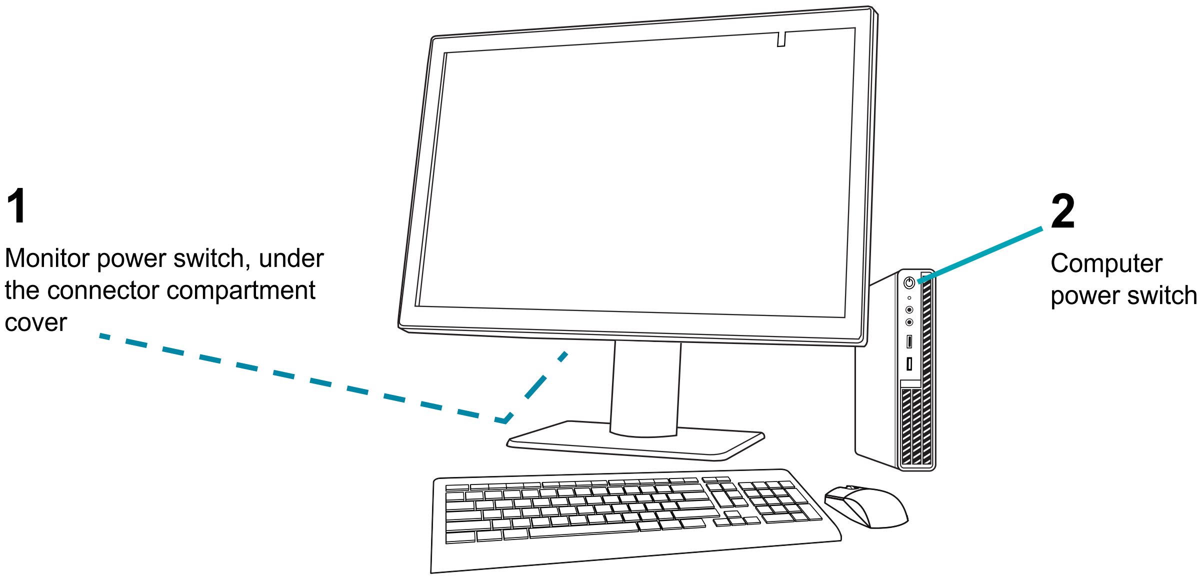


Figure 1-2-4 Power switches

1. Press the power button on the computer. Allow the computer and monitor to initialize. Log in to Windows, if required at your site. Double-click the "Genius Review Station" icon on the computer desktop to launch the Review Station software.

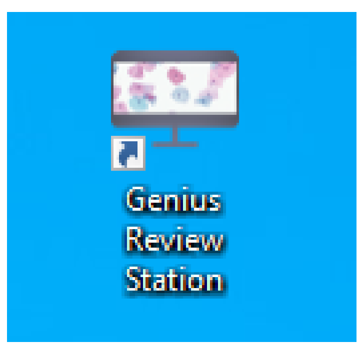


Figure 1-2-5 Launch the application

2. The application launches.

Figure 1-2-6 Launch the Review Station software

There are two specifications that need to be set or confirmed the first time the Review Station is set up. These do not need to be used every time the Review Station is launched to access cases from one Image Management Server. To access cases from a different Image Management Server, a different IP address must be entered at the Review Station. The IP address and network speed information are helpful in troubleshooting communication issues.

IP address and port

1. Select **Set Server Connection**.

2. If the IP address and port fields are empty, enter the IP address and port for the Image Management Server. If the Review Station has previously connected with the Image Management Server, the IP address and port used the last time are shown.

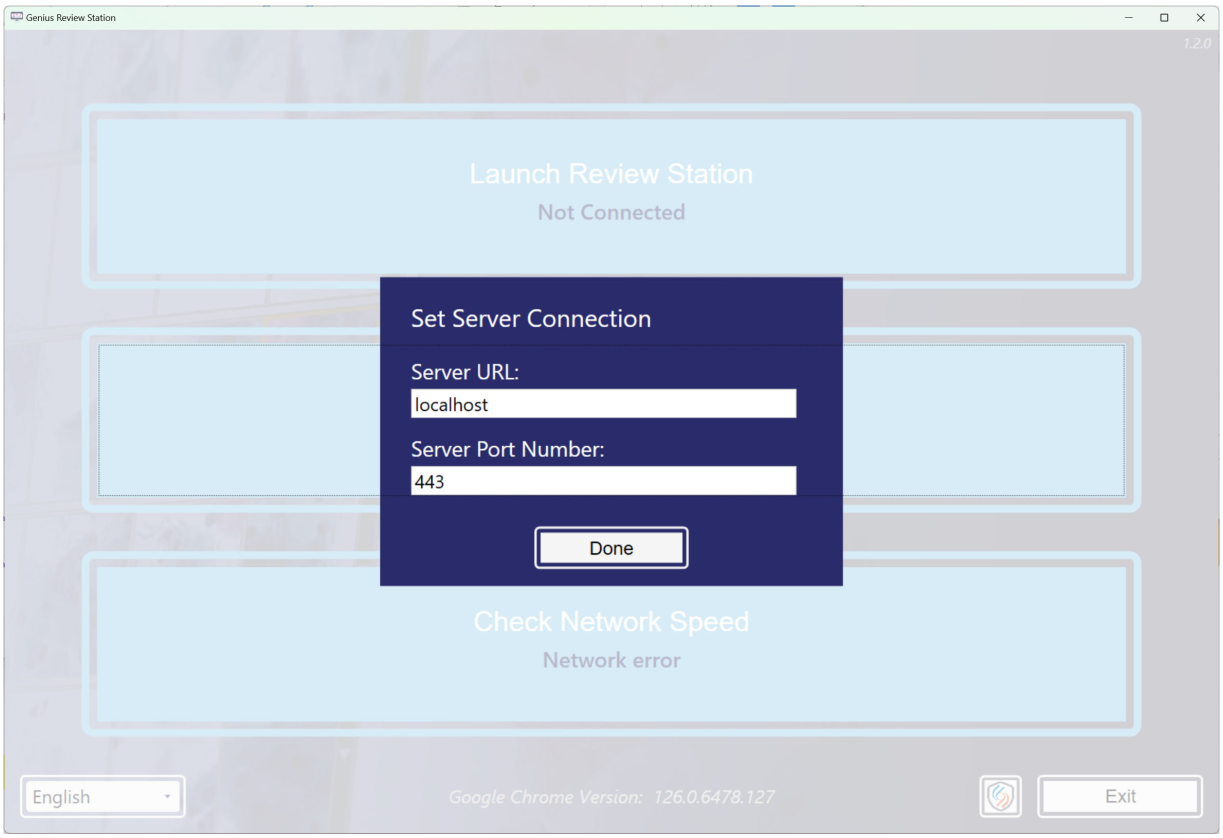


Figure 1-2-7 Enter server IP address

Network speed

1. To check the speed of the connection to the Image Management Server, select **Check Network Speed**.
2. The Review Station software checks the speed of the connection to the Image Management Server and displays the speed in the box.

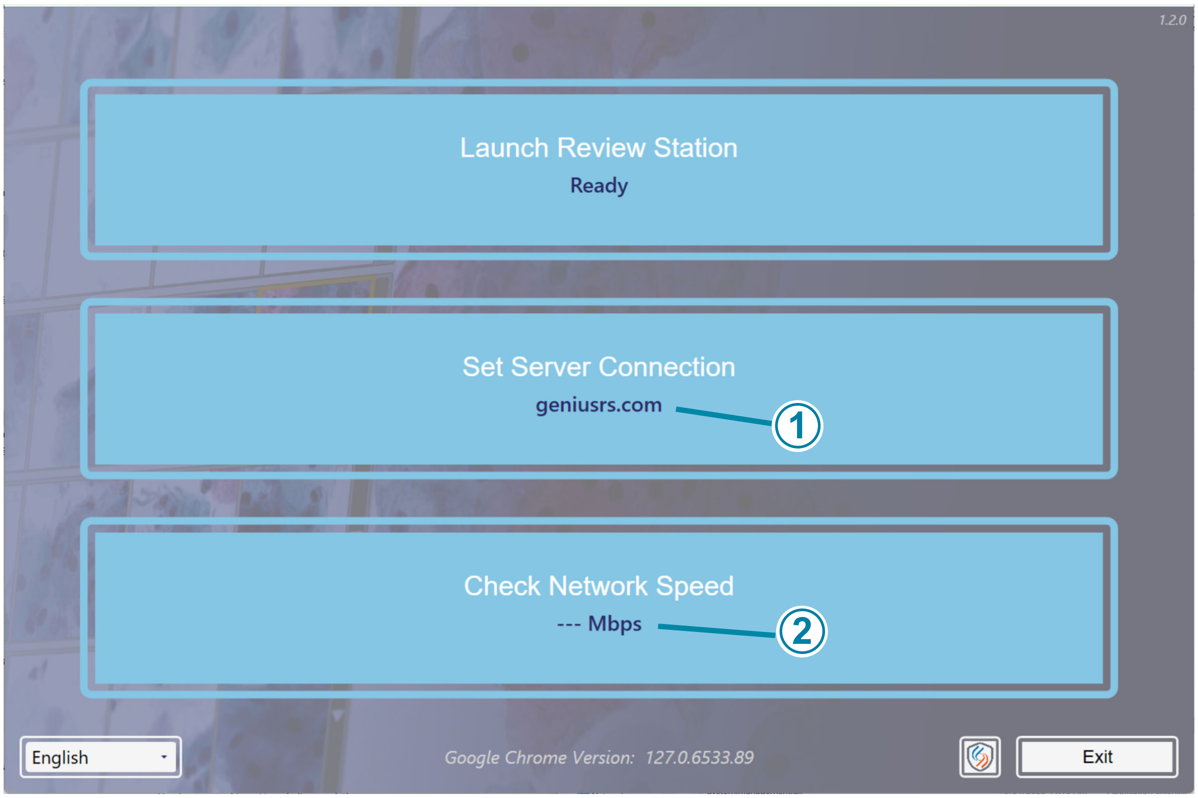


Figure 1-2-8 Review Station startup screen, example

Key to Figure 1-2-8	
1	IP address
2	Network speed

When the Review Station is connected to a network, the screen displays the word, “Ready.” Select **Launch Review Station** to launch the Review Station application.

Next, log in to the application with a username and password. (Refer to “Login screen” on page 3.10.)

Figure 1-2-9 Login screen

The Review Station is ready for use when the Dashboard displays (Figure 1-2-10).

Figure 1-2-10 Review Station Dashboard

<table><tr><td>SECTION
G</td><td>STORAGE AND HANDLING - POST INSTALLATION</td></tr></table>

The Review Station may be stored in the location where it was installed. When it is not in use, the Review Station can be left with the power on. Follow your laboratory's policy for handling computer equipment.

SECTION H

SYSTEM SHUTDOWN

Normal Shutdown

Figure 1-2-11 Exit the application

Key to Figure 1-2-11	
1	**Exit**. Click the arrow next to your name to see the **Exit** command.

It is important to shut down the system in the correct order.

To shut down the Review Station:

1. Click on your name in the lower portion of the menu bar, on the left, to exit the Review Station application.

   Note: To exit the Review Station application from the Login screen, click the "x" in the upper right of the screen.

2. Next, select **Exit** in the window.

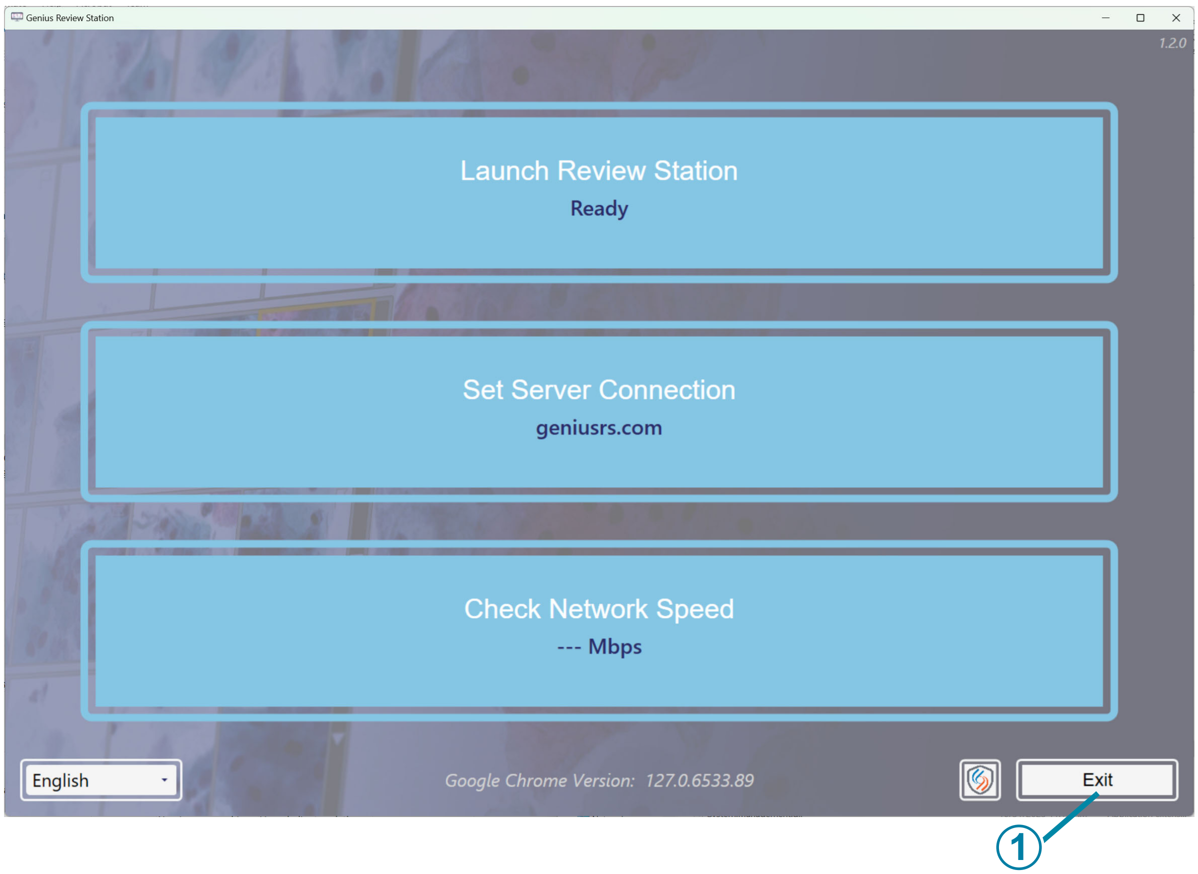


Figure 1-2-12 Exit the launch application

Key to Figure 1-2-12	
1	**Exit** button

3. Shut down from Windows. The computer and monitor will shut down.
4. If necessary, to completely disconnect from the power supply source, unplug the power cords from the outlets.

Extended Shutdown

If the instrument is to be shut down for an extended amount of time or be taken out of service, shut down as described in Normal Shutdown. Completely remove power by unplugging the monitor power cord and the computer cord from the power outlet.

3. User Interface

Chapter Three

User Interface

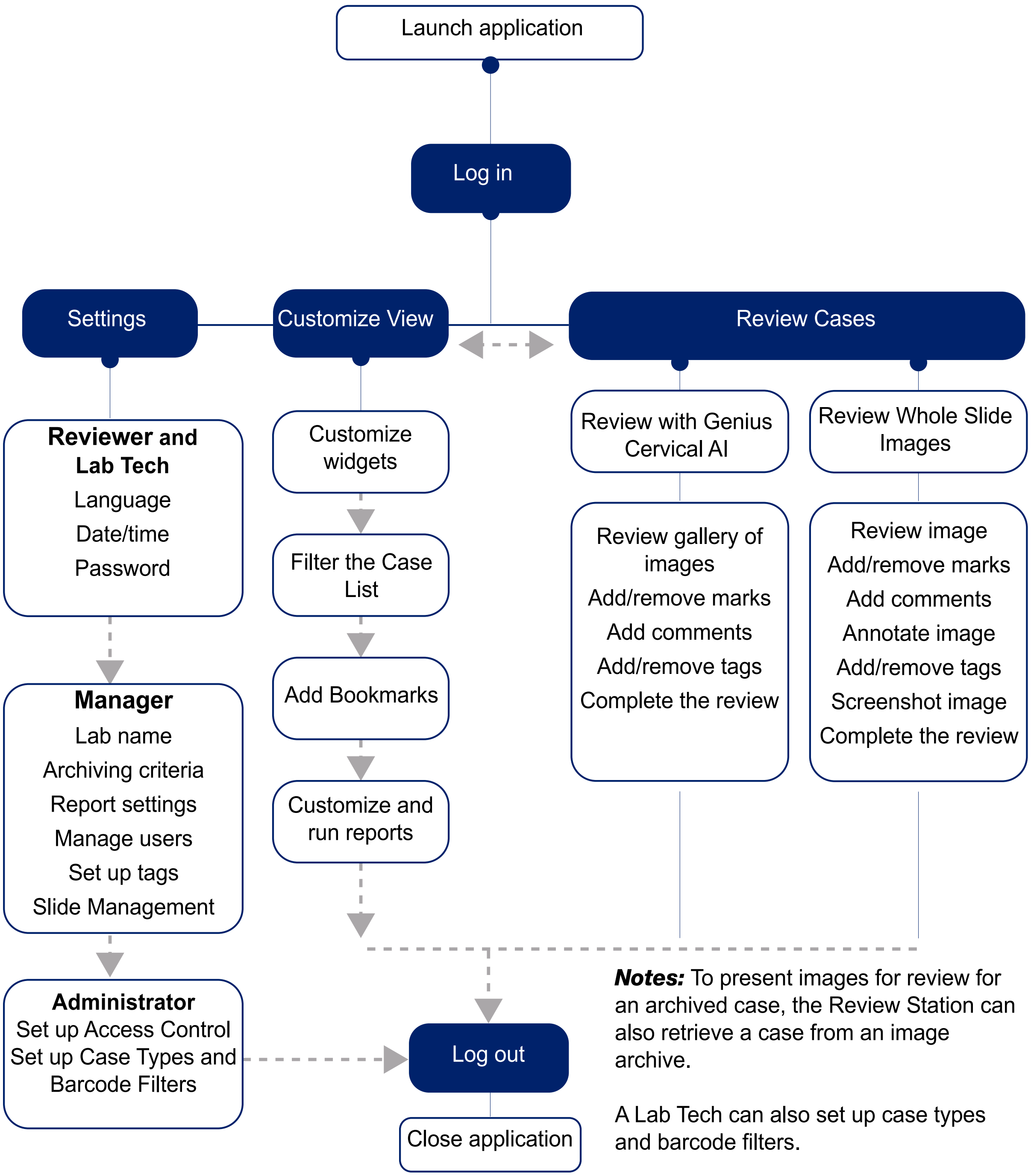
SECTION A OVERVIEW

The Genius Review Station is used to review images created from the Genius Digital Imager.

The user can set some user preferences for the Genius Review Station. The user interacts with the system via a keyboard, mouse, and optional barcode scanner.

There are four user roles for the Review Station: a laboratory technician (lab tech) role, a reviewer role, a manager role and an administrator role. The different user roles have different permissions for different functions. These instructions describe all of the Review Station features.

Refer to Figure 1-3-1 for an overview of the workflow options.



Notes: To present images for review for an archived case, the Review Station can also retrieve a case from an image archive.

A Lab Tech can also set up case types and barcode filters.

When Access Control Filters are used, Slide Management is for an Administrator.

Figure 1-3-1 Overview of Review Station functions

Table 3.1 lists the features of the Review Station available with the different user roles. This chapter introduces the user interface modules of the Review Station and describes the usage of each. It is recommended that users acquaint themselves with the material in this chapter before operating the platform.

The content found in this chapter:

These instructions describe the user interface in the order that the features appear at the Review Station. Laboratory groups with a site that serves as an imaging hub for satellite review sites should consider setting up Access Control Filters before setting up users and other settings, such as tags. Refer to “Access Control Filters” on page 3.42.

Before imaging slides other than ThinPrep Pap tests at the Digital Imager, Case Types must be set up on the Review Station. Refer to “Case Types” on page 3.41.

Table 3.1 Permissions by User Role

	Reviewer	Manager	Adminis-trator	Lab Tech
Log in to a Review Station	✓	✓	✓	✓
Change your own password	✓	✓	✓	✓
Customize dashboard widgets	✓	✓	✓	✓
Set language, date and time	✓	✓	✓	✓
Set up and use bookmarks	✓	✓	✓	✓
Tag cases in the case list	✓	✓	✓	✓
Tag cases during case review	✓	✓	✓	✓
Multi-select cases in the case list	✓	✓	✓	✓
Log in to a Review Station from a Digital Imager	✓	✓	✓	✓
Delete an alert sent to you only	✓	✓	✓	✓
Run reports of Imager System errors	✓	✓	✓	✓
Run slide event reports	✓	✓	✓	✓
Run slide data reports	✓	✓	✓	✓
Set up and run custom reports	✓	✓	✓	✓

✓	Feature is available for this user role.
	Feature is available for this user role. Information is limited by access control filters.
	A lab must have a user with an Administrator role for this feature.
	A manager has this role if the lab does not use access control filters.
	A user with this role cannot perform this action, or performing the action yields no results.

Table 3.1 Permissions by User Role

	Reviewer	Manager	Adminis-trator	Lab Tech
Run system usage reports	✓	✓	✓	✓
Turn on and turn off SecureLink access to your Review Station	✓	✓	✓	✓
Review cases	⧩	⧩	✓	Read-only
View a Review Station case from a Digital Imager	Read-only	Read-only	Read-only	Read-only
Filter and search in the case list	⧩	⧩	✓	⧩
Run reports of informational messages	⧩	⧩	✓	⧩
Run CT workload reports for your workload and history (run reports about yourself)	✓	✓	✓	⊘
Run reviewer workload reports for your workload and history (run reports about yourself)	✓	✓	✓	⊘
Include data about yourself in a widget	✓	✓	✓	⊘
Set maximum number of entries per report	⊘	✓	✓	⊘
Set up new tags for the lab to use	⊘	✓	✓	⊘
Reclaim an in-progress case for yourself	⊘	⧩	✓	⊘
Delete a case that has not been reviewed	⊘	⧩	✓	✓
Reset an in-progress case to the new status	⊘	⧩	✓	⊘

✓	Feature is available for this user role.
⧩	Feature is available for this user role. Information is limited by access control filters.
	A lab must have a user with an Administrator role for this feature.
	A manager has this role if the lab does not use access control filters.
⊘	A user with this role cannot perform this action, or performing the action yields no results.

Table 3.1 Permissions by User Role

	Reviewer	Manager	Adminis-trator	Lab Tech
Reset other user's password	⊘	▼	✔	⊘
Run CT workload reports for several CTs	⊘	▼	✔	⊘
Run reviewer workload and history reports for several reviewers	⊘	▼	✔	⊘
Control user access within an access control filter	⊘	▼	✔	⊘
Include data about others in a widget	⊘	▼	✔	⊘
Send an alert (not a password-reset request)	⊘	▼	✔	⊘
Set the name of the lab	⊘	👤	✔	⊘
Set archiving settings	⊘	👤	✔	⊘
Set slide management settings	⊘	👤	✔	⊘
Change or delete tags for the lab to use	⊘	👤	✔	⊘
Run user account history reports	⊘	👤	✔	⊘
Set up new users, with usernames and passwords. Deactivate defunct users.	⊘	▼ 👤	✔	⊘
Delete alerts sent to all administrators	⊘	⊘	✔	⊘
Set up custom case types	⊘	⊘	✔	✔
Set up access control filters	⊘	⊘	🖥	⊘

✔	Feature is available for this user role.
▼	Feature is available for this user role. Information is limited by access control filters.
🖥	A lab must have a user with an Administrator role for this feature.
👤	A manager has this role if the lab does not use access control filters.
⊘	A user with this role cannot perform this action, or performing the action yields no results.

Table 3.1 Permissions by User Role

	Reviewer	Manager	Adminis-trator	Lab Tech
Run scan profile history usage reports	⊘	⊘	♟	⊘
Turn on and turn off Genius Event Bridge Messaging	⊘	⊘	♟	⊘
Turn on and turn off SecureLink access to a Genius Image Management Server	⊘	⊘	♟	⊘

✔	Feature is available for this user role.
⏷	Feature is available for this user role. Information is limited by access control filters.
♟	A lab must have a user with an Administrator role for this feature.
👤	A manager has this role if the lab does not use access control filters.
⊘	A user with this role cannot perform this action, or performing the action yields no results.

SECTION B LOG IN

Normal Login

1. From the Windows desktop, double-click on the icon for "Genius Review Station", if it is not already running.

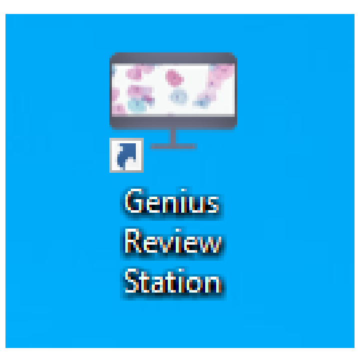


Figure 1-3-2 Launch the application from the computer desktop

2. The application launches.

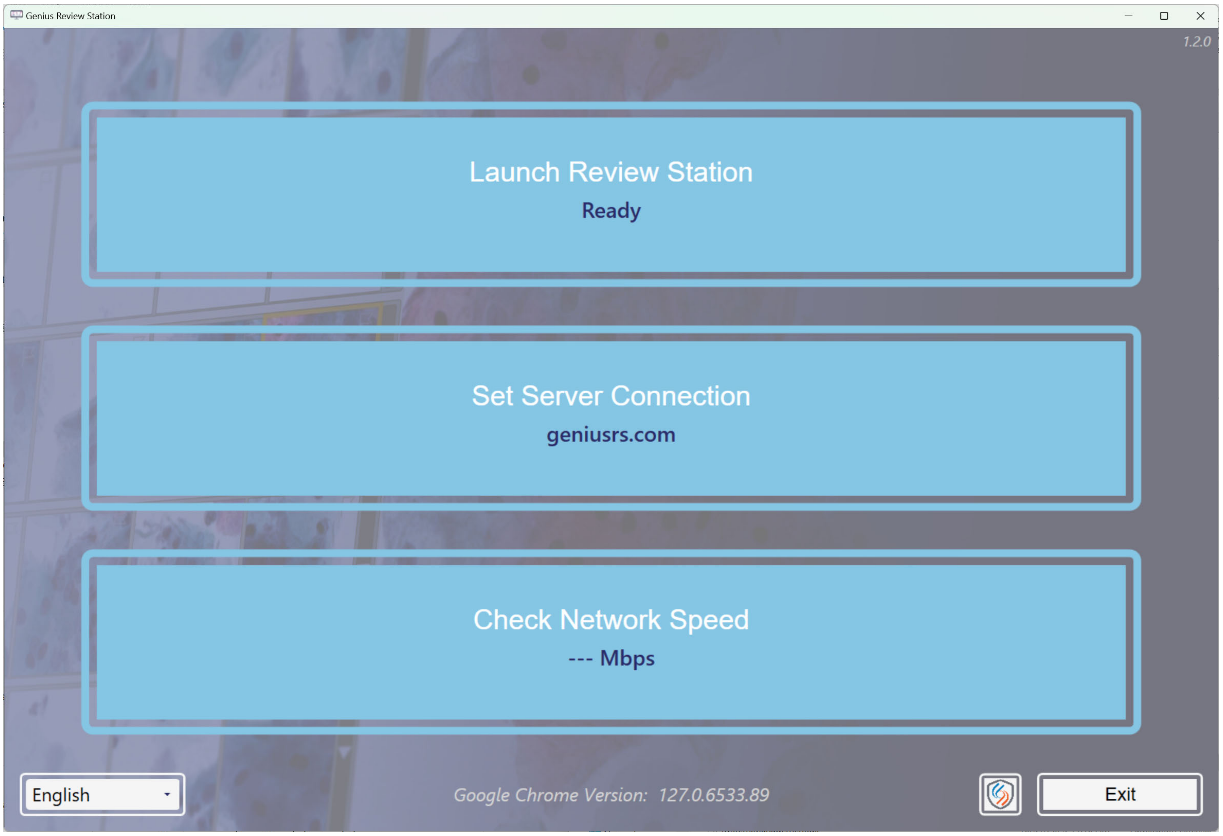


Figure 1-3-3 Launch the Review Station software

- If the screen display is in another language, pick the name of your language from the list in the lower left. The launch screens for the Review Station retain the language setting last used.

If more than one language is spoken in your lab, the language may need to be reset for the Login screen.

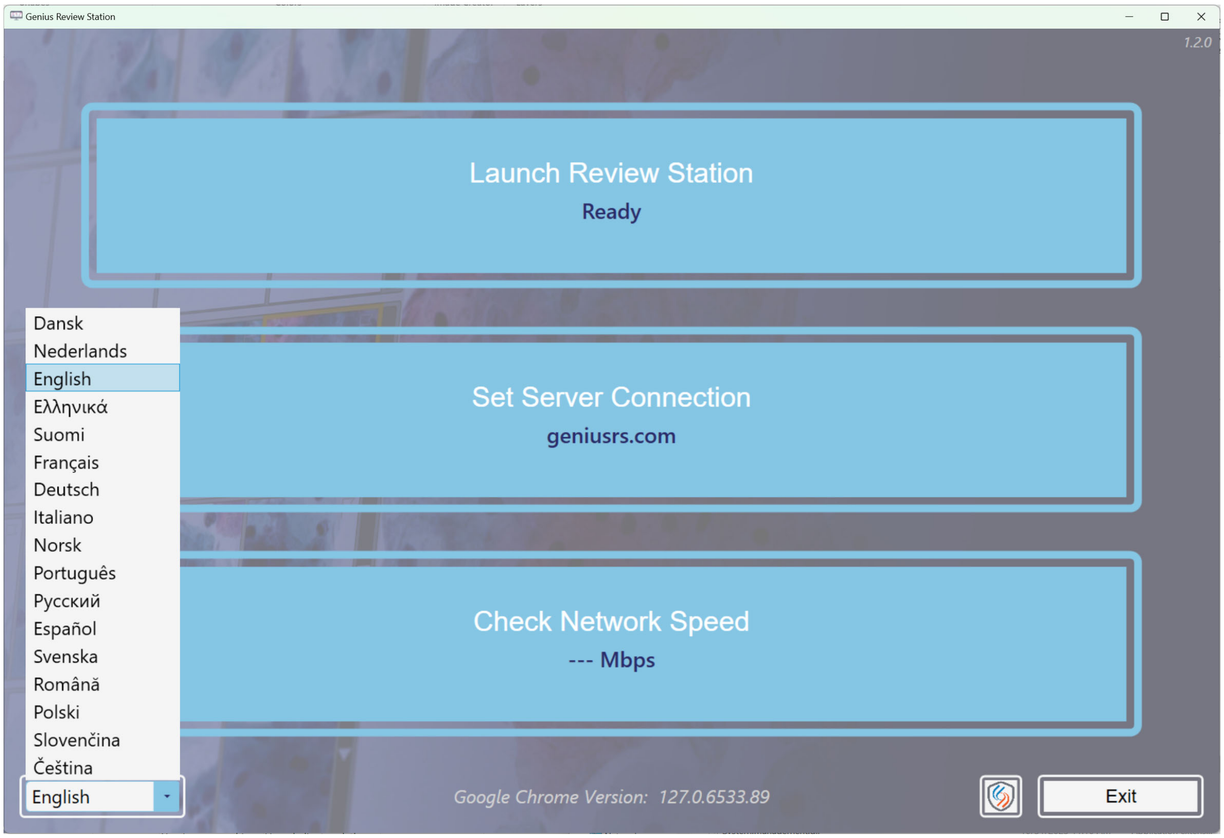


Figure 1-3-4 Select language when launch application (optional)

3. Select **Launch Review Station**.
4. The Review Station application opens.

Figure 1-3-5 Login screen

A user with a valid user account can log in to any Review Station connected to the same Image Management Server.

When the Login screen displays, enter your username and password.

- As part of the Review Station installation, Field Service personnel trained by Hologic will set up an administrator username and password or a manager username and password. The administrator or manager can then set up additional reviewers and managers for the Review Station. A user needs a username and password in order to log in.

Note: Hologic recommends setting up at least one user in your lab with an administrator role.

Note: A Hologic service login field is available for use by service personnel trained by Hologic, and it is password-protected.

Refer to "Password" on page 3.20 for information on setting up usernames and passwords.

Note: A user can log in to the Genius Review Station from a Genius Digital Imager. This offers a means for a lab tech to preview the scan quality if desired. Diagnostic review of cases from a Digital Imager's view of the Review Station is not permitted. Users at the Digital Imager have a "read-only" view of case images.

The log in screen has a button for establishing a SecureLink connection to the Review Station. Refer to "Remote Access Session for the Genius Review Station Computer" on page 5.5 for more information.

Forgotten Username or Password

If a reviewer forgets a password, use the Review Station to notify a laboratory manager.

1. Enter a username or e-mail address and select "Notify My Manager."

Note: If a manager has not stored the e-mail address with a reviewer's user account, the Review Station will not recognize that the e-mail address belongs with your user account.

2. The Review Station sends an alert to the manager's Review Station to reset that user's password.

Notes: If the user selects "Notify My Manager" again, a message appears on screen acknowledging that a notification was already sent to the manager. The manager can reset the password to a temporary password.

If the Review Station is left idle for 30 minutes, the Review Station logs the user out. The user will need to enter their password to continue using the Review Station. If that user had a case open, the Review Station changes the status of the case to In Progress when the Review Station logs the user out.

If a user enters an incorrect password several times, the user account will be temporarily locked after the fifth attempt. The Review Station sends an alert to all managers in the Review Station network. For labs using access control filters, the notification is sent to managers with the same access control filter as the user. A manager or an administrator will need to unlock the account. Refer to "Edit a user account" on page 3.40.

3. Log in using the temporary password and then reset your password. The new password must meet the requirements for passwords. Refer to "Password" on page 3.20 for the requirements for the new password.

SECTION C

DISPLAY OVERVIEW

The Review Station has some elements that are always displayed and some that can be customized for each user. The features for customizing your view on the Review Station are described in "Customize the View" on page 3.49.

After login, the Review Station displays the Dashboard. Figure 1-3-6 shows a typical Dashboard:

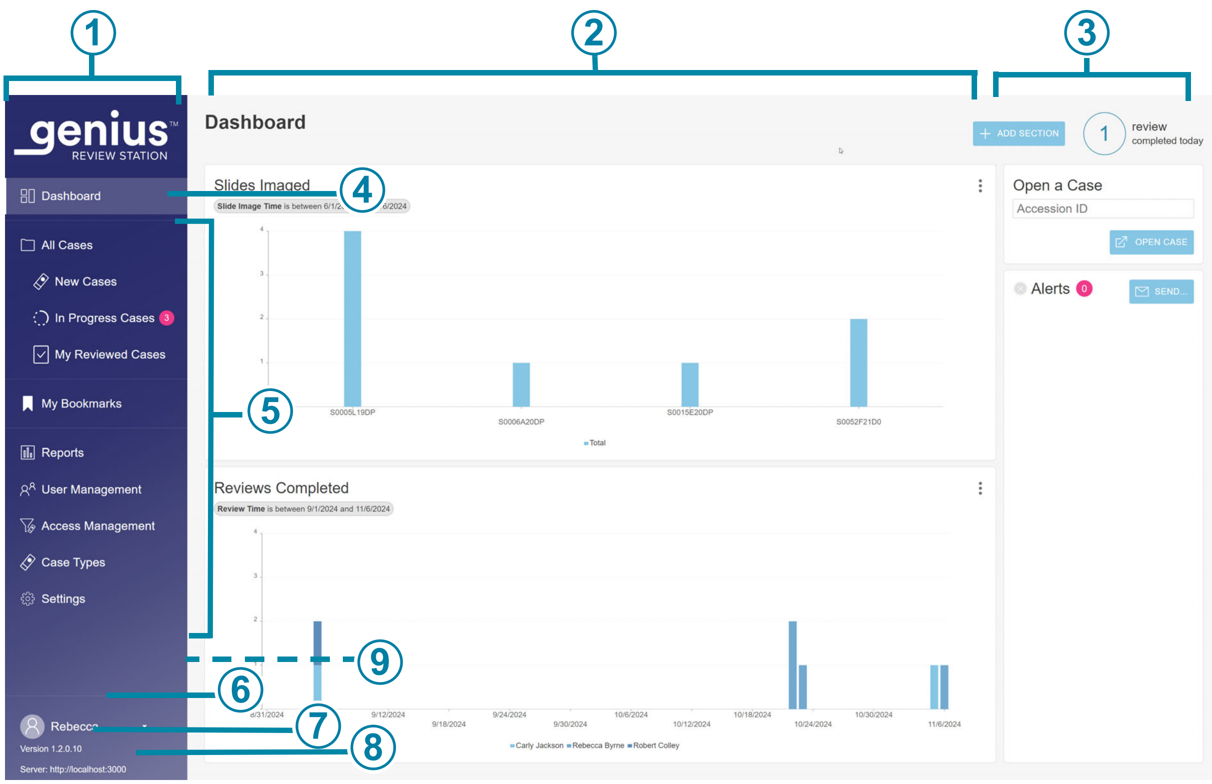


Figure 1-3-6 Review Station Dashboard

Key to Figure 1-3-6	
1	Menu bar on the left. Click on an item in the menu bar to select it.
2	Center pane of the Review Station display
3	Information section on the right. This section provides details on the content selected in the center section, for some of the menu items.
4	The lighter color in the menu bar indicates that the Dashboard view is the current view. The Dashboard provides a quick view of case data, in a way that the user can customize.

Key to Figure 1-3-6	
5	This section of the menu bar provides navigation among: Case Lists, displayed in standard groups and available to customize. Refer to page 3.56. My Bookmarks, which can be customized for each user. Refer to page 3.69. Reports. Refer to page 3.70. User Management settings (available to users with a manager role or an administrator role). Refer to page 3.35. Access Management settings (available only to users with an administrator role). Refer to page 3.35. Case Type settings (available to users with a lab tech role or an administrator role). Refer to "About custom Case Types" on page 3.42. Settings, which can be customized for each user. Refer to page 3.19.
6	The user's first and last name. Use the down arrow to access the log out screen.
7	The version number for the Review Station software.
8	The URL hosting the Review Station software. The URL may be displayed as an IP address or a domain name depending on the setup of your system.
9	A scroll bar is available if a Review Station is customized with a long lists of custom filters.

Menu Bar and Case Lists

The menu bar on the left of the Review Station always displays cases lists in four groups: All Cases, New Cases, In Progress Cases, and My Reviewed Cases.

Click on the Case List in the menu bar on the left, and the center pane displays a list of cases. Figure 1-3-7 shows a typical Case List view:

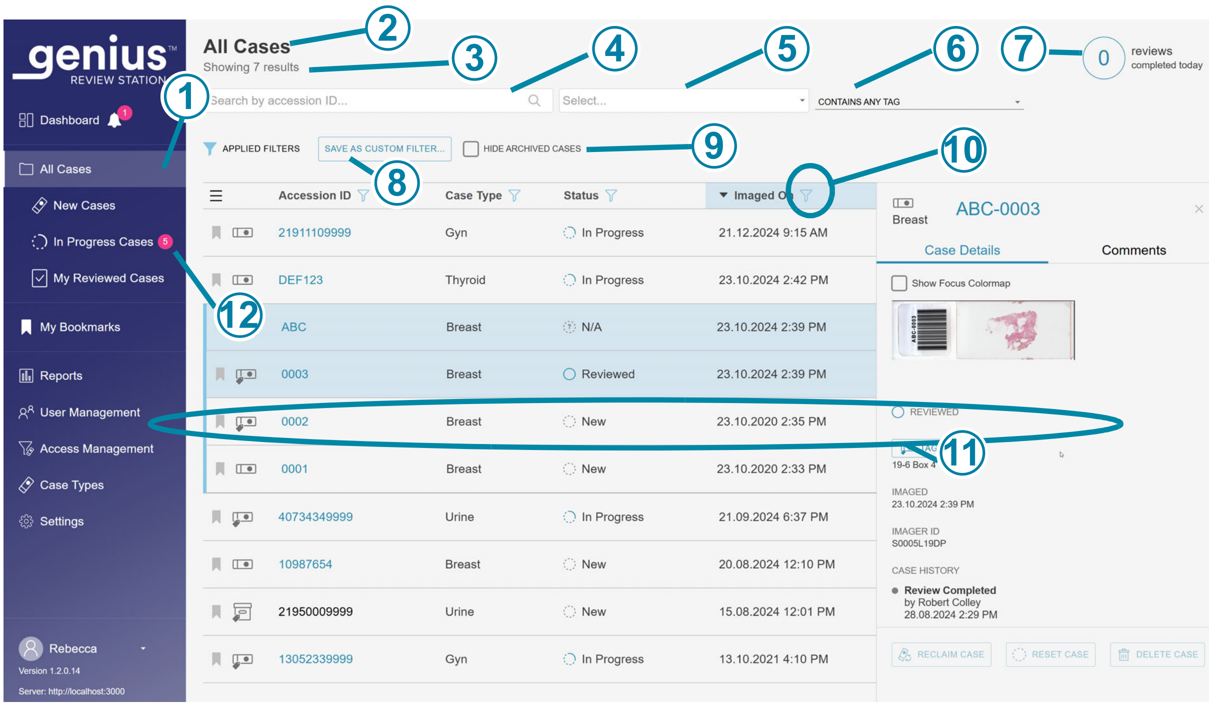


Figure 1-3-7 Typical Case List (All Cases selected in this example, administrator view)

Key to Figure 1-3-7	
1	The lighter color in the menu bar indicates that the **All Cases** view is the current view.
2	The name of Case List
3	The total number of cases in the list
4	A search box, to search for an Accession ID
5	A search box, to search for all of the cases that have the same tag. More than one tag can be included in the search.

Key to Figure 1-3-7	
⑥	An option for search criteria with more than one tag. "Contains all tags" will search for cases associated with a combination of the selected tags. "Contains any tag" will search for any case associated with one or more of the selected tags. Refer to “**Search by tag**” on page 3.56. If no selection is made, the default is to include all cases, with and without tags.
⑦	The number of cases that this reviewer has completed today ***Note:*** This represents the number of cases where this reviewer has clicked the **Complete Review** button at a Review Station today.
⑧	Applied filters describe how the data shown in the center section has been filtered.
⑨	A check box to hide archived cases in the list of cases. When this box is checked, archived cases will not be displayed in the list.
⑩	The filter icon (Refer to “Data Filters” on page 3.64)
⑪	Case data: The data in each row describes one case.
⑫	Pink bubble: This indicates the number of cases whose review is in progress for this reviewer.

For any case in the list (any row in the list), each column in the list presents information:

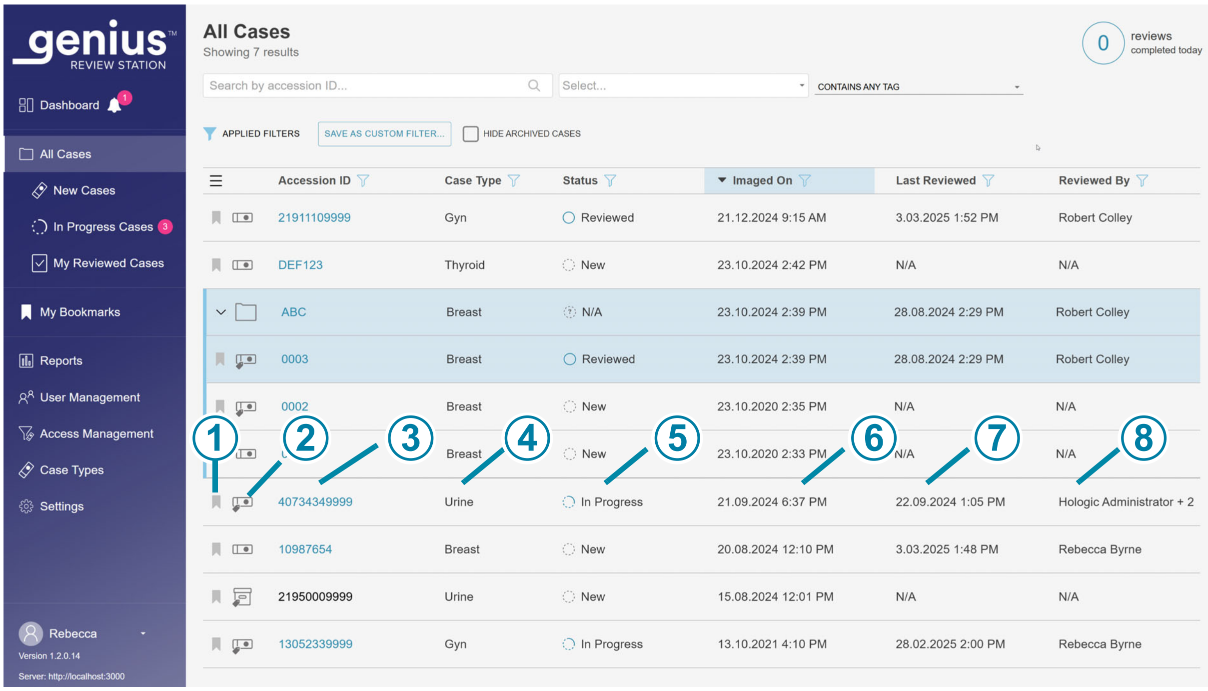


Figure 1-3-8 Typical Case List (All Cases selected in this example)

Key to Figure 1-3-8	
1	Bookmark icon (Refer to “Bookmarks” on page 3.69) Clear bookmark indicates a case is not bookmarked. Solid bookmark icon indicates a case is bookmarked.
2	Slide icon: A case with the slide icon consists of one slide, is available at the Review Station, and has not been archived. Tag icon: A reviewer has applied a tag to this case. Folder icon: A case comprised of multiple slides, grouped together with a primary ID Archived icon: A case with the archived icon has been archived. (Refer to “Archive” on page 3.23.) When retrieval of an archived case is in progress, blue arrows display on the archived icon.

Key to Figure 1-3-8	
3	Accession ID for a case: Clicking on the accession ID for a case displays the images for that case.
4	Case type: Gyn or a case type defined by your laboratory. Refer to “About custom Case Types” on page 3.42.
5	Status: The status is New, In Progress, or Reviewed
6	The date that the slide(s) for the case were imaged on the Genius Digital Imager
7	The most recent date that the case was reviewed on the Review Station
8	The name of the reviewer who completed the most recent review of the case at a Review Station

SECTION D

SETTINGS

Use the Settings screens to customize options on the Review Station. Select **Settings** in the menu bar on the left to set or change:

- the language, date format, time format (the locale) for displaying information
- your password

A user with a manager role or an administrator role can use the **Settings** selections to also set or change:

- the name of the Lab
- the archiving criteria
- the slide management criteria
- the maximum number for entries per report
- the tags available for reviewers
- user privileges

A user with an administrator role can use the **Settings** selections to also set or change:

- access control filters
- permission to enable Genius Events Bridge messaging
- permission for remote access to the Genius Image Management Server

A change to the settings requires the user to click **Save** to apply the setting. If you make changes but do not save them, a message pops up to confirm if you want to discard the changes. Click on **Discard** to discard the changes and keep the current setting, or click **Cancel** to return to the settings screen.

Locale

(All users)

Select the language, date format, and time format for the Review Station. These settings are associated with a username, and, once set, will remain until the user changes them.

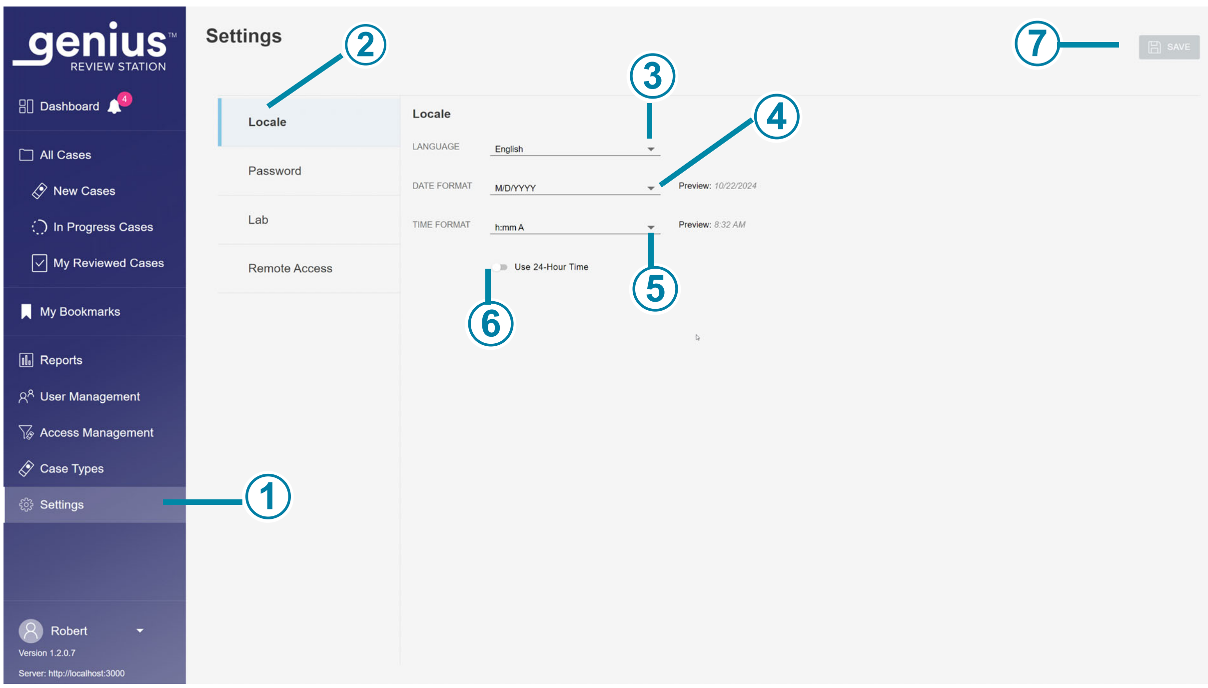


Figure 1-3-9 Set the language, date format, time format

Key to Figure 1-3-9	
1	The lighter color in the menu bar indicates that **Settings** is selected.
2	The blue color in the list of settings indicates that the **Locale** settings are selected.
3	**Language** Select a language. To change the language displayed on the display screen user interface, click on the arrow to the right of the current language name to see the full list of languages. Click on a language name to select it.

Key to Figure 1-3-9	
4	**Date format** Select the date format. To change the date format used on the display screen and in reports, click on the arrow to the right of the current date format to see the available options. Click on a date format to select it. The preview of the date format shows today's date in the selected format.
5	**Time format** Select the time format. To change the time format used on the display screen and in reports, click on the arrow to the right of the current time format to see the available options. Click on a time format to select it. The preview of the time format shows the current time in the selected format.
6	**24-Hour time format** To express the date in 24-hour format, move the slider to the right. To use a 12-hour format, move the slider to the left.
7	**Save** To save the selections, click the **Save** button.

Password

(All users)

Each user account is password-protected. The first time a user logs in, the password is a temporary password that a manager has assigned. The first time a user logs in, a user must change from that temporary password to a different password.

Passwords expire and must be changed every 90 days. If a user enters an expired password, the Review Station displays the Password Expired screen so that the user can change the password.

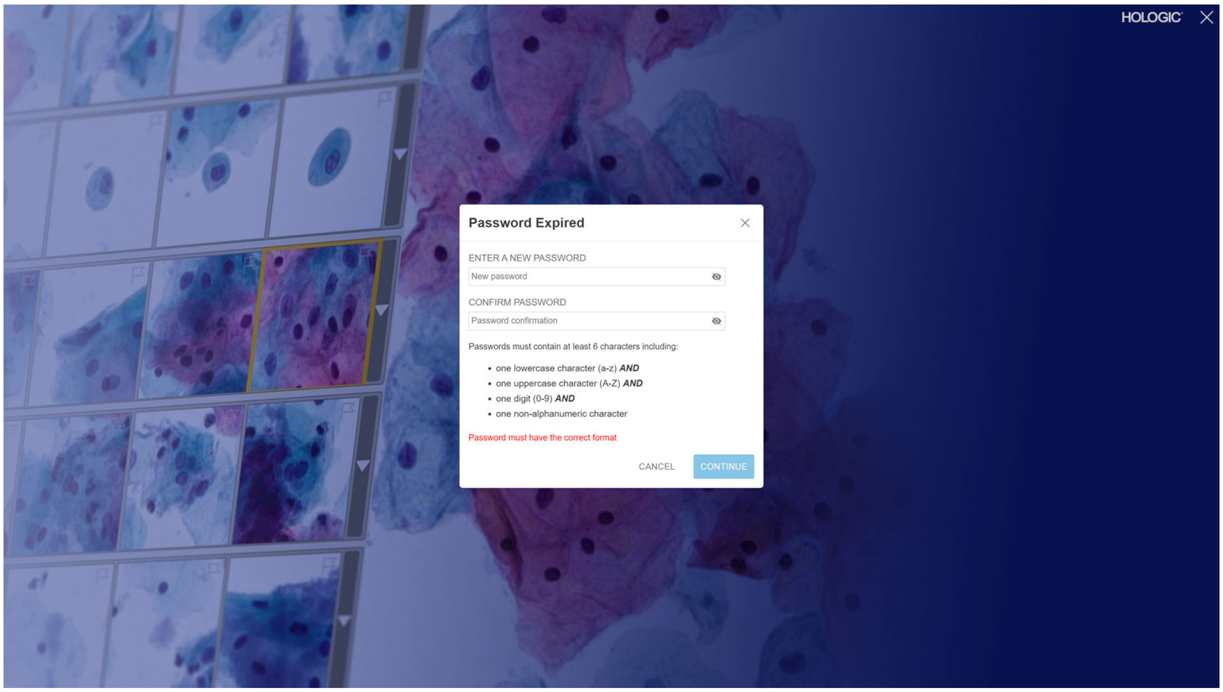


Figure 1-3-10 Reset an expired password

The password can be changed at any time from the Settings screen by the user.

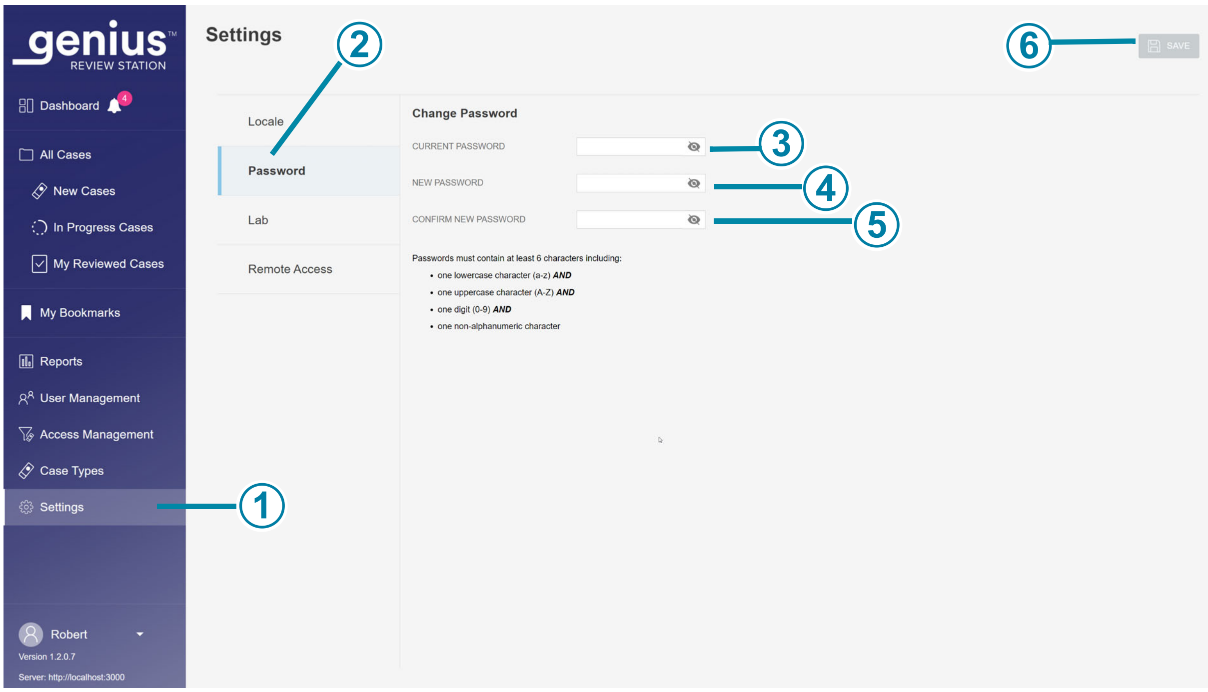


Figure 1-3-11 Change password

Key to Figure 1-3-11	
1	The lighter color in the menu bar indicates that **Settings** is selected.
2	The blue color in the list of settings indicates that the **Password** settings are selected.
3	Enter the current password.
4	Enter the new password.

Key to Figure 1-3-11	
5	Confirm the new password by entering it again. If the new password does not meet the format requirements, or if the new and confirmed passwords do not match, an error message appears. Try to set the password again. And an error will also display if the current password is incorrect.
6	To save the new password, click the **Save** button.

A password must contain at least 6 characters. A password must include:

- one lowercase character (a-z) AND
- one uppercase character (A-Z) AND
- one digit (0-9) AND
- one non-alphanumeric character (such as punctuation marks, @#$%^&*, etc.)

1. Enter the current password.
2. Enter the new password.
3. Confirm the new password by entering it again.

If the new password does not meet the format requirements, or if the new and confirmed passwords do not match, an error message appears. Try to set the password again.

And an error will also display if the current password is incorrect.

To save the new password, click the **Save** button.

Lab

(Manager and administrator)

A user with a manager role or an administrator role can establish settings that apply to all cases reviewed in Review Station network. Unlike the other settings, these lab settings are not customizable for each user account. Refer to Figure 1-3-12 and Figure 1-3-13.

Archive

(Manager and administrator)

There are two conditions that are set from the Review Station that describe when case data will be archived. Archiving a case on the Genius Digital Diagnostics System means that the images and other data for a case are transferred from the Image Management Server to a long-term data storage system. Case data, such as accession ID and reviewer's name(s), are immediately available on the Review Station, even when the images have been archived.

Note: The Review Station cannot archive images for a case when the case has the "In Progress" status.

A case that has been archived needs to be retrieved from the archived storage before that case can be viewed on the Review Station. The conditions for archiving can be set in any combination that meets the requirements of your facility. The conditions for retrieving, such as the amount of time to retrieve the archived images, vary, depending on the set-up at your laboratory.

Report

(Manager and administrator)

A user with a manager role or an administrator role can set the maximum number of lines of data that are retrieved from the Image Management Server for a report.

If there are fewer results than the limit, all of the available data will report. When a report is run, if the number of entries is greater than the report length limit, only the results highest in the sort order appear in the report and a message appears on the screen.

To change the maximum number of records to display in reports, click on the arrow to the right of the current setting to see the available options. Click on a number to select it. Select from the available options of 100, 500, 1,000, 5,000 and 10,000 results.

Tags

(Manager and administrator)

Additional information can be associated with a case on the Review Station in the form of a tag. The name of the tag is text typed into the Review Station by a user with a manager or an administrator role.

- For labs using access control filters, a manager or an administrator can create a tag.
- For labs using access control filters, an administrator can change or delete a tag.
- For labs that do not use access control filters, a manager can create, change and delete a tag.

The name of a tag is limited to 50 characters.

After a tag is set up, any reviewer in the lab can apply or remove a tag from a case. After a case is tagged, any reviewer can search for cases that use that tag.

If a manager or an administrator renames a tag, any reviewer in the lab will see the new name.

If a manager or an administrator removes a tag from the Review Station, that tag is no longer available to any reviewer.

Note: If a manager or an administrator removes a tag from the Review Station, consider deleting any custom filters for that tag, since the filter will yield no results (0 cases). Refer to "Delete a custom filter" on page 3.67.

Refer to Parts 2 and 3 of this manual for instructions for adding tags during case review.

If a lab chooses to do so, users can combine the custom filter feature and tags to guide the lab workflow:

For example, a lab could create a tag with the name of a workflow, and reviewers could tag cases that go through that workflow. A reviewer or manager could create a custom filter for that tag name and quickly display all of the cases that followed that workflow.

Or, for example, a lab could create a tag with the name of a pathologist, and reviewers could tag cases that they would like that pathologist to review. The pathologist could create a custom filter for that tag name to quickly display all of the cases tagged with their name.

Refer to "Save a custom filter" on page 3.66.

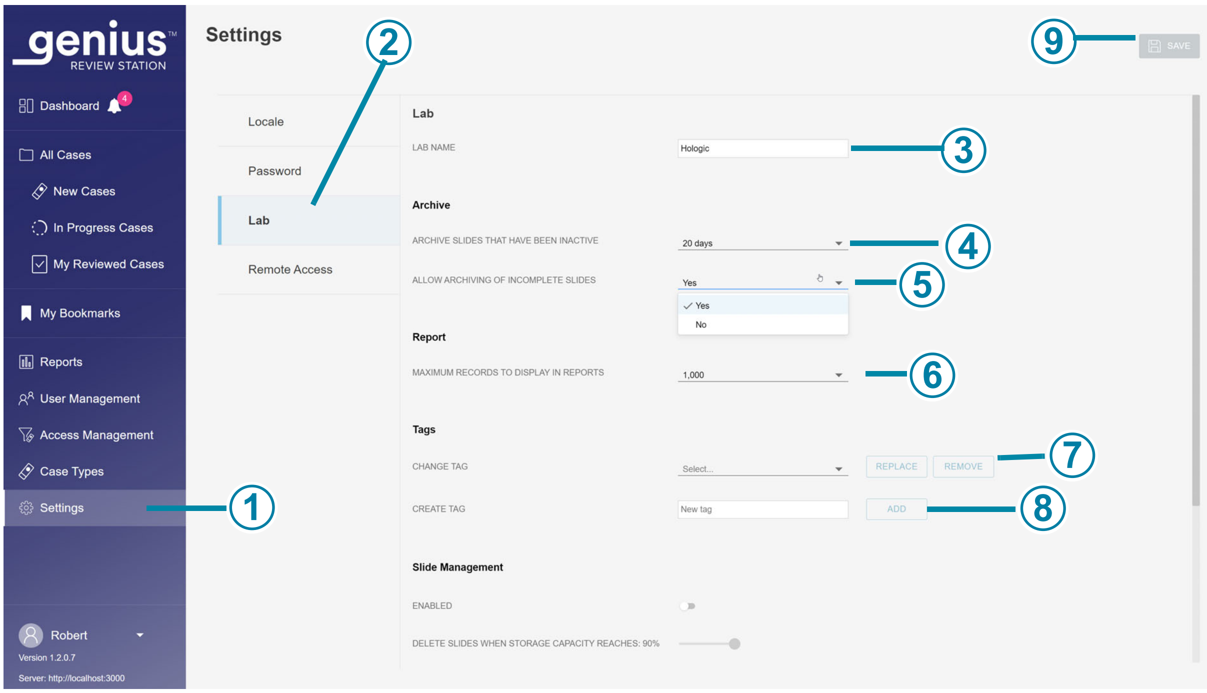


Figure 1-3-12 Lab settings

Key to Figure 1-3-12	
1	The lighter color in the menu bar indicates that **Settings** is selected.
2	The blue color in the list of settings indicates that the **Lab** settings are selected.
3	**Lab name (Manager and Administrator)** To have a lab name appear on Reports, type in the name of your lab.

Key to Figure 1-3-12	
④	**Archive slides that have been inactive** After a period of time, data for inactive cases is transferred to a long-term archive storage system from the Image Management Server. The default setting is 20 days. The storage capacity of the server and a lab's archive system may vary from lab to lab. A lab manager or an administrator can change the archive frequency to a shorter or longer time period. To change that time period, click on the arrow to the right of the current setting to see the available options. Click on a time period to select it. Select a time period from the available options that are 5 days apart, from a minimum of 5 days to a maximum of 45 days.
⑤	**Allow archiving of incomplete slides** This setting either includes or excludes cases where a review has not been completed as archived slides. To change the current setting, click on the arrow to the right of the current setting to choose between the available options of yes or no. Click **yes** or **no**. A "yes" setting will archive inactive new cases and completed cases at the set time or disk capacity. A "no" setting will archive completed cases at the set time or disk capacity, and keep new cases on the Image Management Server. ***Note:*** A case with the "In Progress" status cannot be archived.
⑥	**Maximum records to display in reports** To change the maximum number of records to display in reports, click on the arrow to the right of the current setting to see the available options. Click on a number to select it. Select from the available options of 100, 500, 1,000, 5,000 and 10,000 results.

Key to Figure 1-3-12	
7	**Change tag** To rename or remove an existing tag for all users in the Review Station network, click on the arrow to the right of the Select box to see the list of current tags. Select the tag from the list. For labs using access control filters, an administrator can change a tag. For labs that do not use access control filters, a manager or an administrator can change a tag. To rename the selected tag, click the **Replace** button. Type the new name for the tag in the box where the existing name is displayed. A confirmation message appears. Click **Continue** to change the name and return to the Lab settings screen, or click **Cancel** to leave the tag unchanged. To remove the selected tag from all cases in the Review Station network, click the **Remove** button. A confirmation message appears. Click **Continue** to return to the Lab settings screen, or click **Cancel** to leave the tag as it is.
8	**Create tag** To create a new tag, type the name for the new tag in the **New tag** box. Click **Add**. A manager or an administrator can create a tag in the Lab settings. A manager or an administrator can also create a new tag during case review. The creation and use of tags is optional.
9	To save the Lab settings, click the **Save** button.

Slide management

(Manager and administrator)

The Genius Digital Diagnostics System can be set up to permanently and routinely delete slide images and case data records (slide images and data) from the Genius Digital Diagnostics System. The files are deleted from the Genius Image Management Server. The Genius Digital Diagnostics System can be set up to never delete files from the system. The criteria for slide management are set up at the Review Station.

For labs using access control filters, an administrator can set the slide management parameters. For labs that do not use access control filters, a manager or an administrator can set the slide management parameters.

Follow all applicable record retention policies established by your IT department, health institution, or other groups when considering the slide management settings. The Genius Digital Diagnostics

System does not require files to be deleted; the system does require sufficient storage space on the server.

Caution: Deleted image files, including the Genius Cervical AI gallery of OOIs, cannot be recovered once deleted.

Caution: Deleted image files are not transferred to a lab's long-term storage or archiving system.

After a case is deleted from the Genius Image Management Server, it is possible to re-image the slide to produce another digital image of the slide using the same accession ID. Due to environmental factors such as fading, drying, lighting, and system variability, re-imaging a ThinPrep Pap test slide with the Genius Cervical AI algorithm may not produce a gallery of Objects of Interest (OOIs) identical to the original gallery.

Hologic recommends that customers enable a solution for long-term storage and archive of digital image files. It is a customer's responsibility to determine the storage and archival strategy, which could be affected by rules or requirements affecting retention of such information. Rules or requirements vary from jurisdiction to jurisdiction. Accordingly, Hologic recommends that customers consult with their regulatory and/or legal counsel prior to deciding to delete the digital image files from the local repository on the Genius Image Management Server.

In addition to not storing a long-term archive of the image files with the Slide Management feature, there are other impacts to the Genius Digital Diagnostics System to be aware of.

- The deleted images no longer appear in the Genius Review Station Case List and are not viewable.
- Any comments or marks associated with a case are also deleted.
- The workload reports (CT Workload Summary, CT Workload History, CT Reviews, Workload Summary and Workload History) and the Slide Data reports will only be accurate for the duration of the cached slides (before the case data record is deleted). Reports for date ranges older than the cache will not have the data for the reviews associated with each user. If this reporting is important to your lab, it is recommended that reports be run on a cadence well within the duration of the cache to ensure accurate reports. The report results can be saved or printed.
- Genius Review Station widgets for Slides Imaged and Reviews Completed will only be accurate for the duration of the cached slides.

Note: System Usage History, Slide Events, and Slide Error reports retain all the data from the Digital Imagers and are not impacted by deleting slides with the Slide Management utility.

Genius Event Bridge messaging

(Administrator only)

The Genius Event Bridge feature is an interface to communicate with third-party systems, such as an integration to a Laboratory Information Systems (LIS). At the Review Station, an administrator can enable or disable the interface.

It is the responsibility of the laboratory to set up, validate and monitor communication with third-party systems, including LIS.

Refer to the Genius Event Bridge Interface Specification Guide or contact your Hologic representative for more information.

The settings for slide management and Genius Event Bridge messaging are among the lab settings.

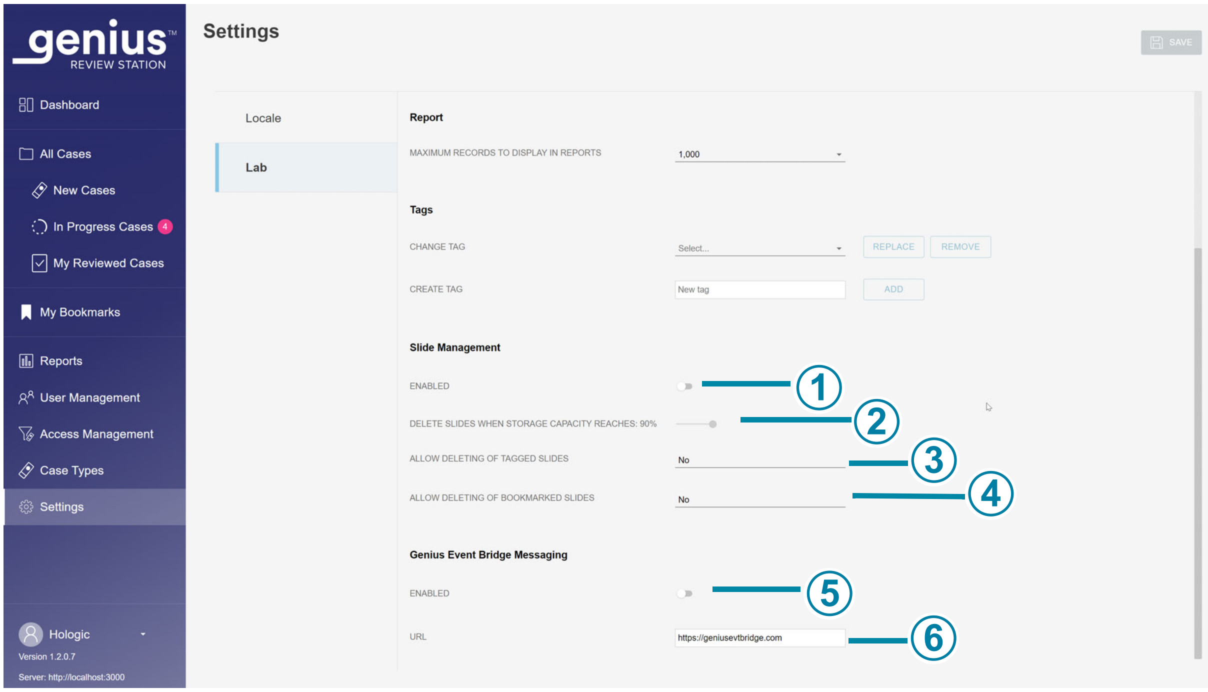


Figure 1-3-13 Settings for Slide Management and Genius Event Bridge

Key to Figure 1-3-13	
1	Slide Management To schedule deletion of digital images and case data from the Genius Image Management Server, enable the Slide Management feature. Refer to “Slide management” on page 3.28 for more information. Enable: To enable Slide Management, move the slider to the right. Using the Slide Management feature is optional. Disable: To disable Slide Management, move the slider to the left. For labs using access control filters, an administrator can set the slide management parameters. For labs that do not use access control filters, a manager or an administrator can set the slide management parameters.

Key to Figure 1-3-13	
②	**Delete slides when storage capacity reaches:** (percentage) When the slide management feature is enabled, move the slider to select the storage capacity threshold over which slides will be permanently deleted from the Genius Image Management Server. The default setting is 90% full. For example, if a lab manager sets the system to delete slides when storage capacity reaches 75%, when 75% of the storage disk space on the Genius Image Management Server is full, the oldest files on the Genius Image Management Server will be deleted until the storage capacity is at or below 75% full.
③	**Allow deleting of tagged slides** When a lab uses the Slide Management feature, this setting either includes or excludes cases with tags applied among slides to be deleted. To change the current setting, click on the arrow to the right of the current setting to choose between the available options of yes or no. Click **yes** or **no**. A “yes” setting will permanently delete cases with any tag applied when the slide management criteria are met. A “no” setting will retain images and case data on the Genius Image Management Server for cases with any tag applied, until the case is eligible for archiving. **This is the default setting.**
④	**Allow deleting of bookmarked slides** When a lab uses the Slide Management feature, this setting either includes or excludes cases with bookmarks applied among slides to be deleted. To change the current setting, click on the arrow to the right of the current setting to choose between the available options of yes or no. Click **yes** or **no**. A “yes” setting will permanently delete cases where any bookmark has been applied when the slide management criteria are met. A “no” setting will retain images and case data on the Genius Image Management Server for cases with any bookmark applied, until the case is eligible for archiving. **This is the default setting.**

Key to Figure 1-3-13	
5	**Enable Genius Event Bridge messaging** To allow the Genius Digital Diagnostics System to send and receive messages about a pre-defined set of data from the Genius Image Management Server, enable the Genius Event Bridge messaging feature. Refer to "Genius Event Bridge messaging" on page 3.30 and the Genius Event Bridge Interface Specification Guide for more information. Enable: To enable Genius Event Bridge, move the slider to the right. Using the Genius Event Bridge messaging feature is optional. Disable: To disable Genius Event Bridge messaging, move the slider to the left. For labs using access control filters, an administrator can enable or disable Genius Event Bridge messaging.
6	**URL for Genius Event Bridge** If a lab enables Genius Event Bridge messaging, use this area to specify the URL where the event message data is exchanged. Type or copy-and-paste in this free text field.

Remote Access

(Administrator only)

The Genius Digital Diagnostics System offers a method for remote product support, SecureLink Remote Diagnostics. A user at the Review Station grants access to service personnel trained by Hologic for each remote access session. Access through the SecureLink Remote Diagnostics platform allows service personnel trained by Hologic to securely access the Genius Digital Diagnostics System to provide system service, view the software graphical user interface, or provide guidance to the local system user. In addition, the platform allows for the remote transfer of files needed to diagnose an instrument error.

The Remote Access information on the Settings page of the Review Station lets an administrator open and close a connection for the SecureLink Remote Diagnostics platform and the Genius Digital Image Management Server. Refer to"Troubleshooting with Remote Access" on page 5.4.

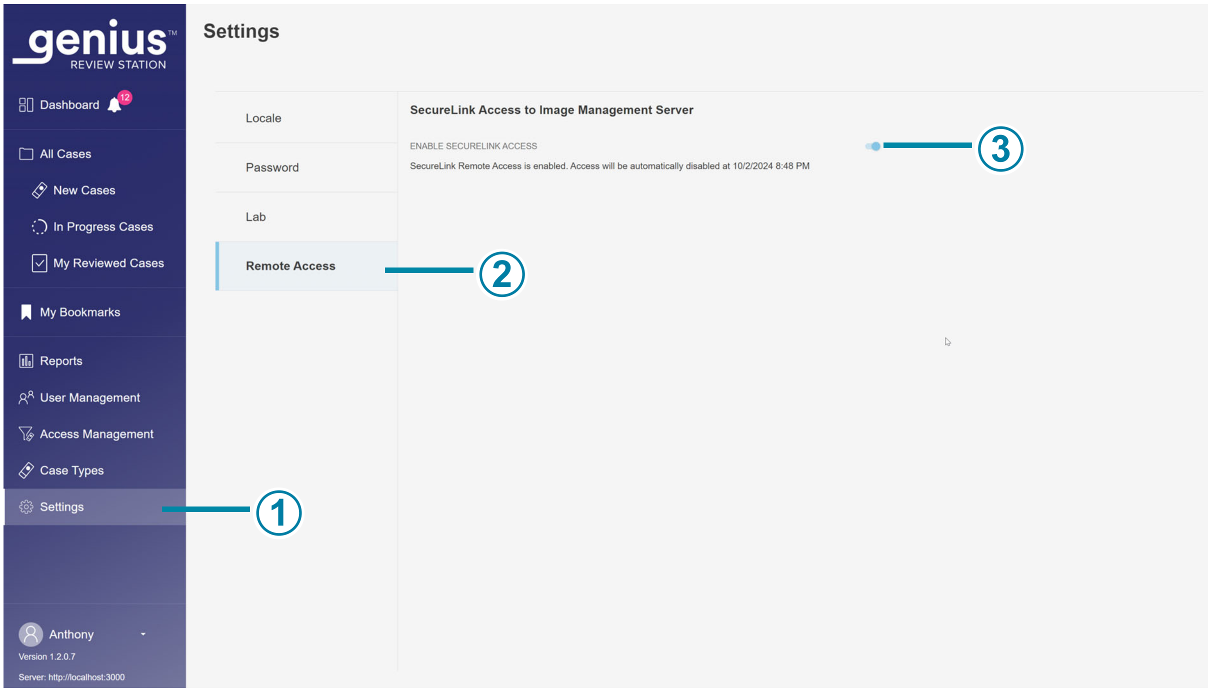


Figure 1-3-14 Review Station settings for remote access to the Image Management Server

Key to Figure 1-3-14	
1	The lighter color in the menu bar indicates that **Settings** is selected.
2	The blue color in the list of settings indicates that the **Remote Access** settings are selected.

Key to Figure 1-3-14	
3	**Enable SecureLink Access to the Image Management Server** To allow Field Service personnel trained by Hologic to access logs and other data from the Genius Image Management Server, enable the SecureLink access at the Review Station. Refer to "Remote Access Session for the Genius Image Management Server" on page 5.4 for more information. Enable: To enable the SecureLink connection, move the slider to the right. Using the SecureLink feature is optional. Disable: To disable the SecureLink connection, move the slider to the left. An administrator is the only user role who can enable or disable SecureLink access to the Genius Image Management Server.

User Management

(Manager and administrator)

From the User Management screen, a manager or an administrator can view and export lists of current users, add or deactivate users, and reset a Review Station password for any user. Click on the User Management menu bar on the left to see a list of users for the Review Station. A user with an active user account can log in to any Review Station connected to the same Image Management Server.

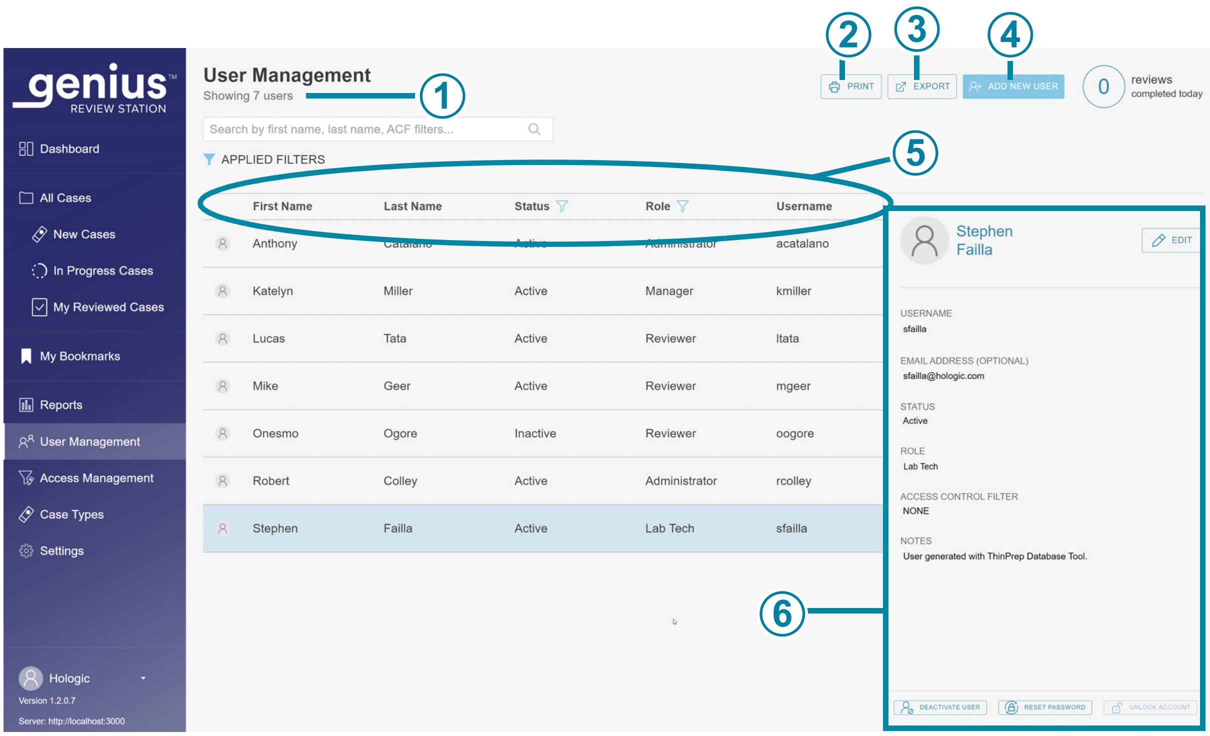


Figure 1-3-15 User management: list of users

Key to Figure 1-3-15	
1	In the upper left, the number of users is shown. The number displayed in the upper left may change if the list is filtered by status or filtered by role.
2	The **Print** button generates a PDF view on the screen, and opens the print dialog window from the web browser. To print out the PDF, use the web browser's print dialog.
3	The **Export** button saves the list of users either as a .csv file (comma-separated variable file) or a PDF file in the downloads folder of the Review Station computer. After clicking the **Export** button, choose **CSV** or **PDF**.
4	The **Add New User** button opens a screen for entering data about a new user. Refer to "Add a new user" on page 3.37.
5	The list of users shows the first name, last name, status, role and username for users in the Review Station network.

Key to Figure 1-3-15	
⑥	**User details** Click on any user in the list to display details describing the user whose name is highlighted in the list.

The list of users has a column for first name, last name, status, role and username. The list can be sorted by each of these columns.

- The list of users can be filtered by status, to display all the active users, all the inactive users and all users.
- The list of users can be filtered by role to display all of the users, all of the users with a lab tech role, all of the users with a reviewer role, and all of the users with a manager role. An administrator can also filter the list to display all of the users with an administrator role.

Note: The username is a different field from the user's first name and the user's last name. A user enters a username in the Login screen to log in to the application.

The details shown when a user's name is highlighted in the list are entered by the manager or administrator:

- The username field
- The email address field is optional. If an email address is part of the user details, a reviewer can enter the email address in place of a username in the Login screen. This field is also a convenient place to store the user's email address. The Review Station cannot send or receive emails.
- The status is either active or inactive. An inactive user cannot log in nor use the Review Station.
- The role for a user is lab tech, reviewer, manager or administrator. Refer to Table 3.1 on page 3.4 for a list of permissions.
- If your lab uses access control filters, the name of the filter or filters to which the user is assigned is listed.
- The notes field is an area where the manager or administrator can type in any additional information appropriate for your lab. The notes field is visible to all managers and administrators on the Review Station network.

Refer to "Edit a user account" on page 3.40 for instructions on editing a user profile.

Add a new user

A user with the manager role or the administrator role can add a new user to the Review Station network. To add and activate a new user:

1. Click on the **Add New User** button.
2. Enter the new user's first name and last name.

3. Enter a username for the new user.
4. Enter a password. This is a temporary password. The temporary password can be as short as one character. The first time a user logs in, a user must change from that temporary password to a different password.
5. Enter the user's e-mail address. (Optional)
6. For a new user, the status field is set to **Active**.
7. Select a role for the new user.
   The lab tech role may be appropriate for someone who needs to perform case management and scanning at the Digital Imager. The activities available to a lab tech user are listed below:
   - A user with the lab tech role can set up, change and delete Case Types at the Review Station that apply to all Digital Imagers using the lab setting. Refer to "Case Types" on page 3.41.
   - A user with the lab tech role can log in to a view of the Review Station from the Genius Digital Imager. Refer to the operator's manual for the Genius Digital Imager.
   - A user with the lab tech role can add a tag to a case, but only from the Case List view. Refer to Parts 2 and 3 of this manual.
   - A user with the lab tech role can run reports, including the Scan Profile Usage History Report.
   - A user with the lab tech role can delete new cases on the Review Station.

   In addition to reviewing cases, a user with the manager role can also perform other activities. For labs using access control filters, the information available to a manager is filtered so that the manager has access to information related to lab techs, reviewers, managers, and cases associated with the access control filter assigned to the manager. A manager does not have access to information associated with access control filters to which the manager is not assigned. The activities available to a manager are listed below:
   - A user with the manager role can search for and review cases. A manager can run reports that can include data from all of the Review Station users assigned to the manager's access control filter(s).
   - A user with the manager role can set up new users, as lab techs, managers or reviewers, and a manager can deactivate lab techs, managers or reviewers. When a manager creates a new user, the filter for the new user is the same as the manager's filter. If a manager is assigned to more than one access control filter, the manager can select among those filters for the new user.
   - A manager can delete a slide record from the Genius Image Management Server. Refer to "Delete a case" on page 3.63.
   - A manager can "reclaim" an in-progress case from a reviewer. Refer to "Reclaim a case" on page 3.61.
   - A manager can "reset" an in-progress case from a reviewer to the "New" status. Refer to "Reset a case" on page 3.62.

- A manager can send Alerts to other users in the Review Station network. Refer to "Send an alert" on page 3.67.
- A manager can establish settings that apply to all users, reset passwords for other users, and activate or deactivate user accounts.
- For labs that do not use access control filters, a manager can set up, change and delete tags that apply to all users.

A user with the administrator role can do the same activities as a manager, and an administrator can set up access control filters. An administrator has access to all of the information related to reviewers, managers, and cases associated with all of the Review Stations connected to the same Image Management Server. Access control filters do not apply to administrators. The activities available to an administrator are listed below:

- A user with the administrator role can search for and review cases. An administrator can run reports that can include data from all of the Review Station users.
- A user with the administrator role can set up new users. The new users can be administrators, managers or reviewers, assigned to any access control filter (if used). An administrator can deactivate administrators, managers or reviewers.
- An administrator can delete a slide record from the Genius Image Management Server. Refer to "Delete a case" on page 3.63.
- An administrator can "reclaim" an in-progress case from a reviewer. Refer to "Reclaim a case" on page 3.61.
- An administrator can "reset" an in-progress case from a reviewer to the "New" status. Refer to "Reset a case" on page 3.62.
- An administrator can send Alerts to all other users in the Review Station network. Refer to "Send an alert" on page 3.67.
- An administrator can establish settings and tags that apply to all users, reset passwords for other users, and activate or deactivate user accounts.
- An administrator can create and control the access control filters. Refer to "Access Control Filters" on page 3.42.
- An administrator can enable and disable the Genius Event Bridge messaging setting. Refer to "Genius Event Bridge messaging" on page 3.30.
- An administrator can enable and disable SecureLink remote access to the lab's Genius Image Management Servers. Refer to "Remote Access" on page 3.33.
- An administrator can set up, change and delete Case Types that apply to all Digital Imagers using the lab setting. Refer to "Case Types" on page 3.41.

8. Enter notes about the user account. (Optional)
9. Click the **Save** button to save the new user information, or click **Cancel** to close the new user pane without adding the new user.

Edit a user account

A user with the manager role can edit existing user accounts. For labs using access control filters, the manager can edit user accounts within the access control filter assigned to the manager. For labs using access control filters, the administrator can edit user accounts for any Review Station user connected to the same Image Management Server.

1. Find and select the user in the list of users.
   - In a lab with a low number of Review Station users, the user's information may already be visible in the list of users.
   - In longer lists, filtering the list of users by status and/or by role may make the user's information easier to find. Furthermore, an administrator can type the name of an access control filter into the box above the list that says, "Search by name..." to display a list of users assigned to that access control filter.
   - Alternatively, a manager or an administrator can search for a specific user by typing all or part of the user's first name, last name, or username in the box above the list that says, "Search by name..." Click on the magnifying glass icon or press enter on the keyboard to start the search.

   When the user appears in the list, click anywhere in that user's information to select that user from the list.
2. To edit the user's username, first name, last name, email address, role or the notes in the user's account, click the edit button next to the user's first and last name.
   - Type any changes into the fields for username, first name, last name, email address, or the notes in the user's account.
   - Click the **Save** button.
3. To edit the users' status, click the button at the bottom of the panel on the right.
   - To activate an inactive user, click the **Activate User** button.
   - To deactivate an active user, click the **Deactivate User** button.
   - To unlock a locked user account, click the **Unlock Account** button. The lock-out expires after 60 minutes. If a manager or an administrator does not unlock a locked user account, the user can log in after the 60-minute lock-out.
   - On the confirmation screen, click **Yes** to continue with the change, or click **No** to cancel the change.
4. To reset a user's password, click the **Reset password** button at the bottom of the panel on the right.
   - Type a temporary password in the box that says, "Enter a new password."
   - Click the **Continue** button to continue with the change, or click **Cancel** to cancel the resetting of the password.
   - Communicate the new password to the user. When the user logs in with this temporary password, the system prompts the user to reset the password.

Case Types

(Lab tech and administrator)

A Case Type is a combination of the settings that are used to image slides on the Digital Imager. Custom Case Types are set up at the Review Station.

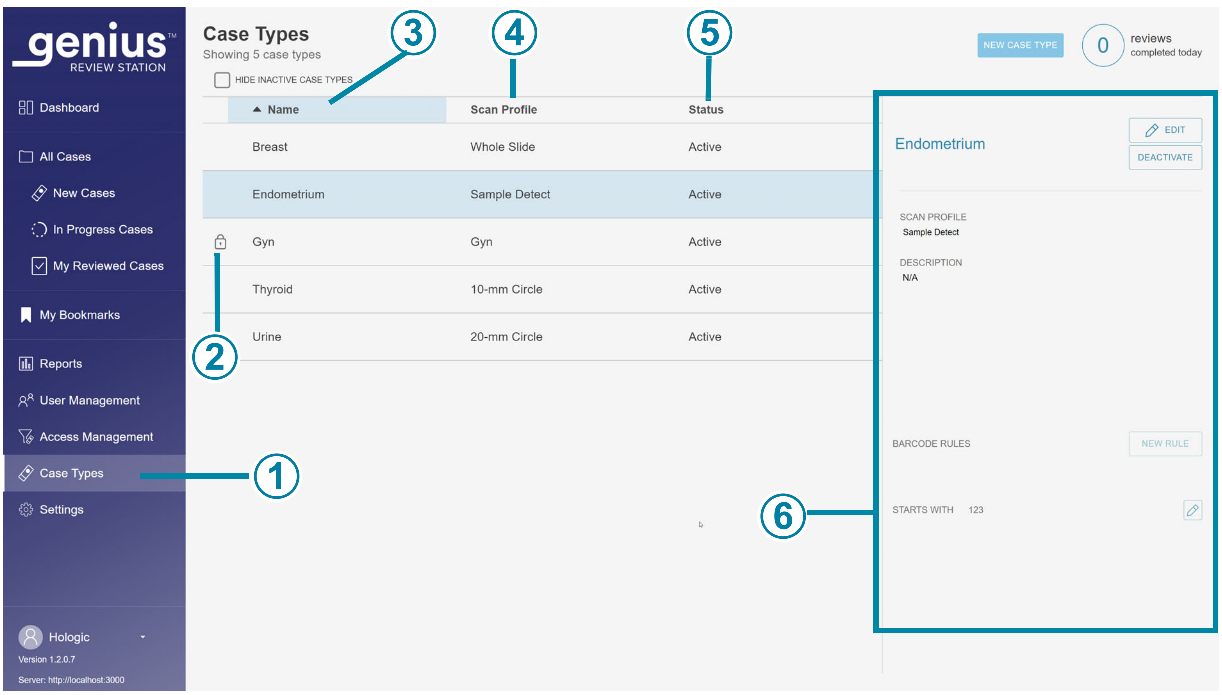


Figure 1-3-16 Case Types

Key to Figure 1-3-16	
1	The lighter color in the menu bar indicates that **Case Types** is selected.
2	 The settings for the Gyn case type are locked and cannot be changed.

Key to Figure 1-3-16	
3	**Name** The name that your laboratory establishes for a case type at the Genius Review Station appears in the carrier selection options at the Genius Digital Imager. The name of the case type also appears in several reports.
4	**Scan Profile** The list of case types shows the scan profile for each case type.
5	**Status** The list of case types shows the status for each case type. A case type must be in the active status in order to image slides.
6	This panel shows more information about existing case types. Use this panel to create a new case type, edit an existing case type, or change the status of an existing case type.

Gyn

Your Genius Digital Diagnostics System may be configured for reviewing ThinPrep Pap tests for cervical cancer screening with the Genius AI algorithm. The Case Type for reviewing ThinPrep Pap tests for cervical cancer screening with the Genius AI algorithm is “Gyn” on the Review Station. The Gyn Case Type can be deactivated by a lab, but the name and scan profile for the Gyn Case Type cannot be changed.

About custom Case Types

To use the Genius Digital Diagnostics System with cases that are not ThinPrep Pap tests, a Case Type must be set up at the Review Station first. Each laboratory can set up as many or as few Case Types as suits the workflow in your lab. After a custom Case Type is set up at a Review Station, that Case Type will be an available option for scanning slides on every Digital Imager connected to the same Genius Image Management Server.

Note: If your facility used the Non-gyn or UroCyte™ case type in a Genius Digital Diagnostics System with software version 1.1.1 or earlier, Field Service personnel trained by Hologic can assist your laboratory by setting up two, active custom Case Types: “Non-gyn” with 20-mm circle and “UroCyte” with 10-mm circle.

Part 3 of this manual includes instructions for setting up and using custom Case Types.

Access Control Filters

(Administrator only)

From the Access Control Filters screen, an administrator can create filters to allow managers and reviewers access to only the cases that meet the filtering criteria. The filtering is based on characteristics in the Accession ID. To use access control filters, an administrator must first set up access control filters, and then associate users with the access control filters.

Access control filters let an administrator control which Review Station users have access to the case data, based on the Accession ID. A user with the administrator role in the Genius Review Station has access to all of the cases in the Genius Digital Diagnostics System, and the administrator can use the accession ID to control which cases are available to managers and reviewers at their Review Stations.

Access control filters may be helpful when a laboratory group has a site that serves as an imaging hub for satellite review sites. Access control filters can be set up so that slides imaged for one review site will not be visible at other review sites. The access is controlled by filtering on characteristics in the slides' accession IDs.

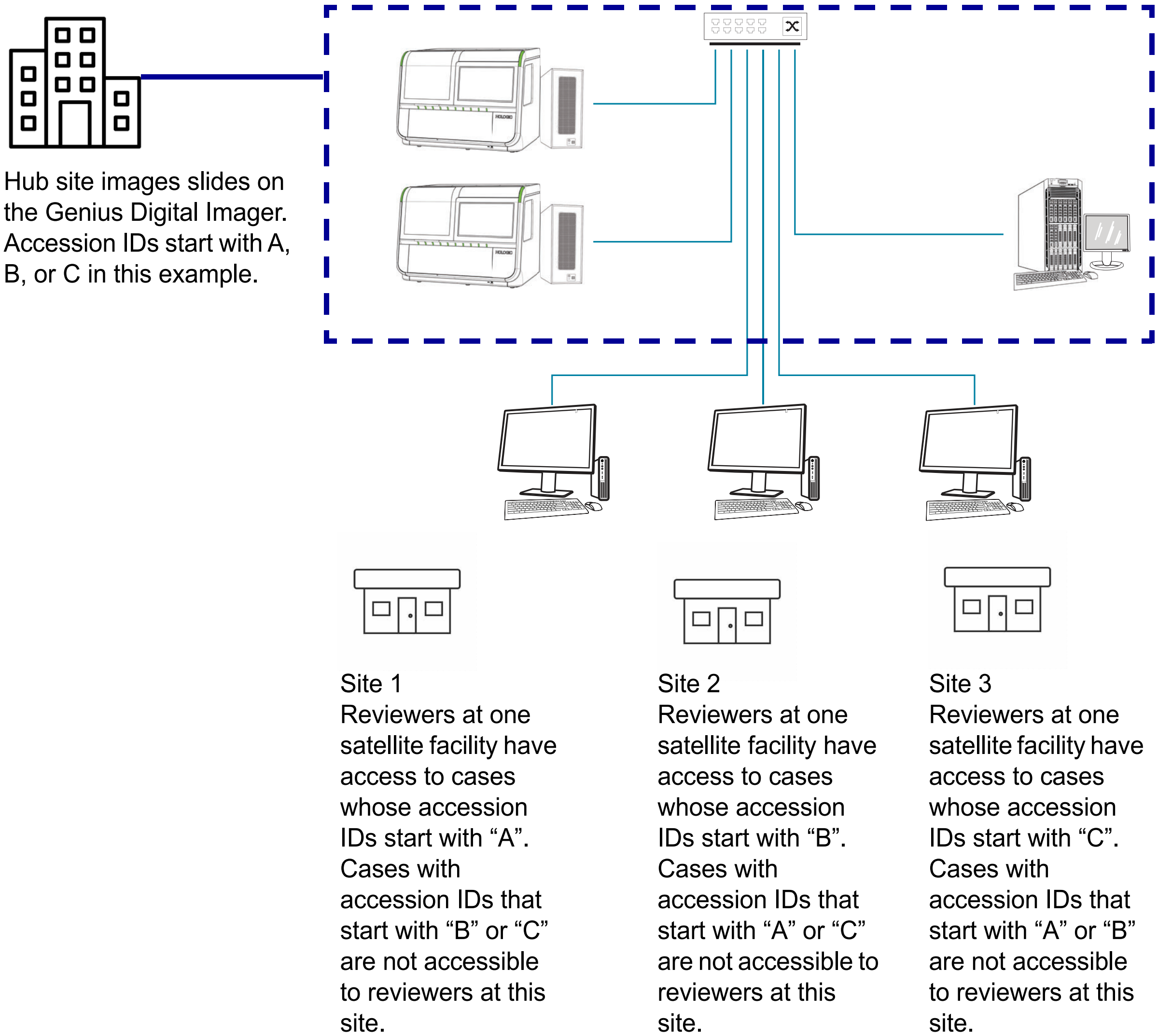


Figure 1-3-17 Controlling access by accession ID, example

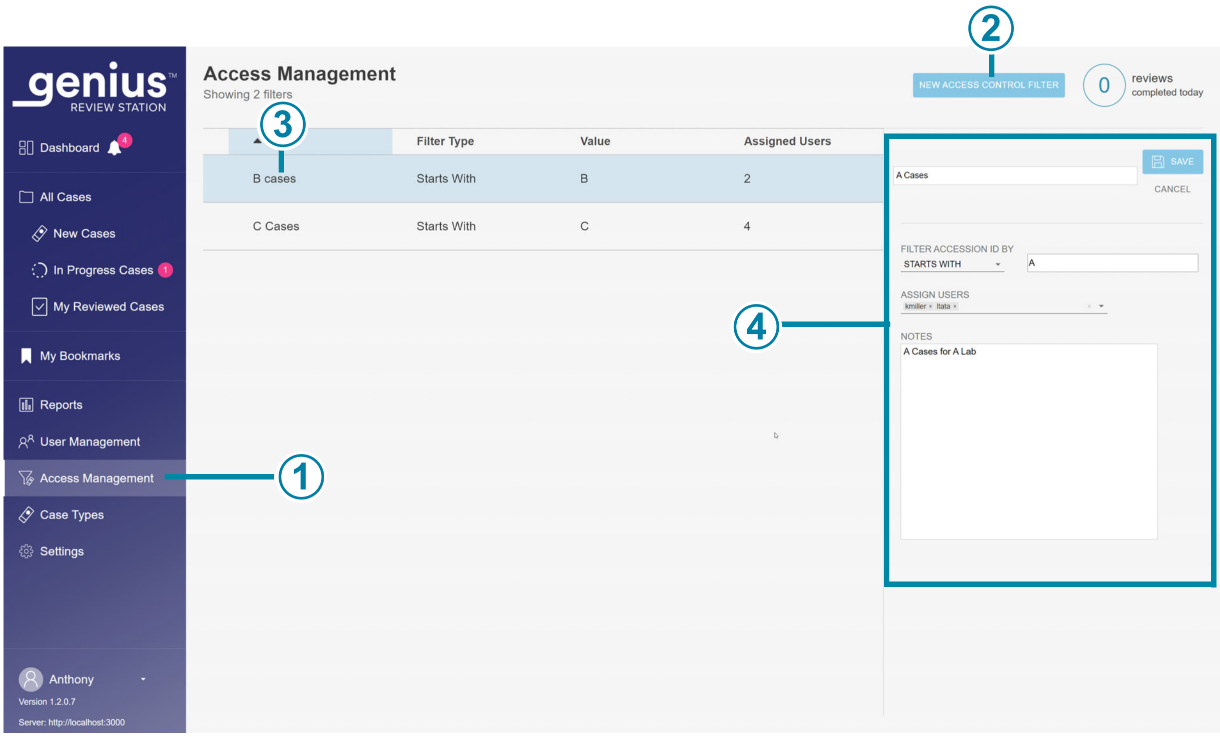


Figure 1-3-18 Access management (administrator only)

Key to Figure 1-3-18	
1	Access Management appears in the menu bar for Review Station administrators.
2	The **New Access Control Filter** button creates a new filter. Refer to “Create an access control filter” on page 3.46.
3	The list of existing access control filters shows the names of all of the access control filters in all of the Genius Review Stations connected to the same Genius Image Management Server. The list displays the name of the filter, the criteria used to filter the accession ID for that filter, and the number of users (administrators, managers, and reviewers combined) who have access to the cases filtered this way.
4	Select any access control filter in the list to display details about that filter.

The details shown when an access control filter is highlighted in the list are entered by the administrator:

- The name of the access control filter
- The criteria for filtering accession IDs
- The usernames of Review Station users who have access to the cases in this access control filter

Note: The username is different from the user's first name and the user's last name. A user enters a username in the Login screen to log in to the application.

- The notes field is an area where the administrator can type in any additional information appropriate for your lab. The notes field is visible to all administrators on the Review Station network.

Refer to "Edit an access control filter" on page 3.48 for instructions on editing an existing access control filter.

Create an access control filter

A user with the administrator role can create a new access control filter in the Review Station network. Access is controlled immediately when the administrator saves the new access control filter. To create a new access control filter:

1. Select Access Management in the menu bar. The Access Management screen appears.
2. Click on the **New Access Control Filter** button.
3. Type the name for the new access control filter.
4. Set the criteria for controlling the access to cases for this filter.
   An accession ID must meet the criteria in order for that case to be accessible to a user assigned to this access control filter. The Genius Digital Diagnostics System stores images and case data for every slide imaged at the Digital Imager(s) in the system. An access control filter controls which Review Station users have access to cases whose accession IDs starts with, ends with, or contains certain characters.
   Select a filter type from the drop-down menu from the available options:
   - Starts with: all accession IDs that start with the character(s) typed in the "value" field will be available to managers and reviewers with access to this filter. The characters and the number of characters are determined by your laboratory.
   - Contains: all accession IDs with the character(s) typed in the "value" field will be available to managers and reviewers associated with the access control filter. The characters and the number of characters are determined by your laboratory.

Note: The characters used as the filtering criteria must be consecutive in the accession ID. For example, if the filter is for accession IDs that contain "ABCD", then a case with an accession ID of "123ABCD456" will be visible to users with access to the filter, and a case with an accession ID of "123A-BCD456" will not be available to users with access to the filter.

- Ends with: all accession IDs that end with the character(s) typed in the “value” field will be available to managers and reviewers with access to this filter. The characters and the number of characters are determined by your laboratory.

5. Assign users to the new access control filter. An access control filter has no effect if it does not have any users assigned to it. Without users assigned to an access control filter, every Review Station user can see cases with the accession ID characteristics that the filter would otherwise control. There are two ways to assign users to an access control filter:
   - An administrator can assign every user. An administrator selects the down-arrow in the “Assign Users” field. Select one or more username from the list of usernames for all of Review Station users. Use the shift key to select multiple usernames adjacent in the list. Use the control key to select multiple usernames that are not adjacent in the list. To add a high number of users, consider adding some users, saving the filter and editing the filter to add more.
   - Or, an administrator can assign a manager to the access control filter, and then the manager can assign reviewers and other managers to that access control filter. An administrator selects the down-arrow in the “Assign Users” field. Select the username of a manager from the list.

Note: If your facility uses access control filters, assign every reviewer to at least one access control filter. A user who is not assigned to any access control filter in a facility that uses access control filters will have access to all of the cases, since none of the access is filtered.

Note: If your facility does not use access control filters, you may not need a user with the administrator role. Conversely, if your facility does not have anyone in the Review Station administrator role, you cannot use access control filters. All users will have all cases available to them.

6. Click **Save** to save the new access control filter, or click **Cancel** to discard the changes.
7. The new filter appears in the list of access control filters.

Edit an access control filter

A user with the administrator role can edit an existing access control filter in the Review Station network.

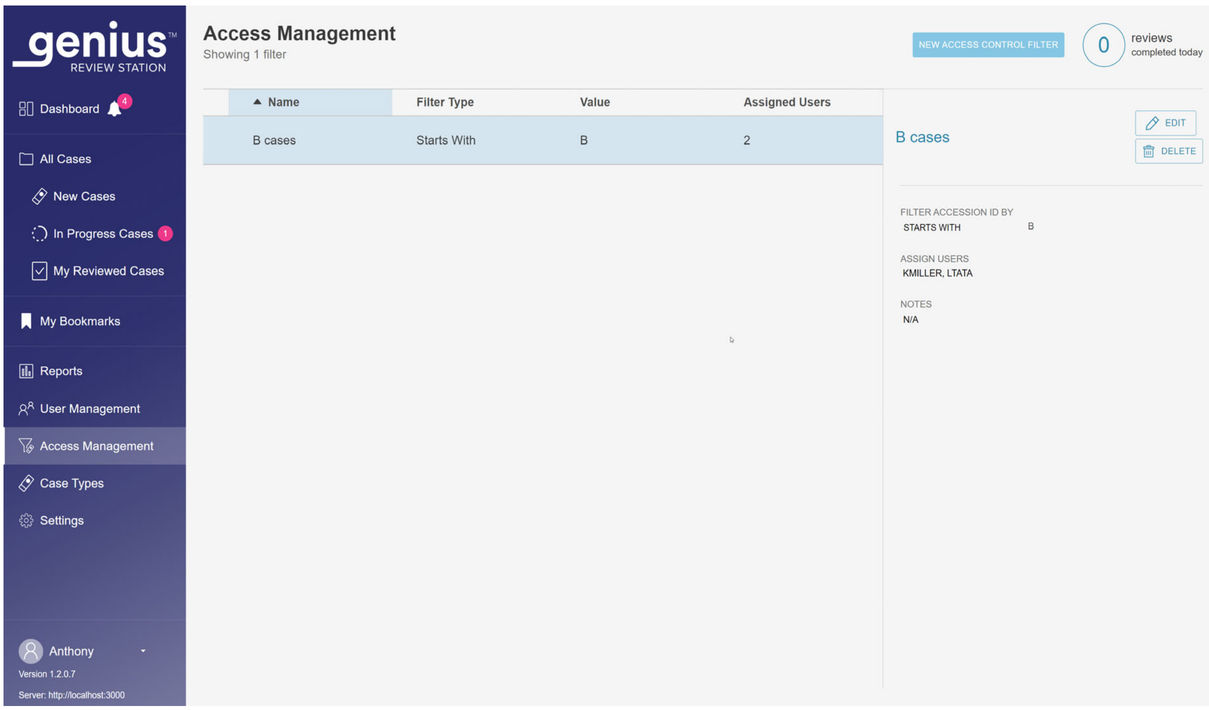


Figure 1-3-19 Edit or delete an access control filter

To edit an access control filter:

1. Select Access Management in the menu bar. The Access Management screen appears.
2. Click anywhere in the access control filter's information to select that filter from the list.
3. To edit the name of the filter, change the filtering criteria, add or remove users assigned to the filter, or make changes to the notes, click the **Edit** button.

Note: A manager can add and remove users in an access control filter that the manager belongs to. Refer to "User Management" on page 3.35.

4. Click in the field(s) to change them.
5. Click **Save** to save the new access control filter, or click **Cancel** to discard the changes.
6. The new filter appears in the list of access control filters.

Delete an access control filter

A user with the administrator role can delete an existing access control filter in the Review Station network. To delete an access control filter:

1. Select Access Management in the menu bar. The Access Management screen appears.

2. Click anywhere in the access control filter's information to select that filter from the list.
3. To permanently delete the access control filter, click the **Delete** button.
4. On the confirmation screen, click **Yes** to continue with the deletion, or click **No** to keep the filter.

Note: If there is a case on the Genius Image Management Server, whose access was controlled by a filter, and then the filter is deleted, the case will be available to an administrator, or to a reviewer or manager who is not assigned to any access control filter. If the case was reviewed, the case is available with read-only access to the reviewer(s) who completed the review of that case.

Note: If a case has been archived from the Genius Image Management Server and retrieved from the archive and that case was controlled by an access control filter that has been deleted, then the case will be available to an administrator, or to a reviewer or manager who is not assigned to any access control filter. If the case was reviewed, the case is available with read-only access to the reviewer(s) who completed the review of that case.

SECTION E

CUSTOMIZE THE VIEW

There are several areas where a reviewer can customize the view of what the Review Station displays. The customization is for that one reviewer. The Dashboard presents a graphical view of data that is similar to data presented in reports. In Case Lists, a reviewer can filter a list of cases so a list shows cases that meet certain, user-defined, custom criteria.

The custom views can be changed by a reviewer whenever the reviewer chooses. The customization is associated with the user's account, so a reviewer will see the customization no matter which Review Station the reviewer logs in to.

Customize the Dashboard Widgets

The area in the center of the Review Station Dashboard can be customized with widgets. The widgets on the Review Station are graphs representing case review data and/or slide imaging data. The content and the format for displaying the content can be customized by the reviewer.

The default set up shows two widgets: Slides Imaged and Reviews Completed.

Figure 1-3-20 Review Station Dashboard, default widgets of Slides Imaged and Reviews Completed

Key to Figure 1-3-20	
1	The lighter color in the menu bar indicates that the **Dashboard** view is the current view. The name **Dashboard** also appears at the top of the center window. After login, the Review Station opens to the Dashboard, and a reviewer can navigate to the Dashboard at any time.
2	The name of the widget in the first widget section. **Slides Imaged** is one of the two default widgets and is shown in this example. The default format for the **Slides Imaged** widget is a column graph of slides imaged over time.
3	The name of the widget in the second widget section. **Reviews Completed** is one of the two default widgets and is shown in this example. The default format for the **Reviews Completed** widget is a column graph of case reviews completed over time.
4	A section (horizontal row) for widgets. Each section can be divided into one, two, or three columns. One column is shown in this example.
5	A section (horizontal row) for widgets, shown with one column in this example.

There are four options for widgets:

- **Slides Imaged**: The Slides Imaged widget graphs the number of slides imaged over a period of time. The data to display can be filtered by case type, by Digital Imager, and by time. The data can be segmented to show each Digital Imager. Or, the data can be segmented to show each case type. An administrator also has the option to filter the data by access control filter.
- **Reviews Completed**: The Reviews Completed widget graphs the number of slides reviewed over a period of time. Users with a reviewer role can see data for reviews they completed, and a manager or an administrator can include additional reviewers. The data to display can be filtered by case type, by reviewer, and by review time (the date and time). The data can be segmented by reviewer. Or, the data can be segmented to show each case type. An administrator also has the option to filter the data by access control filter.
- **Imager Error Rate**: The Imager Error Rate graphs the error rate (the number of slide events expressed as a percentage of the total number of slides processed) for a Digital Imager over a period of time. The data displayed can be filtered by case type, by Digital Imager, and by time. The data can be segmented to show each Digital Imager. Or, the data can be segmented to show each case type.
- **Slide Processing Errors**: The Slide Processing Errors widget graphs the number of slide processing errors (slide events) on a Digital Imager over a period of time. The data to display can be filtered by the error code, by Digital Imager, and by time. The data can be segmented to show the number of errors on each Digital Imager over a period of time or to show the number of occurrences of an error code over a period of time.

A user can remove a widget from the Dashboard, change the type of graph used in an existing widget, and change the range of data included in the graph. Dashboard widgets can be set up with a custom data filter and a custom name in many combinations to suit each user.

Figure 1-3-21 Review Station Dashboard, widget options button

Key to Figure 1-3-21	
1	Use the **+Add Section** button on the Dashboard. See “Add a widget to the Dashboard” on page 3.55.
2	The options button looks like three dots. Use the options to remove or edit the existing widgets on the Dashboard. In this example, this button allows the user to edit or remove the Slides Imaged widget.
3	The options button looks like three dots. Use the options to remove or edit the existing widgets on the Dashboard. In this example, this button allows the user to edit or remove the Reviews Completed widget.

Remove a widget from the Dashboard

1. To remove a widget, select the options button (the three dots).
2. Select **Remove Widget**.
3. A confirmation message appears. Select “yes” to confirm.

If desired, select the "x" in the upper corner to remove the box surrounding the empty area.

Figure 1-3-22 Review Station Dashboard, add widget section, remove or edit widget

Key to Figure 1-3-22	
1	The options button looks like three dots. Click here to see the **Edit Widget** and **Remove Widget** options.
2	**Edit Widget** Refer to "Edit a widget" on page 3.54.
3	**Remove Widget** Click here to remove this widget from the Dashboard.

Edit a widget

There are several options for editing a widget. Choose as many or few customizations as desired. To edit a widget, select **Edit Widget**. The Edit Widget window opens and shows the options for that widget.

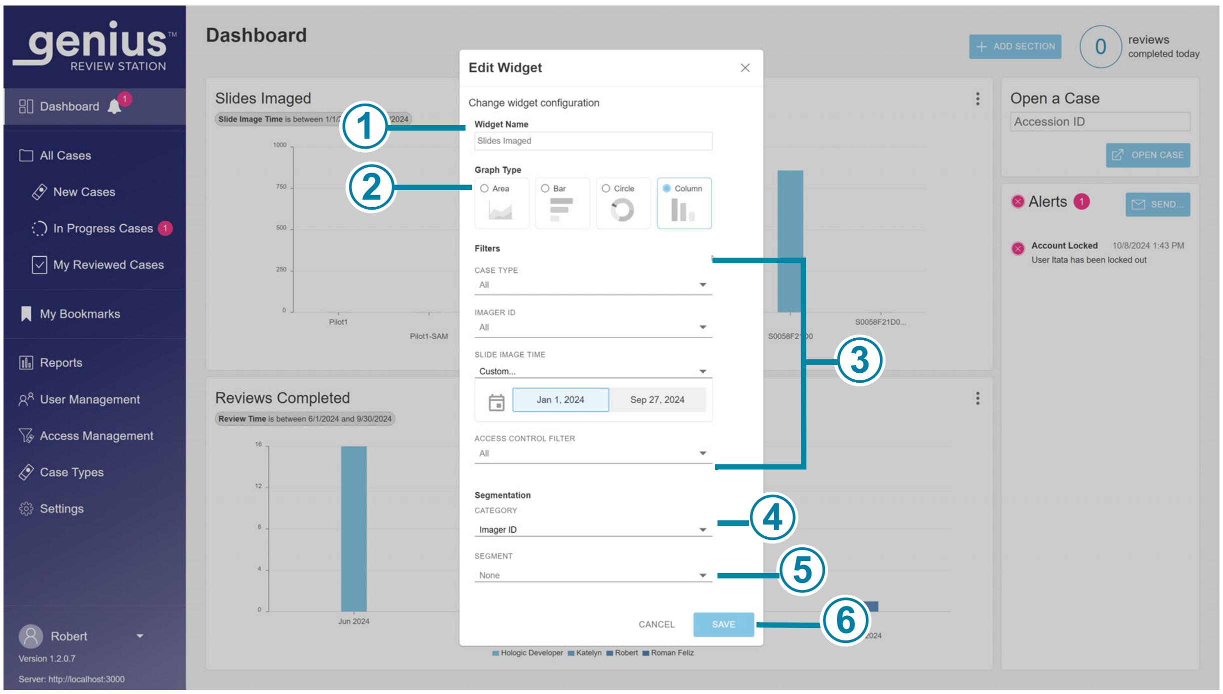


Figure 1-3-23 Review Station Dashboard, edit a widget

Key to Figure 1-3-23	
1	**Widget Name** Type in a name for the widget.
2	**Graph Type** Click on the icon representing the kind of graph for the widget (graphed area, horizontal bar chart, circle, or vertical columns).

Key to Figure 1-3-23	
3	**Filters** Use the drop-down menus to set the criteria for a filter. In this example, the data displayed in the widget can be filtered by case type, by Digital Imager, by slide image time (because this example is a Slides Imaged widget), and/or by the name of an access control filter. The filter criteria differ for the different widgets. **Caution:** There are limits on how much data can be displayed in a graph. If the filter will generate too much data, an error message will appear, recommending that the selections for the filter be changed. ***Note:*** Choose the interval that is one unit smaller than the desired time period. For example, for a graph of slides imaged in a one-year period, try selecting a time interval of month; for a graph of slides imaged in a month, try selecting a time interval of a week.
4	**Category or segmentation category** Depending on the graph type, the edit widget screen may have a category section for choosing x- and y-axes for the graph, and it may have a segmentation category. When segmentation is used and the user hovers the mouse over a portion of the graph, the values for each segment in that section of the graph are displayed. Use the drop-down menu to set the criteria for the graph axes or the segmentation. Using segmentation in one of the widget graphs shows more detail, showing which data contributed to the section of the graph.
5	**Segment** When some segmentation categories are used, such as time, a segment can also be specified. For example, a user can set up a widget with a segmentation category of slide image time and a segment of "day" to see how many slides per Digital Imager were imaged in a day.
6	Click **Save** to save the changes and return to the Dashboard screen, or click **Cancel** to leave the widgets as they are.

Select the attributes that you want to change. Choose from Widget Name, Graph Type, Filters, and Segmentation.

Add a widget to the Dashboard

1. To add a section and a widget, select **+Add Section**.
2. Choose the layout for the section. The Dashboard can show the widgets in one, two or three columns. Select the number of columns that you prefer.
3. Select **Continue**. An empty space for graphs appears on the screen.
4. Select "+" in the center of the empty space for graphs. The screen shows the four options for widgets.

5. Select one of the options and the widget is added to the Dashboard. To edit the widget, select the three dots. The options for editing a new widget are the same for editing an existing widget. Refer to “Review Station Dashboard, edit a widget” on page 3.54.

Case Lists

Hide archived cases

The reviewer can specify whether the list of cases should show or hide cases that have been archived.

Data for archived cases is stored in the Genius Digital Diagnostics System database. The images for archived cases are not immediately available for viewing on the Review Station. An archived case must be retrieved from storage before its images can be viewed. For more information on archived cases, refer to “Archive” on page 3.23.

An archived case has an icon shaped like a file box to the left of its accession ID.

Search by accession ID

The **Search by accession ID** box at the top of a Case List allows a user to search for a case by entering in the entire accession ID or by typing in the first few characters of the accession ID.

Click on the magnifying glass icon or press enter on the keyboard to start the search.

The list of cases changes to the search results.

If the search was conducted from the first few characters of the accession ID, all of the cases that start with the search criteria appear in the Case List.

If one case matches the search criteria, that one case appears in the Case List.

If there is no match for the search criteria, the Case List is empty and the number of cases is zero.

Search by tag

The **Select...** box at the top of the Case List allows a user to search for all of the cases that have been tagged with the same tag (a keyword set up by a manager or administrator).

Select the tag from the drop-down list or by typing the first few characters of the tag's name.

If there are no tags set up for the lab, there is nothing in the drop-down list.

The list of cases changes to the search results. The search criteria for this tag can be saved as a custom filter. When the search results are displayed in the Case List, click **Save as Custom Filter...**. For information on saving custom filters, refer to “Save a custom filter” on page 3.66.

If the tag selected for the search has not been applied to any cases, the Case List is empty and the number of cases is zero.

- "Contains all tags" will search for cases associated with a combination of the selected tags. For example, if Tag A, Tag B, and Tag C are entered in the "Select..." box, with "Contains all tags" selected, the search results will be cases with the combination of Tag A, Tag B, and Tag C (all three tags) applied.
- "Contains any tag" will search for any case associated with one or more of the selected tags. For example, if Tag A, Tag B, and Tag C are entered in the "Select..." box, with "Contains any tag" selected, the search results will be cases with:
  Tag A, Tag B, or Tag C applied, including cases tagged with combinations of:
  Tag A and Tag B,
  Tag B and Tag C,
  Tag A and Tag C, and
  Tag A, Tag B and Tag C.

Multi-select menu in the case list

The menu above the icons in the Case List screen allows a reviewer to apply a tag to one or more cases. The same menu allows a manager to reclaim one or more cases, reset one or more cases, or delete one or more cases.

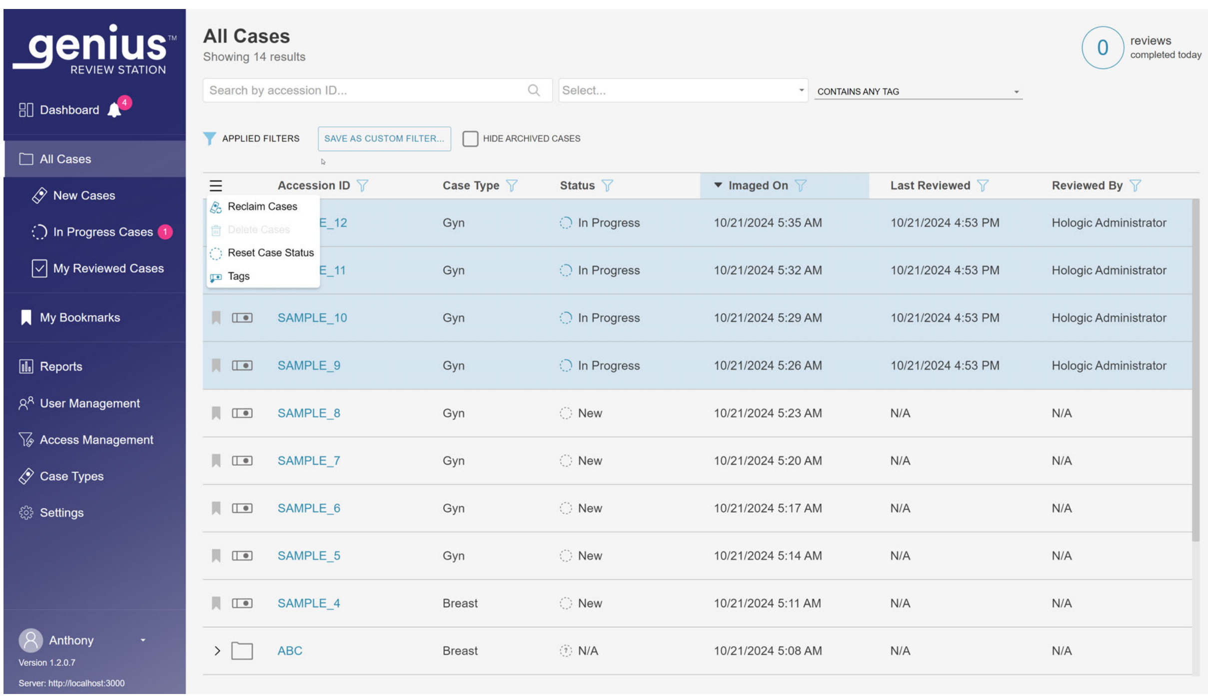


Figure 1-3-24 Select multiple cases (administrator role shown)

Note: Consider using the search bar or filtering the case list to prepare to select multiple cases.

1. To select multiple cases in the Case List:
   - Click anywhere other than the accession ID in the case list to select one case.

- Hold the shift key and scroll up or scroll down to select the cases adjacent to the selected case in the list.
- Hold the control key and select other case(s) in the list.

2. Click the menu icon and choose between the available options:
   - Reclaim cases (Manager or Administrator). Refer to "Reclaim a case" on page 3.61.
   - Delete cases (Manager or Administrator). Refer to "Delete a case" on page 3.63.
   - Reset cases (Manager or Administrator). Refer to "Reset a case" on page 3.62.
   - Tags (Reviewer, Manager or Administrator). Refer to Parts 2 and 3 of this manual.

All Cases

The All Cases section lists all of the slide data stored on the Image Management Server.

Select "All Cases" on the menu bar on the left and the main pane displays all of the slide data.

The data in the list of cases can be filtered by different criteria. The lists of cases can include or exclude archived cases by un-checking or checking the "Hide Archived Cases" button. Your view of the data may be filtered to only include accession IDs relevant for your site, if your lab uses access control filters.

New Cases

"New Cases" are cases that are ready to review, but review data has not yet been saved nor marked as reviewed.

For New Cases, columns in the main pane can be filtered, similar to filtering "All Cases". The Status cannot be filtered because the status is always "New".

In Progress Cases

"In Progress" cases are the cases that the current reviewer has saved, but not completed, with the status of "In Progress".

For In Progress Cases, columns in the main pane can be filtered, similar to filtering "All Cases". The Status column cannot be filtered because the status is always "In Progress". The "Reviewed by" cannot be filtered because the reviewer is always the current user logged in at this Review Station.

My Reviewed Cases

"My Reviewed Cases" are the cases for which the current reviewer has completed the review.

For My Reviewed Cases, columns in the main pane can be filtered, similar to filtering “All Cases”. The Status column cannot be filtered because the status is always “Reviewed”. The “Reviewed By” column cannot be filtered because the reviewer is always the current user logged in at this Review Station.

Case Details

Click anywhere in the Case List other than the Accession ID, and a new pane describing that case opens. To close the section on the right, click the “x” in the upper right, or click on any of the column headings in the Case List.

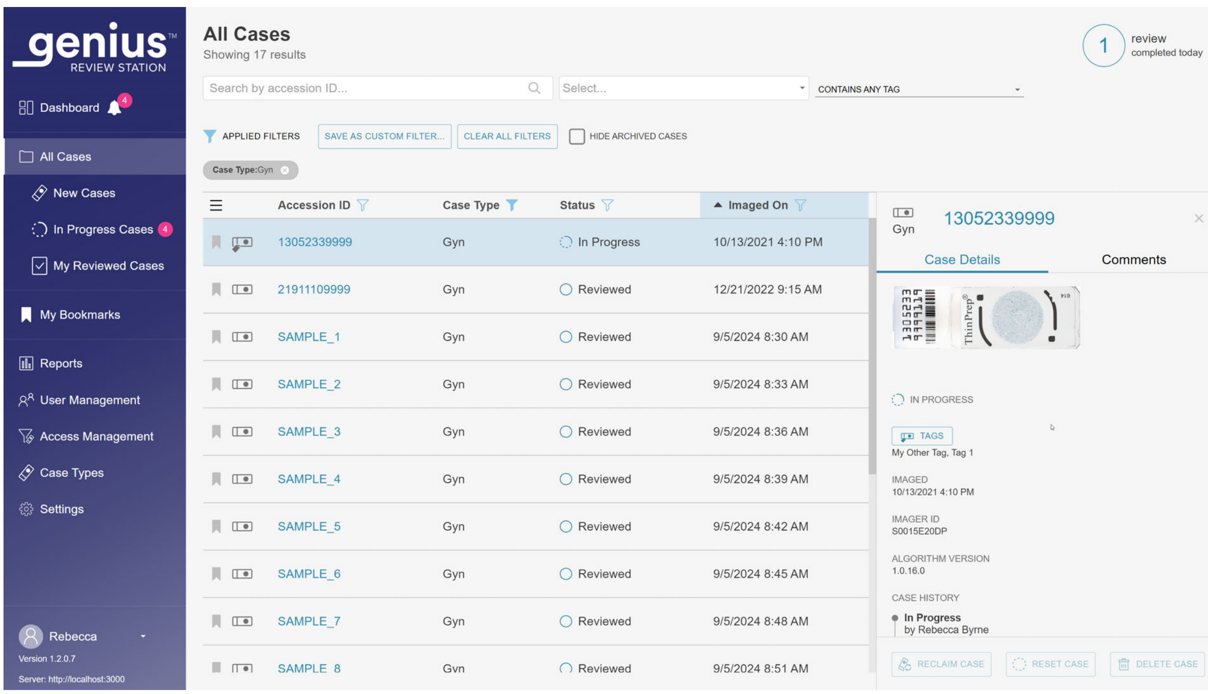


Figure 1-3-25 Case Detail - Gyn example, administrator role shown

The Case Details section shows the case type, a photo of the entire slide including its label, a status indicator describing if the case has been reviewed or not, a status indicator describing if any tags have been applied, the date the slide was imaged, and the Imager where the slide was imaged. A Case History summarizes the review status, review date and reviewer. A scroll bar is available on the right when the Case History section contains information.

The Comments section shows any comments that a reviewer added along with the reviewer’s name and a date/time stamp.

In the Case Details section, a manager or an administrator has three options that are not available to a reviewer: reclaim a case, reset a case and delete a case. A lab tech can also delete a case.

Focus colormap of the scan area

(Custom Case Types only)

If a case is imaged using a custom Case Type, the Digital Imager software generates a colormap that shows information about focus quality control. A user at the Review Station has the option to see the colormap on the Case Details screen as shown in Figure 1-3-26. A reviewer also has the option to see the colormap as a layer on the whole slide image during case review. Additional information for Case Review of custom Case Types is available in Part 3 of this manual.

The colormap uses blue to indicate pixels that the software considers as in-focus, red for out-of-focus, yellow for the edge of the slide, and purple for the painted markings on certain ThinPrep slides. The colormap data is part of the slide data set saved for the case at the Genius Image Management Server.

The scan area colormap can be helpful for quickly identifying cases where the Digital Imager was not able to capture a good digital image on the entire case. For example, a lab tech at the Digital Imager might decide to delete an image after noticing bubbles due to improper coverslipping of the slide. After correcting the slide preparation issue, the slide can be re-imaged.

Note: The colormap is not shown for Gyn cases, which run the Genius Cervical AI algorithm. The informational messages generated by the Genius Cervical AI algorithm describe characteristics of portions of the image, such as out-of-focus objects.

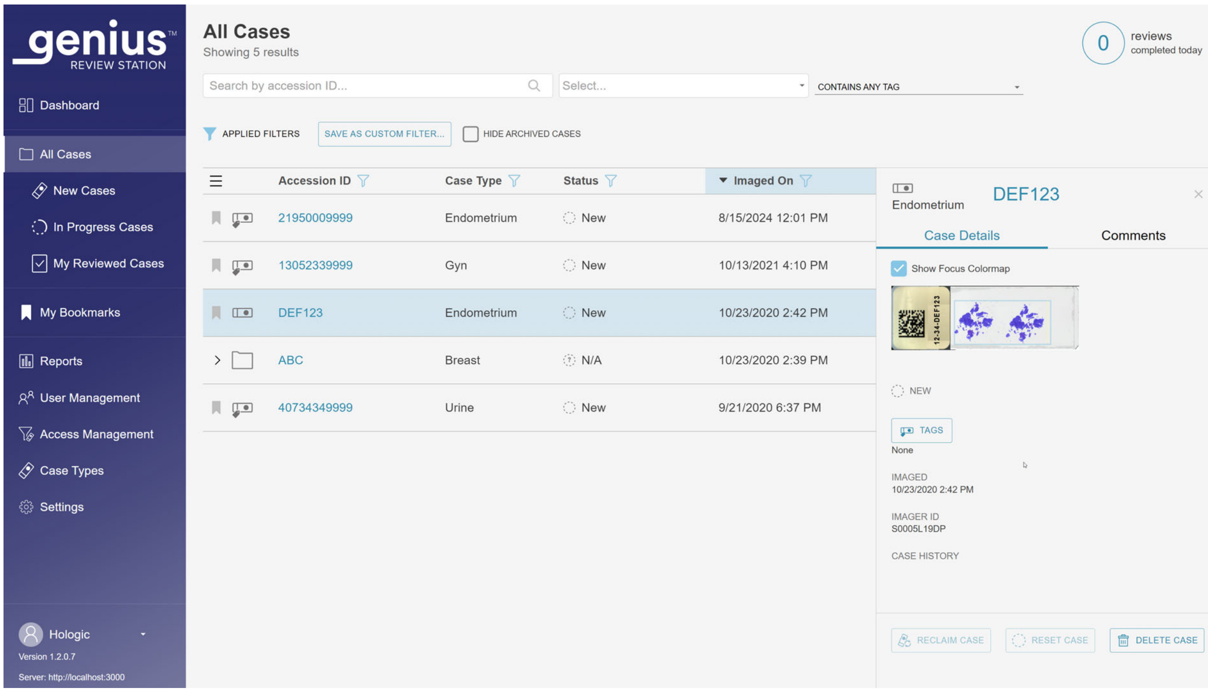


Figure 1-3-26 Case Detail, custom Case Type example

Reclaim a case

(Manager or administrator, in-progress cases only)

If a reviewer has a case in progress, it is not available for other reviewers to add marks, add comments, or complete the review. In situations where there is the need to re-assign the case from the current reviewer, for example, if the reviewer is out sick, a manager or an administrator can reclaim an in-progress case.

Find and select the case or cases to reclaim. Use the "Search by Accession ID" search bar, or consider filtering "In Progress Cases" by a reviewer's name. A manager or an administrator has the **Reclaim Case** button available in the Case Details section of an in-progress case and in the menu above the icons in the Case List.

1. Click on the **Reclaim Case** button.
2. A confirmation message appears to confirm that you want to reassign the case.
    - Click **yes** to confirm and reclaim the case.
    - Click **no** to keep the case in progress with the current reviewer.

The case remains in the In Progress status, and that manager or administrator is now assigned as the reviewer for the case. The existing comments and marks are included with the case. The manager or administrator can now complete the review for the case.

Or, the manager or administrator can discard the existing comments and marks from the original reviewer and make the case available to other reviewers.

1. Open the In Progress case that was reclaimed.
2. Click on the **Cancel** button in the upper right.
3. On the screen that asks, “Save changes from this review session?”, click on **Don’t Save** to remove the existing comments and marks. The case returns to the status it was at before this most recent review started.

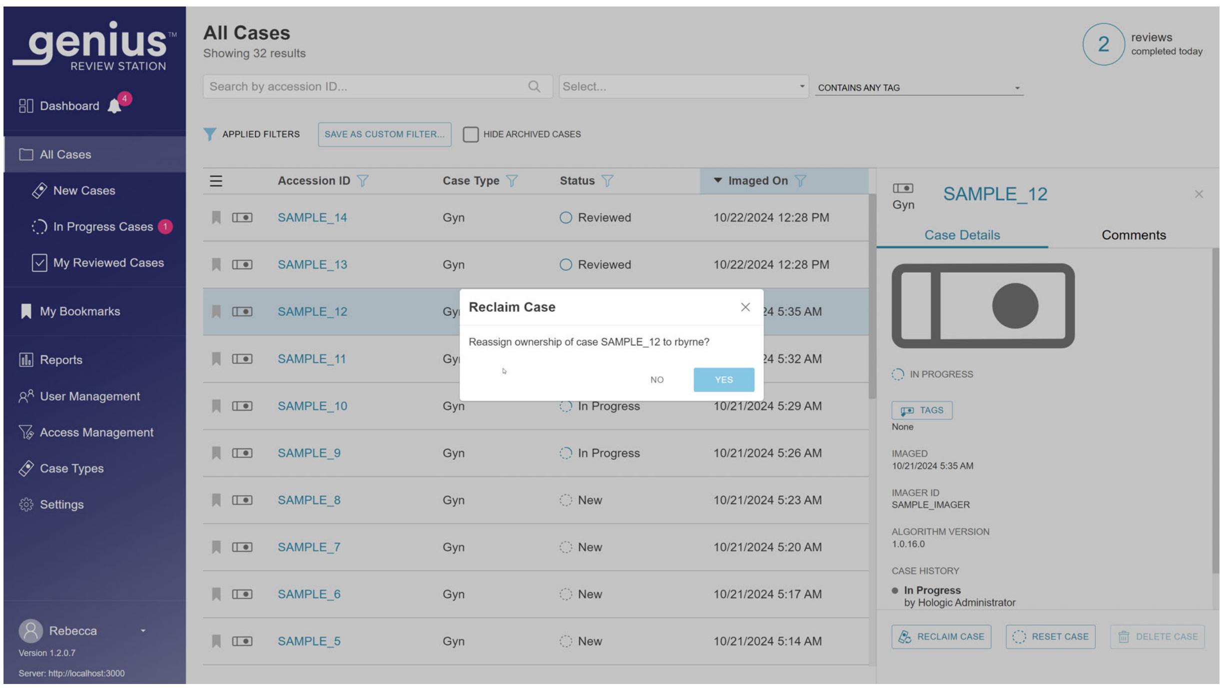


Figure 1-3-27 Reclaim an in-progress case, administrator Case Details view

Reset a case

(Manager or administrator, in-progress cases only)

If a reviewer has a case in progress, it is not available for other reviewers to add marks, add comments, or complete the review. In situations where there is the need to re-assign the case from the current reviewer, for example, if the reviewer is out sick, a manager or administrator can reset an in-progress case to the "New" status, making the case available for any reviewer to review.

Find and select the case or cases to reset. Use the “Search by Accession ID” search bar, or consider filtering “In Progress” cases by a reviewer’s name. A manager or an administrator has the **Reset Case** button available in the Case Details section of an in-progress case, and in the menu above the icons in the Case List.

1. Click on the **Reset Case** button.

A confirmation message appears to confirm that you want to reset the status to "new" for the case.

- Click **yes** to confirm and reset the case.
- Click **no** to keep the case in progress with the current reviewer

The status changes from “In Progress” to "New". Any tags applied to the case remain. A reviewer can now complete the review for the case.

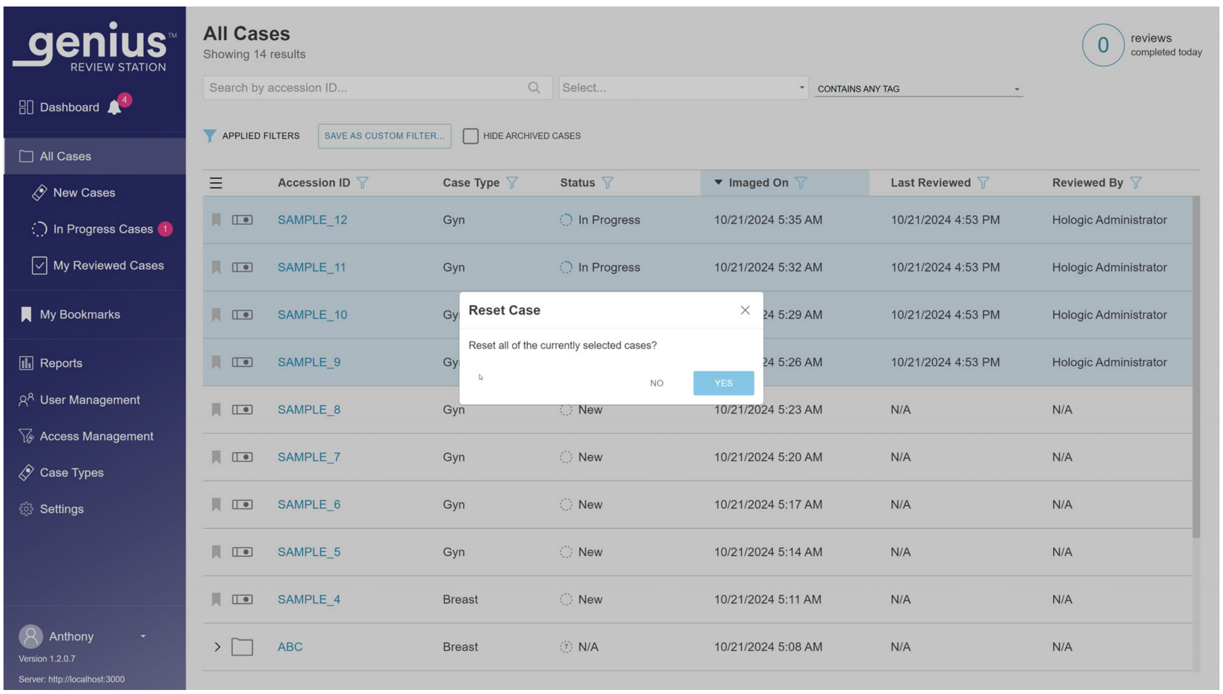


Figure 1-3-28 Reset a case, multiple cases selected from the Case List, administrator view shown

Delete a case

(Manager, administrator or lab tech; new cases only)

A manager, an administrator or a lab tech has a **Delete Case** button available in the Case Details section of new cases and in the menu above the icons in the Case List. This feature may be helpful in cases where there is a need to re-image the slide. Cases where a review is in progress or that are already reviewed cannot be deleted with the **Delete Case** button.

Once an accession ID is deleted from the Genius Digital Diagnostics System, that accession ID can be used again in the system.

Click on the **Delete Case** button to irreversibly remove the case from the Genius Digital Diagnostics System.

Figure 1-3-29 Confirm deletion (manager, administrator, or lab tech, new cases only)

Click **Yes** to confirm, or click **No** to leave the slide as a New Case.

Note: If multiple cases are selected from the Case List and the selection includes one or more cases that are not all eligible to be deleted, a message appears describing the number of cases that will be deleted. For example, if one of four selected cases is in progress, the message explains that 3 of 4 cases will be deleted.

Data Filters

Using data filters

For each of the columns of data in a list of cases in the main pane, use the arrow at the top of the column to toggle between ascending order and descending order.

For each of the columns in the main pane, the data can be filtered. Use the filter icon to set filter criteria.

Accession ID Filter – the Accession ID Filter can be used to search for all cases that contain specific number or letters. Or, the Accession ID Filter can be used to search for all cases between a specific numeric range. And, an administrator or a user assigned to more than one access control filter can also filter accession IDs by the name of the access control filter.

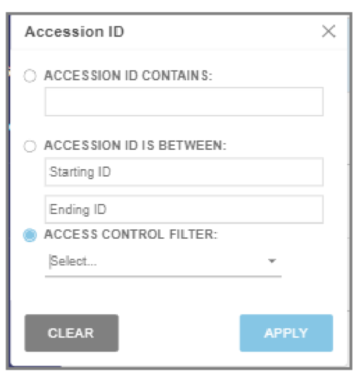


Figure 1-3-30 Accession ID filter, administrator example

Case Type Filter – Filter by Case Type to display cases with only one specimen type.

- Set the filter to Gyn to display only ThinPrep Pap tests using Genius Cervical AI.

- Set the filter to any other case type to display cases of only that case type.

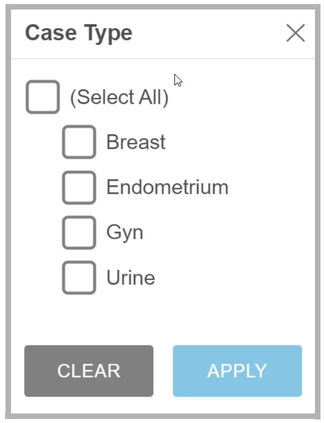


Figure 1-3-31 Case Type filter, with examples of custom Case Types

Status Filter – the Status Filter can be used to display cases of a certain review status.

- Set the filter to "New" to display cases where no review of the slide image has started.
- Set the filter to "In Progress" to display cases where a review of the slide image has started but has not been completed.
- Set the filter to "Reviewed" to display cases where the review of the slide image has been marked as reviewed in the Review Station.

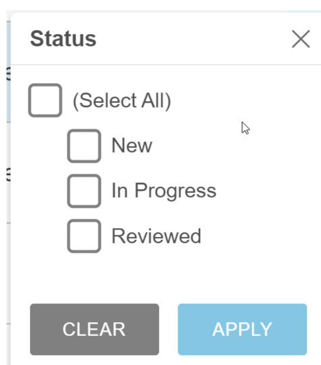


Figure 1-3-32 Status filter

Imaged On Filter – to display results for cases that were imaged on a certain date or a certain period of time, use the Imaged On filter.

- Click on the filter icon and select from the pre-set options or set a custom filter for the date.
- The pre-set options are: Today, Yesterday, Last 7 days, Last 30 days.
- The "Custom" option opens a calendar. Select one date or a range of dates on the calendar.

Note: The date is set on the Image Management Server. The same date settings apply to all Digital Imagers and all Review Stations connected to the Image Management Server.

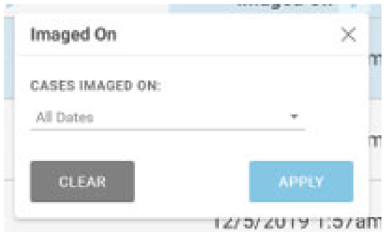


Figure 1-3-33 Imaged On filter

Last Reviewed Filter – to display results for cases that were reviewed on a certain date or a certain period of time, use the Last Reviewed filter. The "Last Reviewed" date is the latest date that review data for a case was saved from any Review Station connected to the Image Management Server, reviewed by any reviewer.

- Click on the filter icon and select from the pre-set options or set a custom filter for the date.
- The pre-set options are: Today, Yesterday, Last 7 days, Last 30 days.
- The "Custom" option opens a calendar. Select one date or a range of dates on the calendar.

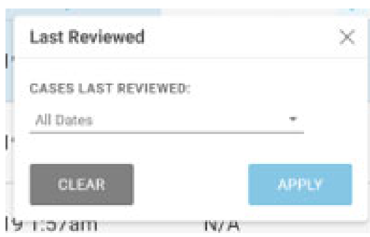


Figure 1-3-34 Last Reviewed filter

Review by Filter - Filter by "reviewed by" to see all of the cases for a particular reviewer or reviewers in the lab. The drop-down list shows all of the users with Review Station accounts. Select one or more names from the list. This filter is not available on "My Reviewed Cases" because the reviewer is pre-set to the current user for "My Reviewed Cases".

Review status – Filter by "Reviewed" to see all of the cases that are in the same status (All Cases, New Cases, In Progress, Reviewed). This filter is only available when the Case List is viewed in the All Cases filter group.

Save a custom filter

From any of the predetermined filter groups (All Cases, New Cases, In Progress Cases, My Reviewed Cases), filter the data in the custom way that suits your needs. To save the filter criteria as a custom filter, select **Save as Custom Filter**. Type in a name for the custom filter. Select **Continue**.

The custom filter is added to the menu bar on the left.

After a custom filter is created, the custom filter can be edited, and the custom filter can be deleted.

Edit a custom filter's filter criteria

1. To change the filter criteria for a custom filter, select the custom filter in the menu bar on the left.
2. Select the **Edit** button in the upper right.
3. To change a custom filter's filter criteria, filter the column(s) in the manner you would like to edit. Select **Save** in the upper right.

Edit the name of a custom filter

1. To change the name of a custom filter or its filter criteria, select the custom filter in the menu bar on the left.
2. Select the **Edit** name button in the upper right.
3. Type the new name where the existing custom name is shown.
4. Select **Continue** to change the name, or select **Cancel** to leave the name unchanged.

Delete a custom filter

1. To delete a custom filter, select the custom filter in the menu bar on the left.
2. Select the **Delete Filter** button in the upper right.
3. Select **Delete** to delete the custom filter, or select **Cancel** to leave the filter unchanged.

Log Out

To log out of the system, click on your name in the lower left of the menu bar on the left.

From the menu, select **Log Out** and confirm the intent to log out.

Alerts

The Alerts feature provides a way for a manager or an administrator to send a message to the Dashboard of one or more reviewers, managers or lab techs. For labs using access control filters, a manager can send an alert to users within the manager's access control filter. An administrator can send an alert to any user at Review Stations connected to the same Image Management Server.

Send an alert

(Manager, administrator and automatic)

Alerts come from two sources. Some alerts are automatically generated by the software and present information about the system status. For example, when the system successfully retrieves an archived case from the server, an alert notifies the reviewer that the case has been retrieved.

A manager or an administrator can also type in a message and send it to reviewers as an alert.

1. Click the **Send...** button in the Alerts area on the right side of the Dashboard screen.
2. Select the recipient(s) for the alert from the available options in the drop-down menu. The options are to select each user by name, select all reviewers, select all reviewers within a

particular access control filter, select all managers, or select all managers within a particular access control filter.

3. Using the keyboard, type the text for the alert in the **Message** field.
4. Click **Send** to send the alert. Or, to delete the alert without sending it, click the **Cancel** button.

Figure 1-3-35 Send an alert, administrator example

Key to Figure 1-3-35	
1	Click **Send...** to open the dialog box to create a new alert.
2	Select the recipients from the options in the drop-down list.
3	Type the message that the recipients will see.
4	Click **Send** to send the alert. Or, to delete the alert without sending it, click the **Cancel** button

Receive and read an alert

On the Dashboard, when a reviewer, lab tech, manager, or an administrator has an unread alert pending, a bell-shaped icon and a pink circle with the number of unread alerts display next to the title, **Dashboard**.

When there is an unread alert, the **Alert** section on the right side of the Dashboard screen shows the alert message and the number of alerts. This area is empty when there are no unread alerts.

1. When you no longer need the alert displayed, click on the "x" to the left of an alert message.
2. A confirmation message appears to confirm that you want to clear the alert.
    - Click **yes** to confirm and clear the alert permanently.
    - Click **no** to keep the alert visible on the Dashboard.

Clear all alerts

As an alternative to clearing each alert individually, a lab tech, a reviewer, a manager, and an administrator can permanently delete all of their alerts with the **Clear all alerts** button.

1. When you no longer need the alerts displayed, click on the "x" to the left of an alert message.
2. A confirmation message appears to confirm that you want to clear all of the alerts.
    - Click **yes** to confirm and clear the alerts permanently.
    - Click **no** to keep the alerts visible on the Dashboard.

If an alert was sent to all managers or all administrators, each user has the option to only clear the alerts from their own Dashboard.

SECTION F BOOKMARKS

Use the Bookmarks feature to save an individual case or groups of cases for future reference. The Bookmarks feature is intended to make individual cases and individual categories of cases readily available. Bookmarks are private "collections" of cases that cannot be shared or viewed by other users. The use of bookmarks is optional.

Setting up Bookmarks

Categories

The Review Station allows a user to group individual cases together. The name of a category is created by the user. For example, if it might be convenient to a reviewer to be able to quickly refer to a classic example of a case or a particular disease, consider setting up a Bookmark category for that disease and then adding cases that all fall into that same category to the Bookmark.

Uncategorized

Individual cases can be bookmarked without being put into a category. Select "Uncategorized" to save an individual case in your bookmarks.

Create a Bookmark

1. In the Case List, select the bookmark icon for the case to be added.
2. The "Add Bookmark" window opens.
3. To add the case to an existing category of bookmarks, select "Existing Category".
4. Select the down-arrow to open the list of existing categories.
5. Select the name of the existing category.
6. To create a new category of bookmarks, select "New Category".
7. Type in a name for the new category.
8. Select Continue to add the case to that category.

When a case has a bookmark associated with it, the bookmark icon is black.

Using Bookmarks

To access cases that have been bookmarked, select My Bookmarks from the menu bar on the left.

The category that was viewed most recently displays. The cases in the bookmark category appear in the Case List. The name of the category is repeated as an "Applied Filter" to case data, resulting in a Case List of cases for that category.

To view cases in a different bookmark category, select the down-arrow next to the category name.

To view the images for a case in the Case List, click on the Accession ID.

SECTION G REPORTS

There are several standard reports available on the Review Station and variations of the standard reports can be saved as custom reports by the user.

There are reports that are specific to the Gyn case type using Genius Cervical AI. Refer to Part 2 of this manual for information on these reports.

The reports described below relate to any case type and can include data for Gyn cases using Genius Cervical AI.

Standard Reports

Each of the standard reports requires the user to enter some criteria, such as a date range. Each report is displayed on the screen, can be printed as a PDF, and can be saved.

1. To view reports, select "Reports" in the menu bar on the left.

2. Select a report from the list. A description and criteria for filtering and sorting appear on a pane on the right.
3. For each report, select the filter criteria and select the sorting criteria.
4. Either select **Run Report** to run the report
   or
   Select **Save as Custom**. Saving a custom report saves a report with the specified filter criteria and sorting criteria. When the “Save as New Report” screen appears, type in a name for the custom report. To add an optional description for the report, type a description into the “Description” box.

Note: A name for the report must be entered. The same name cannot be used for more than one report.

To save the name and description, press “Continue.”
Once it is saved, the custom report is available in the list of reports for the reviewer who created the custom report. Select the report name to run the report.

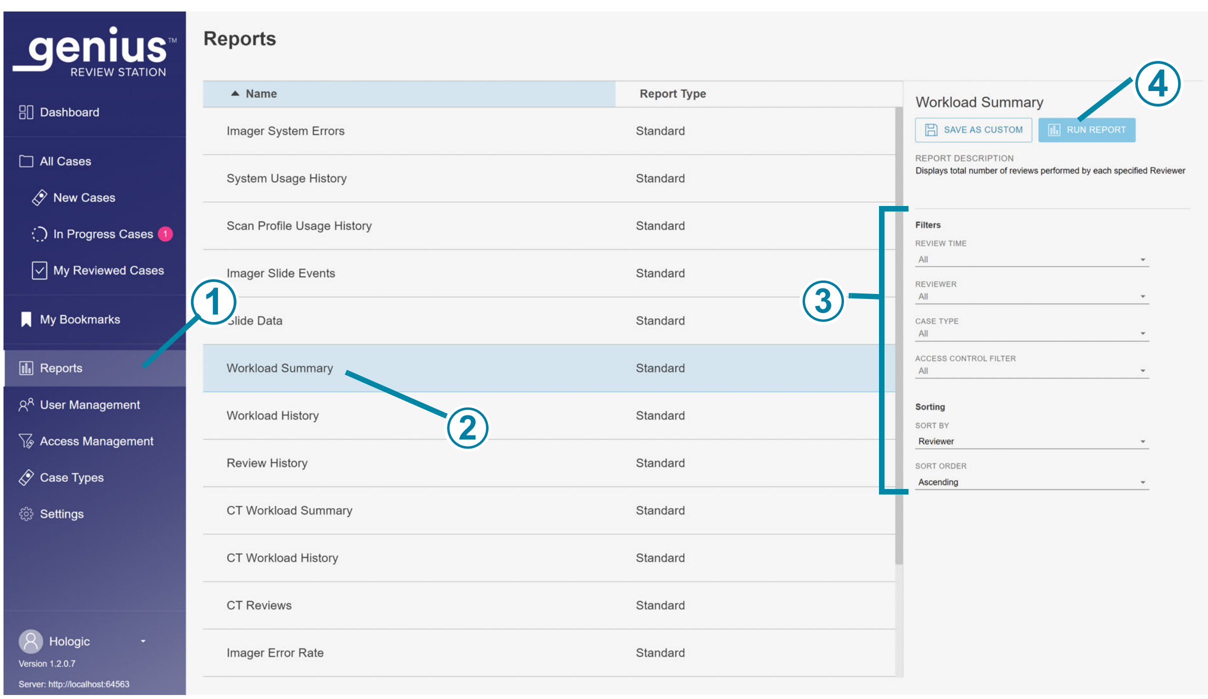


Figure 1-3-36 List of reports, Workload Summary selected

Key to Figure 1-3-36	
1	Click on **Reports**.

Key to Figure 1-3-36	
2	Select the name of an existing report.
3	Select the criteria for filtering and sorting the data in the report.
4	Select **Run Report**, or save the report as a custom report and then run the report.

5. When a report is run, the report results appear in a new window on the screen.
   The heading shows the name of the report, the number of entries in the report, the date the report was generated, and the lab name.
   Use the buttons on the upper right to print the report as a PDF or to export the report as a CSV file. Reports saved as CSV will open in a spreadsheet software application, if an application such as Microsoft Excel is installed on the Review Station computer. A PDF or CSV file can be saved on the Review Station computer.

   Note: The site must have a secure firewall and strong network security for devices connected to the Image Management Server and Review Station computer.

The columns in any report are always the same. Using different criteria to filter and sort a report changes the appearance of the report. Above the columns in a report, the Applied Filters section describes the criteria used in generating the report.

If the number of entries for the report exceeds the maximum set up for your laboratory, a message at the top of the report explains that only some results are shown. To report large amounts of data, consider running several reports each covering a smaller range, such as a smaller time period.

Custom time period for reports

Reports on the Review Station can be run for several standard time periods, or the time period can be customized. To use a custom time period in a report:

1. Select **Custom...** from the drop-down list of time periods for the report.
2. On the calendar graphic that appears, the box on the left represents the start date and the box on the right represents the end date for the custom time period. Click on dates in the calendar to select the start and end date. If needed, navigate through the months with the arrows.
3. Click the **Done** button to close the custom calendar screen.

Review History

The Review History Report lists individual accession IDs reviewed at the Review Station during a period of time. A manager or an administrator can select more than one reviewer to include in the report. For labs using access control filters, a manager selects from reviewers within the manager's access control filter, and an administrator selects from the users of all of the Review Stations connected to the same Image Management Server. When a reviewer runs the report, the data only includes that one reviewer.

1. Choose the time period for the report data.
   Select a review time from the available options of:
   - All (all of the data in the server's database)
   - Today
   - Yesterday
   - Last 7 days
   - Last 30 days
   - Custom
2. A manager or an administrator must also choose which reviewers to include in the report data.
   - Select one or more reviewers by clicking on the name of the reviewer in the list, or
   - All (all of the reviewers in the server's database)

   When a reviewer runs this report, that reviewer's name is preselected and is the only available option.

   Note: Each completed review of a case at the Review Station is considered a review by the Review Station. For example, an initial review by a CT, a subsequent review for quality control and a review by a pathologist, are each considered a review by the Review Station.
3. Choose which Case Type(s) to include in the report. Select from the available options:
   - Gyn
   - Any custom Case Type
   - All

   Note: Reports on the Review Station list the entire Accession ID. In instances where a case consists of several slides, the Accession ID for each slide is reported, regardless of whether the Genius Digital Diagnostics System has been set up to group the slides from one case together in the Case Lists on the Review Station.
4. If access control filters are used, choose the access control filter(s) that will be included in the report data.
   - Select one or more access control filter by clicking on the name of the filter(s) in the list, or
   - All (cases from all of the access control filters in the server's database)
5. Choose the category that will be used to sort the data in the report. Choose from:
   - Review time (the date and time)
   - Accession ID

- Reviewer
- Review marks

6. Choose the order in which the data will appear:
    - Sort the results in ascending or descending order.

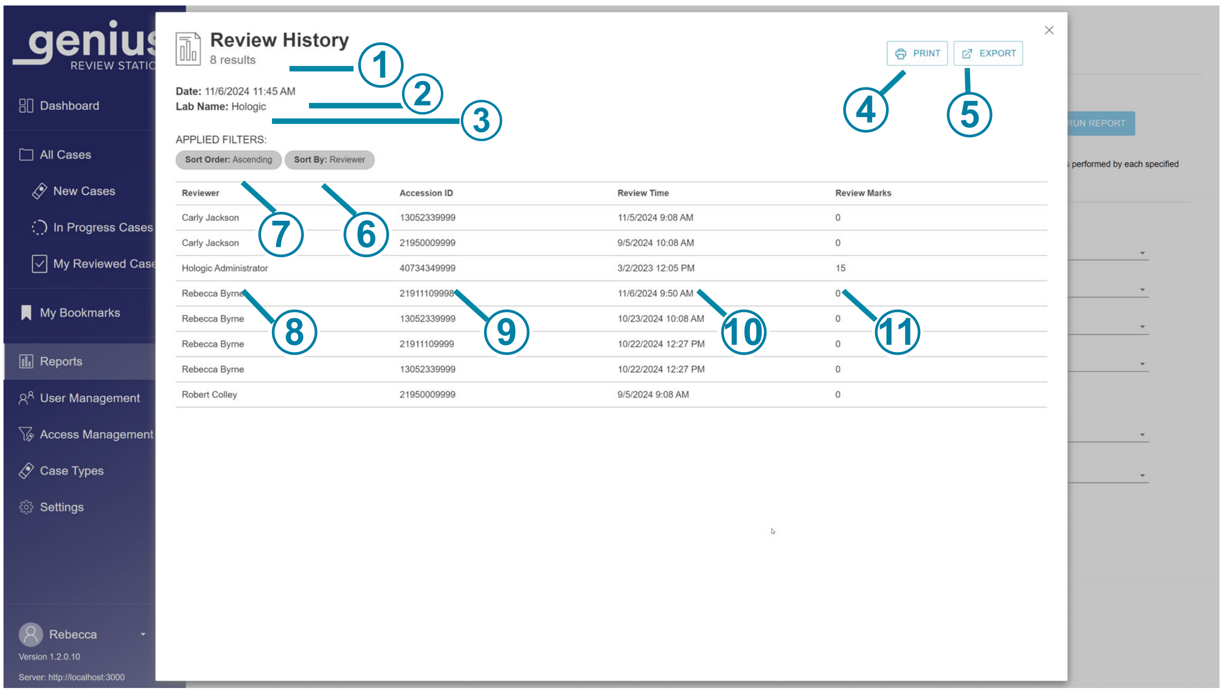


Figure 1-3-37 Review History Report, example

Key to Figure 1-3-37	
1	Total number of reviews during the time period for the report ***Note:*** For any report, if there is no data that meets the report criteria, the report will list "0 results" in the header.
2	Date the report is run (today's date)
3	Lab name
4	Print to PDF

Key to Figure 1-3-37	
5	Export the data as a CSV file
6	The sorting criteria for the data in the report.
7	The sorting order for the data in the report.
8	The name of the reviewer(s) whose data is in the report. For users with the reviewer role, all of the data is for that person.
9	The Accession ID for each case reviewed by this reviewer during this time period
10	The date and time that the case review was completed
11	The number of marks saved on that case

Workload History

The Workload History Report lists the total number of reviews completed by a Review Station user (reviews per person) during a period of time. A manager or an administrator can select more than one reviewer to include in the report. For labs using access control filters, a manager selects from reviewers within the manager's access control filter, and an administrator selects from the users of all of the Review Stations connected to the same Image Management Server. When a reviewer runs the report, the data only includes that one reviewer.

Note: The Workload History Report separates out the workload by a time interval over a period of time. For example, the Workload History Report can show the number of reviews each week for a month.

1. Choose the time period for the report data.
   Select a review time from the available options of:
   - All (up to one year of data on the server, starting at the current date)

- Today
- Yesterday
- Last 7 days
- Last 30 days
- Custom

2. A manager or an administrator must also choose which reviewers to include in the report data.
    - Select one or more reviewers by clicking on the name of the reviewer(s) in the list, or
    - All (all of the reviewers in the server's database)

   When a reviewer runs this report, that reviewer's name is preselected and is the only available option.
3. Choose which Case Type(s) to include in the report. Select from the available options:
    - Gyn
    - Any custom Case Type
    - All

   Note: Reports on the Review Station list the entire Accession ID. In instances where a case consists of several slides, the Accession ID for each slide is reported, regardless of whether the Genius Digital Diagnostics System has been set up to group the slides from one case together in the Case Lists on the Review Station.
4. Chose a time interval. This determines the level of detail for the data in the report. Select from the available options of:
    - All (this selects the largest interval, which is by the calendar year)
    - Hour
    - Day
    - Week (the start of each reviewer's week in the report is the day of the week that the first review by that reviewer was completed. In the report, the week may or may not start on a Sunday or a Monday.)
    - Month
    - Year
5. If access control filters are used, choose the access control filter(s) that will be included in the report data.
    - Select one or more access control filter by clicking on the name of the filter(s) in the list, or
    - All (cases from all of the access control filters in the server's database)
6. Choose the category that will be used to sort the data in the report. Choose from:
    - Reviewer

- Review count (the number of reviews completed at the Review Station)

7. Choose the order in which the data will appear:
    - Sort the results in ascending or descending order.

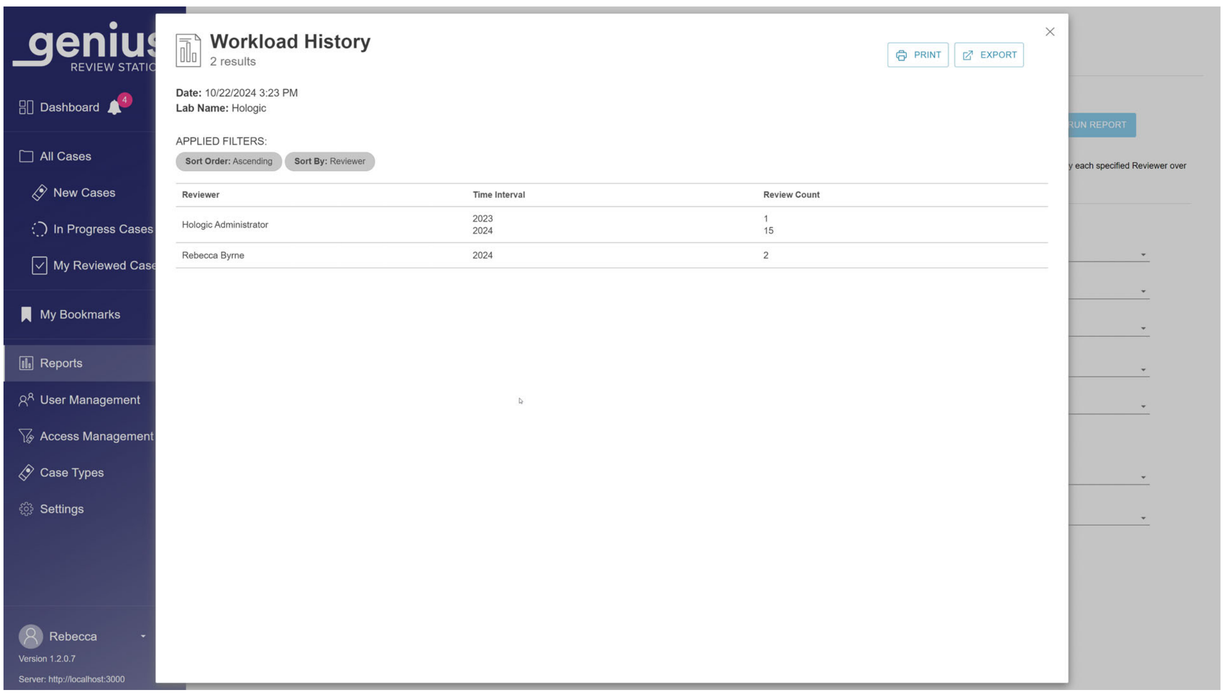


Figure 1-3-38 Workload History Report, example

Workload Summary

The Workload Summary lists how many reviews were done by each reviewer over a specific time period. When a manager runs the Workload Summary Report in a lab the does not use access control filters, the report includes all reviewers in the database. For labs using access control filters, the report run by a manager includes reviewers within the manager's access control filter, and a report run by an administrator includes all of the users of all of the Review Stations connected to the same Image Management Server. When a reviewer runs the report, the data only includes that one reviewer.

Note: The *Workload Summary Report* summarizes the workload over a period of time (for example, the total number of reviews completed by a reviewer in a particular month). By contrast, the *Workload History Report* includes a "segment" for the period of time (for example, the total number of reviews completed by a reviewer each week in a particular month).

1. Choose the time period for the report data.

Select a review time from the available options of:

- All (all of the data in the server's database)
- Today
- Yesterday
- Last 7 days
- Last 30 days
- Custom

2. A manager or an administrator must also choose which reviewers to include in the report data.
    - Select one or more reviewers by clicking on the name of the reviewer(s) in the list, or
    - All (all of the reviewers in the server's database)

    When a reviewer runs this report, that reviewer's name is preselected and is the only available option.
3. Choose which Case Type(s) to include in the report. Select from the available options:
    - Gyn
    - Any custom Case Type
    - All

    Note: Reports on the Review Station list the entire Accession ID. In instances where a case consists of several slides, the Accession ID for each slide is reported, regardless of whether the Genius Digital Diagnostics System has been set up to group the slides from one case together in the Case Lists on the Review Station.
4. If access control filters are used, choose the access control filter(s) that will be included in the report data.
    - Select one or more access control filter by clicking on the name of the filter(s) in the list, or
    - All (cases from all of the access control filters in the server's database)

5. Choose the category that will be used to sort the data in the report. Choose from:
    - Sort the results by the reviewers' names.
    - Sort the results by Review count (the number of reviews completed at the Review Station).
6. Choose the order in which the data will appear:
    - Sort the results in ascending or descending order

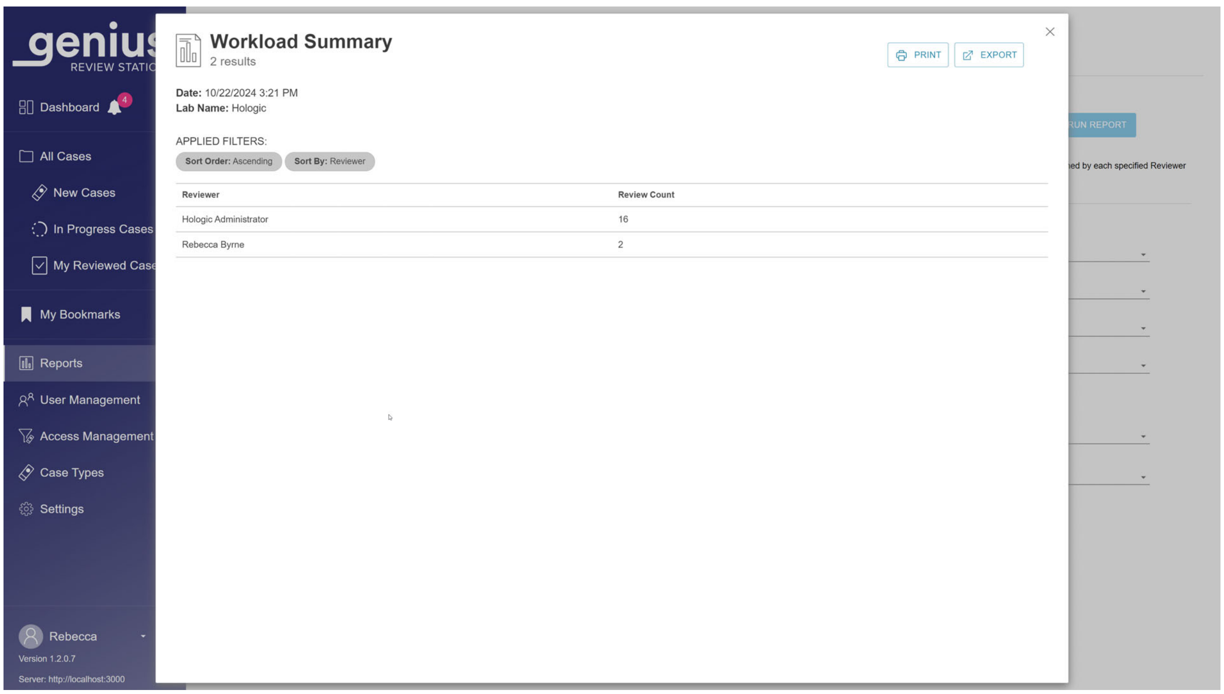


Figure 1-3-39 Workload Summary Report, example

Review Station reports for errors

There are several standard reports available on the Review Station that report data from the Digital Imager.

Imager slide events on the Digital Imager are errors related to slide processing. The Imager slide events codes are described in "Slide Event Messages" on page 5.6.

Imager System errors are errors related to instrument performance. The Imager System error codes are described in "Imager Error Codes" on page 5.10.

The operator's manual provided with the Genius Digital Imager also has more information about Digital Imager errors.

Imager Error Rate

The Imager Error Rate Report lists the error rate for a specific Digital Imager during a period of time.

The error rate is the percentage of slides with slide events (Error Count) from the total number of slides imaged on a Digital Imager (Slide Image Count).

For example, if the time period for the report is set as today and a Digital Imager processed 100 slides today, with one of those 100 slides generating a slide event, the Imager Error Rate is 1%.

Note: The Imager Error Rate Report is similar to the Imager Slide Events Report. The Imager Error Rate Report expresses the result as a percentage, and the Imager Slide Events Report does not.

1. Choose the time period for the report data.
   Select a slide image time from the available options of:
   - All (all of the data in the server's database)
   - Today
   - Yesterday
   - Last 7 days
   - Last 30 days
   - Custom
2. Choose which Digital Imager(s) to include in the report. All of the Digital Imagers connected to the same Image Management Server are available.
   Select the name of one or more Digital Imagers from the list, or select **All**.
3. Choose the category that will be used to sort the data in the report. Choose from:
   - The name of the Digital Imager (Imager ID)
   - The quantity of slides for each Digital Imager in the report (Slide Image Count)
   - The quantity of slide events (Error Count)
   - The percentage of errors (Error Rate)

4. Choose the order in which the data will appear:
   - Sort the results in ascending or descending order.

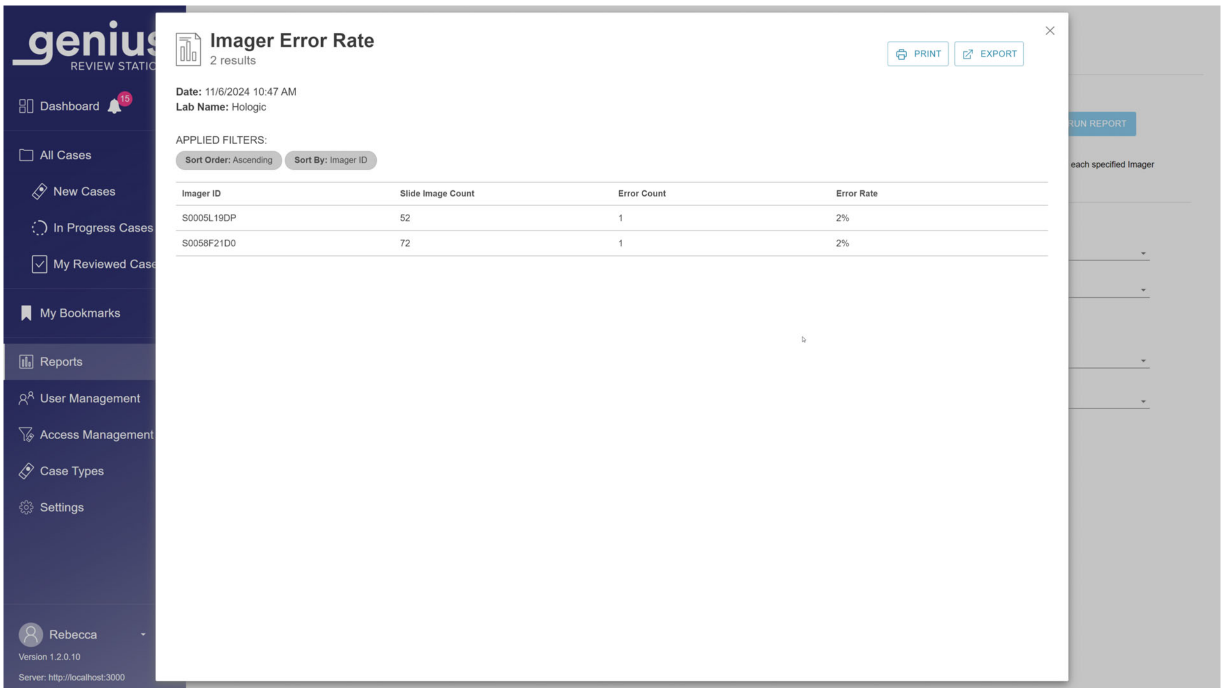


Figure 1-3-40 Imager Error Rate Report, example

Imager Slide Events

The Imager Slide Events Report lists detailed information about errors from one or more Digital Imager over a specific time period. The Imager Slide Events Report lists the Accession ID, the date and time that the slide was imaged (and when the error occurred), the error code, the case type, the name of the Digital Imager and the version of software running on the Digital Imager at the time.

1. Choose the time period for the report data. The time in this report is the time the slide was processed on the Digital Imager.
   Select the time period from the available options of:
   - All (all of the data in the server's database)
   - Today
   - Yesterday
   - Last 7 days

- Last 30 days
- Custom

2. Choose which Case Type(s) to include in the report. Select from the available options:
   - Gyn
   - Any custom Case Type
   - All

Note: Reports on the Review Station list the entire Accession ID. In instances where a case consists of several slides, the Accession ID for each slide is reported, regardless of whether the Genius Digital Diagnostics System has been set up to group the slides from one case together in the Case Lists on the Review Station.

3. Choose which Digital Imager(s) to include in the report. All of the Digital Imagers connected to the same Image Management Server are available.
   Select the name of one or more Digital Imagers from the list, or select **All**.
4. Choose the category that will be used to sort the data in the report. Choose from:
   - The Accession ID
   - The Slide image time (the date and time)
   - The error code
   - The case type
   - The name of the Digital Imager (Imager ID)
   - The software version

5. Choose the order in which the data will appear. Sort the results in ascending or descending order.

Note: In the report, click on an error code to see a brief description of that error.

Note: In the report, if the error prevented the Digital Imager from reading the Accession ID, the Accession ID field will be blank in the report.

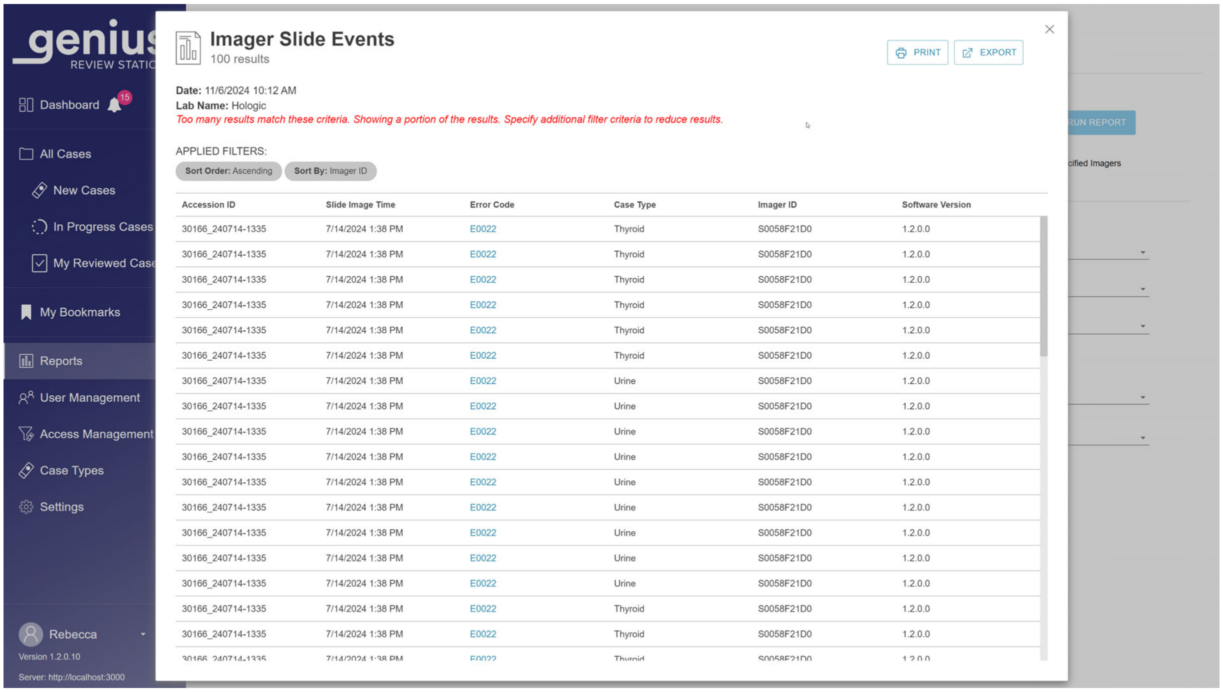


Figure 1-3-41 Imager Slide Events Report, example

Imager System Errors

The Imager System Errors Report lists the system errors from one or more Digital Imager over a specific time period.

1. Choose the time period for the report data. The time in this report is the time that the error occurred on the Digital Imager.
   Select the time period from the available options of:
   - All (all of the data in the server's database)
   - Today
   - Yesterday
   - Last 7 days

- Last 30 days
- Custom

2. Choose which Digital Imager(s) to include in the report. All of the Digital Imagers connected to the same Image Management Server are available.
   Select the name of one or more Digital Imagers from the list, or select **All**.
3. Choose the category that will be used to sort the data in the report. Choose from:
   - The name of the Digital Imager
   - The time the error occurred
   - The error code
   - The software version
4. Choose the order in which the data will appear. Sort the results in ascending or descending order.

Note: In the report, click on an error code to see a brief description of that error.

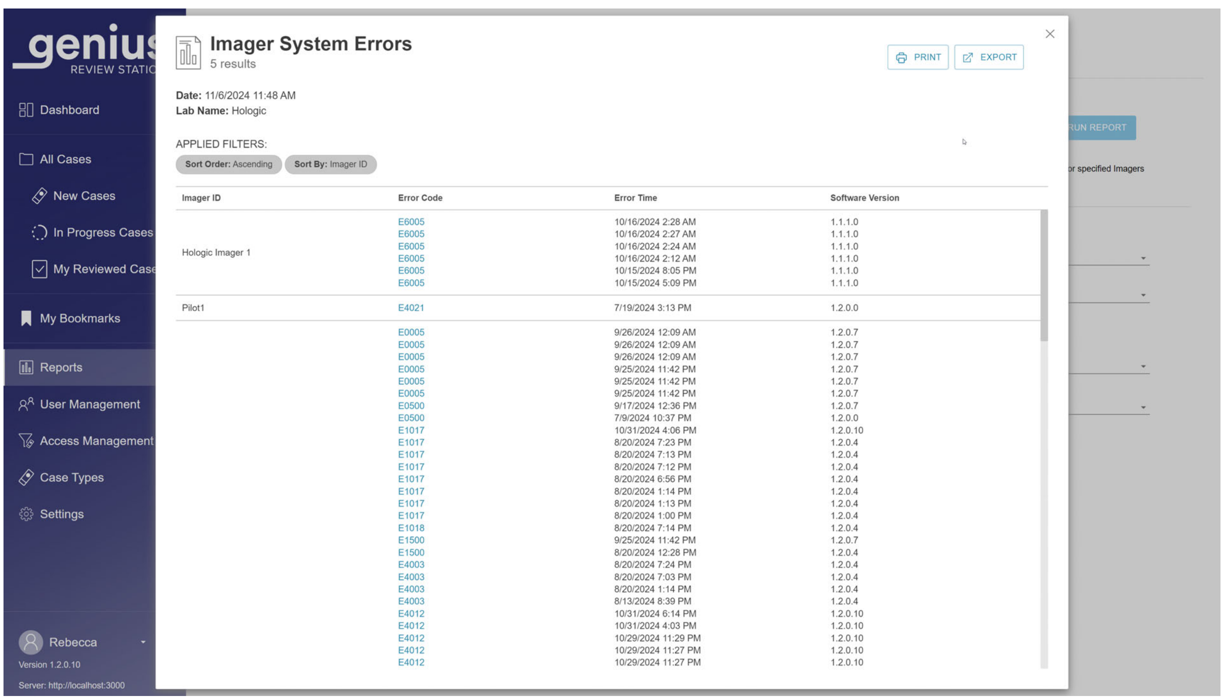


Figure 1-3-42 Imager System Errors Report, example

Slide Data

The Slide Data Report lists detailed information about slides reviewed over a specific time period. The report can be configured in many ways. The Slide Data Report lists: the Accession ID, the name of the Digital Imager where the slide was imaged, the date and time the slide was imaged, the status of the slide imaging, the case type, the name of the Review Station where the case was reviewed, the date and time that the case was reviewed, the name of the reviewer who completed the review, and any tags applied to the case.

For labs using access control filters, when a manager or reviewer runs the report, the slide data is from accession IDs within the manager or reviewer's access control filter. When an administrator runs the report, all of the slide data on the Image Management Server is eligible for the report.

Note: Consider using the **Save As Custom** button after configuring a Slide Data Report with the settings that best suit your laboratory.

Note: When a case is reviewed by more than one reviewer, the Slide Data Report can be configured to list each of those reviews.

Select the criteria for the Slide Data Report

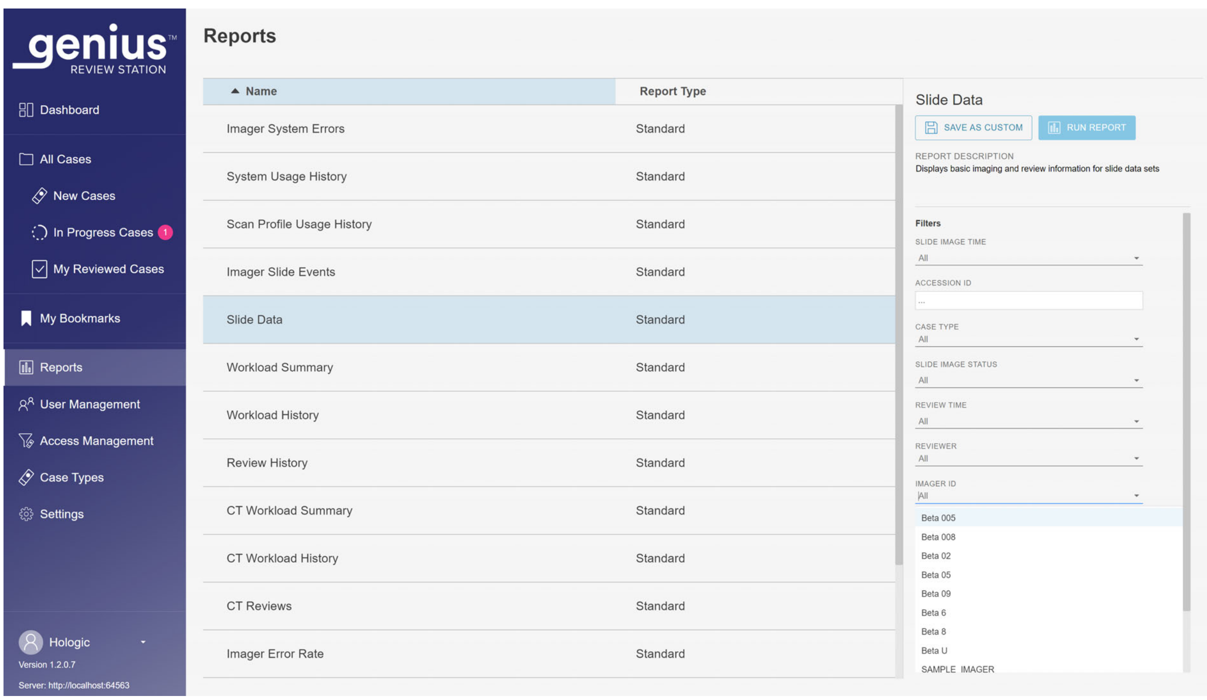


Figure 1-3-43 Select criteria for Slide Data Report

1. Choose the slide image time period for the report data. This is the time the slide was processed on the Digital Imager. Select the time period from the available options of:
    - All (all of the data in the server's database)
    - Today
    - Yesterday
    - Last 7 days

- Last 30 days
- Custom

Note: If there is no data that meets the report criteria, the report will list "0 results" in the header.

2. Choose which Accession IDs to include in the report.
   Enter several characters that appear in Accession IDs, the entire Accession ID, or leave the field blank to include all Accession IDs.

Note: Review Station reports list the entire Accession ID. In instances where a case consists of several slides, the Accession ID for each slide is reported, regardless of whether the Genius Digital Diagnostics System has been set up to group the slides from one case together in the Case List on the Review Station.

3. Choose which Case Type(s) to include in the report. Select from the available options:
   - Gyn
   - Any custom Case Type
   - All
4. Choose which Slide Image Status criteria to include in the report. This includes or excludes slides with slide imaging events. Select from the available options:
   - All
   - Success
   - Error
5. Choose the case review time period for the report data. This is the time span in which any reviewer reviewed cases that meet the report criteria.
   Select a review time from the available options of:
   - All (all of the data in the server's database)
   - Today
   - Yesterday
   - Last 7 days
   - Last 30 days
   - Custom

   Note: When a case has been reviewed more than once, if any of the reviews is in the date range specified for the report, the case is included in the report.
6. A manager or an administrator can also choose which reviewers to include in the report data.
   - Select one or more reviewers by clicking on the name of the reviewer(s) in the list, or
   - All (all of the reviewers in the server's database)

   When a reviewer runs this report, that reviewer's name is preselected and is the only available option.

7. Choose which Digital Imagers to include in the report.
   Select the name of one or more Digital Imagers from the list, or select **All**.
8. Choose whether to include or exclude archived cases in the report. Select a "Slide Archived" status from the available options of:
   - All - The report will include data for active cases and for inactive cases that have not been archived yet.
   - Yes - The report will only include archived cases.
   - No -Archived cases will be excluded from the report.

   Note: Depending on the range of data selected for the report, reporting out archived data could generate a very high number of results.
9. Choose which tag criteria to include in the report. Select from the available options.
   - All - The report will include data for cases that do not have tags applied and for cases that do have any tag applied.
   - The tags listed in the drop-down list for the Slide Data Report are the tags available in your laboratory, established by a manager or administrator.
10. An administrator can also choose which access control filter criteria to include in the report. Select from the available options.
11. Choose the category that will be used to sort the data in the report. Choose from:
    - The Slide image time (the date and time)
    - The Accession ID
    - The Case Type
    - The name of the Digital Imager
    - The slide image status
    - The Review Station ID
    - The reviewer
    - The review time
    - The name of a tag

12. Choose the order in which the data will appear. Sort the results in ascending or descending order.

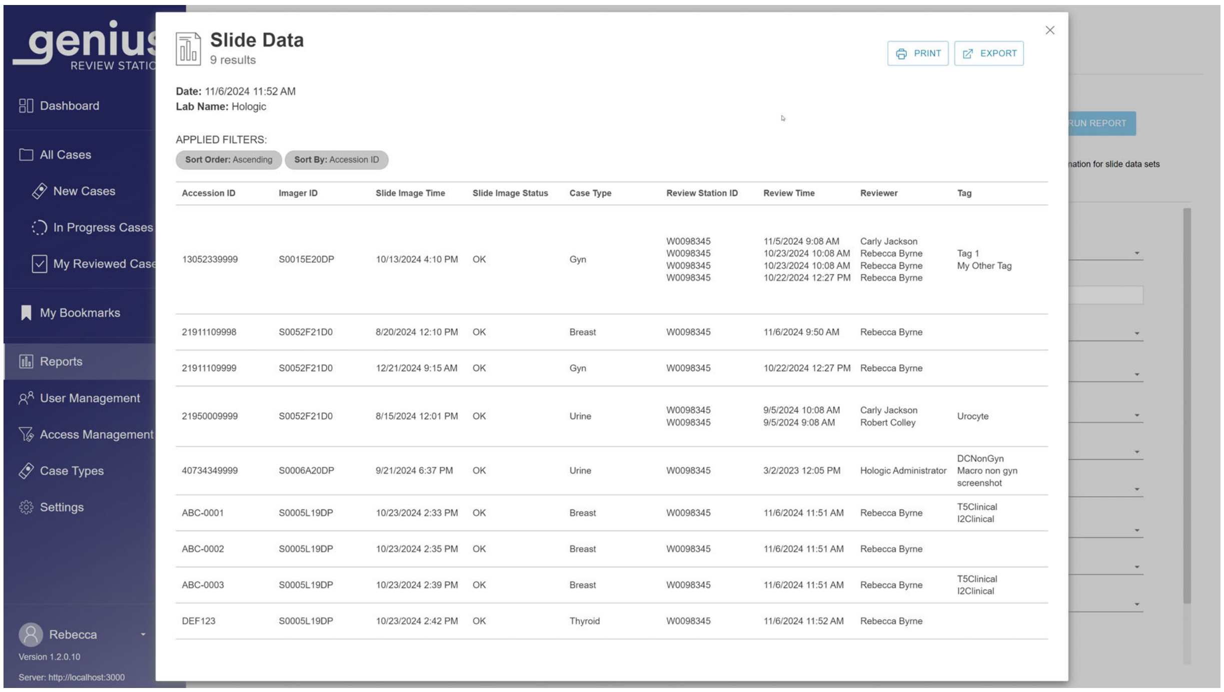


Figure 1-3-44 Slide Data Report, example

System Usage History

The System Usage History Report lists instrument activity.

1. Choose which systems to include in the report. The options are:
    - All of the Review Station IDs connected to the same Image Management Server as the Review Station where the user is running this report.
    - All of the Digital Imagers that are connected to the same Image Management Server
    - Or **All** (all of the Digital Imagers and Review Stations connected to the same Image Management Server)
2. Choose the category that will be used to sort the data in the report. Choose from:
    - System ID
    - System type

3. Choose the order in which the data will appear. Sort the results in ascending or descending order.

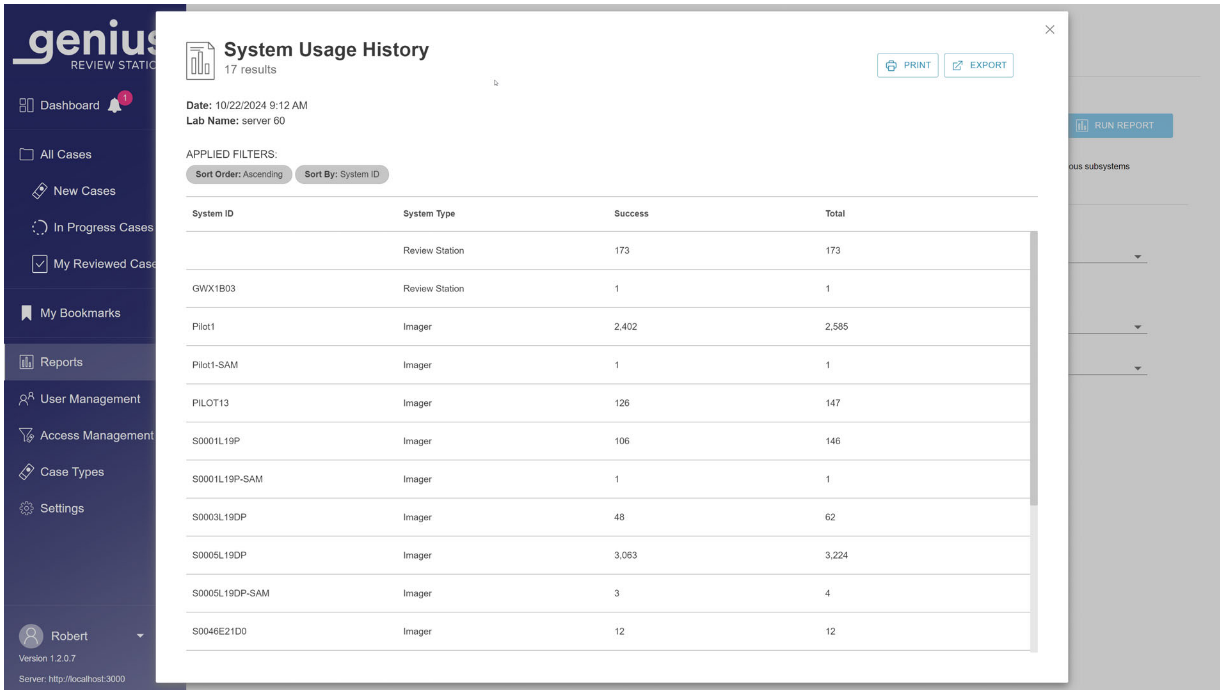


Figure 1-3-45 System Usage History Report, example

Note: The System Usage Report uses data stored on the Genius Image Management Server. If your laboratory uses the Slide Management feature to delete case information from the Genius Image Management Server, the System Usage History Report does not include review data for cases that have been deleted from the Genius Image Management Server. By contrast, imaging data cannot be excluded from the System Usage History Report.

Scan Profile Usage History

The Scan Profile Usage History Report lists Digital Imager activity for each scan profile installed in the lab since the time the Digital Imager or the Scan Profile was installed, whichever is older.

1. Choose the time period for the report data.
   Select an imaged time from the available options of:
   - All (all of the data in the server's database)
   - Today
   - Yesterday
   - Last 7 days
   - Last 30 days
   - Custom

2. Choose which scan profiles to include in the report. Select the name of one or more scan profile from the list, or select **All**.

   Note: The Scan Profile Usage History could list scan profiles that were configured for your lab in the past and uninstalled later.

3. Choose which Digital Imager(s) to include in the report. All of the Digital Imagers connected to the same Image Management Server are available. Select the name of one or more Digital Imager from the list, or select **All**.
4. Choose the category that will be used to sort the data in the report. Choose from:
   - Scan Profile
   - Total (quantity of slides scanned)
   - Imager ID (Imager name)
   - Install date (the date that the scan profile was installed)
   - Whether a Scan Profile is enabled in your configuration or not
   - Profile Information (may be blank)
5. Choose the order in which the data will appear. Sort the results in ascending or descending order.

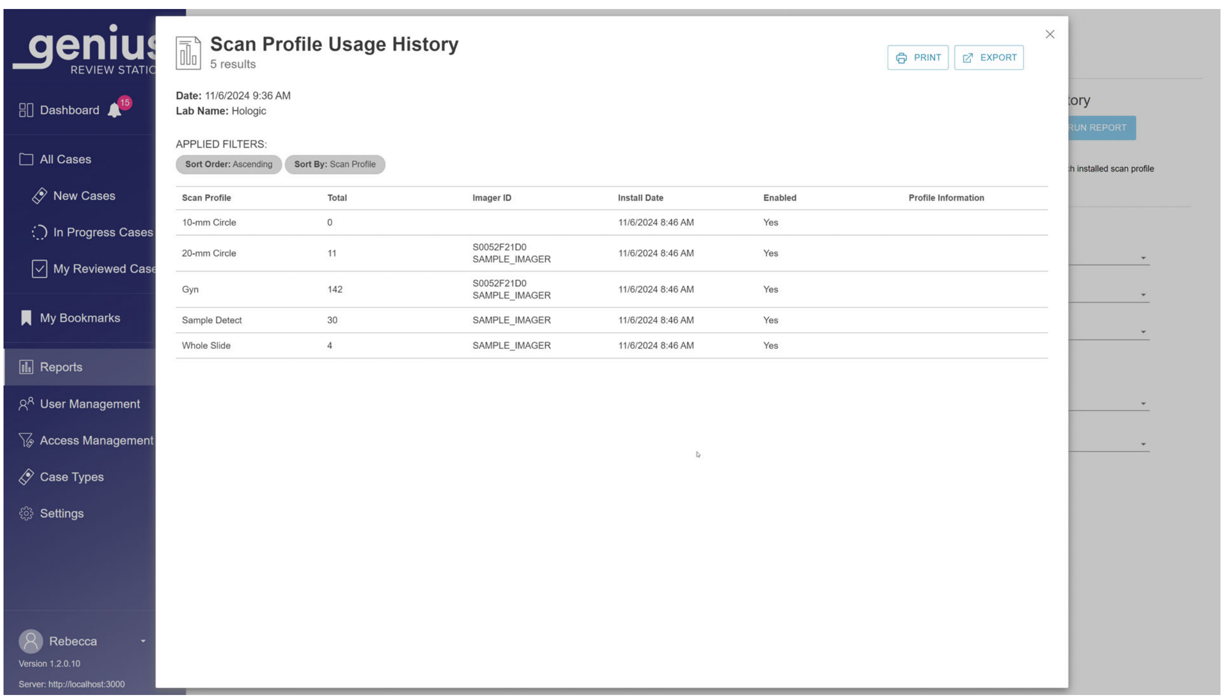


Figure 1-3-46 Scan Profile Usage History Report, example

Note: Because the Scan Profile Usage History Report is a tally of cases that were imaged, if a case is deleted, that case remains in the tally in the report.

Note: Cases imaged after the installation of the 20-mm circle scan profile and/or the 10-mm circle scan profile are included in the report. ThinPrep Non-gyn cases and ThinPrep UroCyte cases from early versions of the Genius Digital Diagnostics System, imaged before the installation of the 20-mm circle scan profile and/or the 10-mm circle scan profile, are not included in the report.

User Account History

The User Account History Report lists user activity over a specific time period. The report shows activities related to user access to the system, such as login dates and times and requests to reset passwords.

For labs using access control filters, a manager's report can only include users within the manager's access control filter. An administrator's report can include any user at Review Stations connected to the same Image Management Server. A reviewer or a lab tech cannot run this report.

1. Choose which users to include in the report. Select the username of one or more user from the list or select **All**.

Note: The User Account History Report results display usernames rather than the first and last name of the user.

2. Choose the time period for the report data. Select an event time from the available options of:
   - All (all of the data in the server's database)
   - Today
   - Yesterday
   - Last 7 days
   - Last 30 days
   - Custom
3. Choose the event or events for the report. Select the name of the event from the available options of:
   - Access requested
   - Account created
   - Auto logout (Review Station left idle for more than 30 minutes)
   - Invalid reset code (invalid temporary password)
   - Login fail (due to an incorrect password)
   - Login success
   - Password changed (excludes changes for the 90-day password expiration)
   - Password reset
   - Role changed

- User activated
- User deactivated
- User logout (when a user selects and confirms the logout)
- User unlocked

4. If access control filters are used, choose the access control filter(s) that will be included in the report data.
   - Select one or more access control filter by clicking on the name of the filter(s) in the list, or
   - All (cases from all of the access control filters in the server's database)
5. Choose the category that will be used to sort the data in the report. Choose from:
   - Reviewer (username rather than the first and last name of the user)
   - Event time
   - Event name
6. Choose the order in which the data will appear. Sort the results in ascending or descending order.

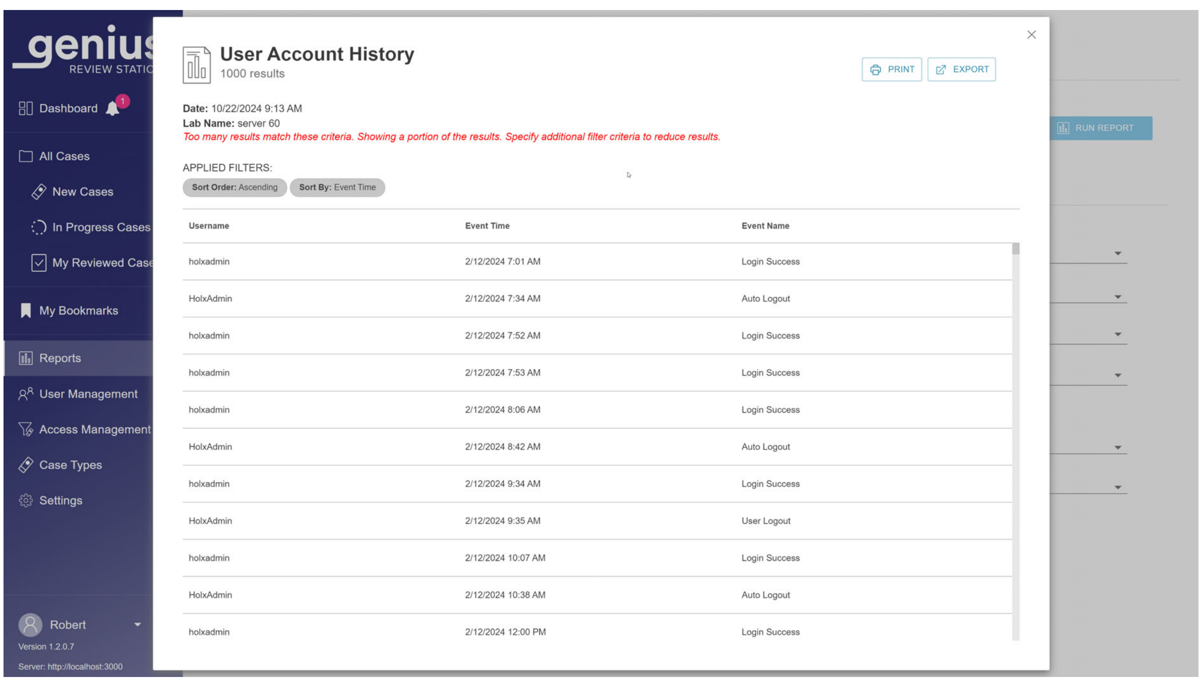


Figure 1-3-47 User Account History Report, example

4. Maintenance

Chapter Four

Maintenance

SECTION A GENERAL CLEANING

Hologic does not require preventive maintenance for the Genius Review Station monitor or Genius Review Station computer.

CAUTION: Do not use strong solvents on painted or plastic surfaces.

CAUTION: Do not scratch the monitor. Take care with rings and other jewelry when wiping the monitor surface. Wipe gently.

CAUTION: Do not spray liquid on the monitor. Apply water to a lint-free wipe or cloth and then wipe the monitor.

Wipe down the exterior of the monitor monthly or as needed with a lint-free wipe or cloth dampened with water.

Note: Do not detach or remove any covers or panels on the monitor or computer.

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5. Troubleshooting

Chapter Five

Troubleshooting

SECTION A NO CONNECTION TO IMAGE MANAGEMENT SERVER

The Review Station must have an active connection to the Image Management Server in order to work.

If communication is disrupted before a user logs in, the application will not launch.

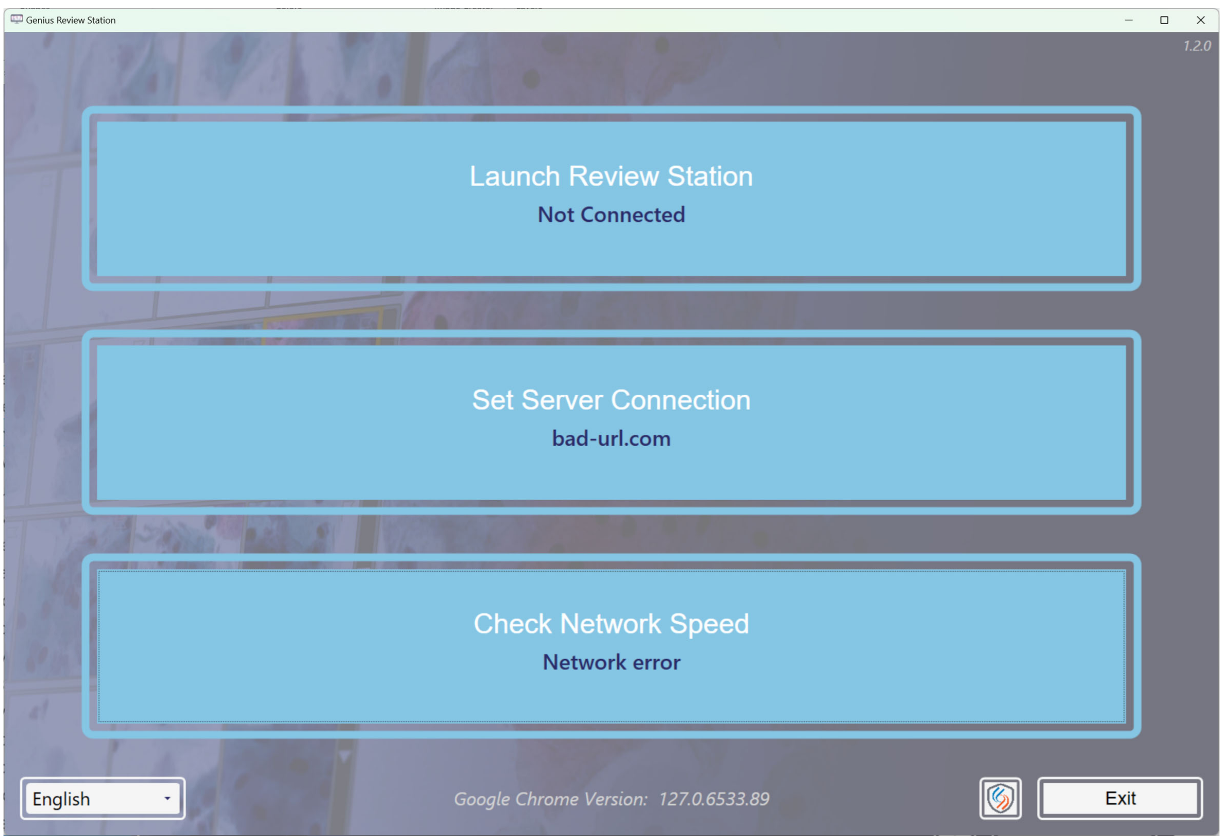


Figure 1-5-1 Review Station, not connected

If the server connection is disrupted while the Review Station application is running, the Review Station may present an error that it cannot display information. An error message displays.

Figure 1-5-2 Review Station server connection error

If the server connection is disrupted while a case is being reviewed, the case is saved as In Progress. When the server connection is restored, the case will be in the In Progress status with the reviewer who had the case open when the server connection was lost.

Depending on the cause of the disruption, your laboratory's computer network administrator may be able to reestablish the network connection, or Hologic Technical Support may be required. The Genius Digital Diagnostics System network design varies from lab to lab, depending on volume requirements, and infrastructure integration.

SECTION B

DATA RETRIEVAL ERROR

If the Review Station has an active connection to the Image Management Server, but there is an error in retrieving data from the Image Management Server, an error message displays.

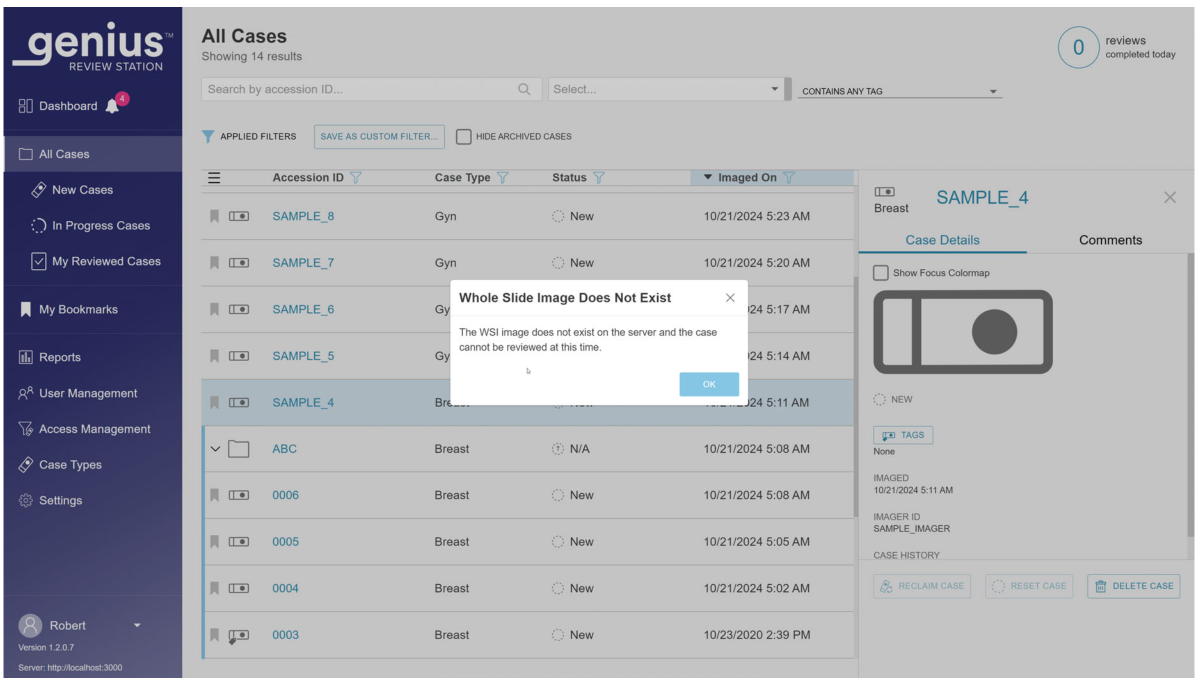


Figure 1-5-3 Review Station notification of Image Management Server error

If there has been an error related to a laboratory's archiving system that the laboratory can resolve, then the Genius Review Station will be able to display the case when the archiving system returns the image files.

Contact your laboratory's system administrator to power cycle the Image Management Server.

SECTION C

TROUBLESHOOTING WITH REMOTE ACCESS

Hologic offers an optional, remote support system, SecureLink software, for the Genius Digital Diagnostics System. SecureLink software allows authorized Hologic support personnel to view certain computers running Hologic software, installed in your laboratory, in real time and to transfer files remotely over secure servers, after the operator grants access to Technical Support personnel to initiate communication. The Technical Support personnel must be trained by Hologic. Your lab can disable access at any time from a Genius Review Station.

From the Review Station, an administrator can initiate a remote session to allow Field Service personnel trained by Hologic to access the Genius Image Management Server. From the kiosk application at the Review Station, any user can initiate a remote session to allow Field Service personnel trained by Hologic to access the Genius Review Station computer.

The use of remote access troubleshooting is optional.

- If a laboratory does not want to allow Field Service personnel trained by Hologic remote access to the Genius Image Management Server, the SecureLink software is not installed on the Genius IMS for that lab.
- If a laboratory does not want to allow Field Service personnel trained by Hologic remote access to Genius Review Station computers, the SecureLink software is not installed on the Genius Review Station computers for that lab.

The SecureLink software for remote access must be installed by Field Service personnel trained by Hologic at a customer site before it can be used. The installation and configuration can be part of the site visit to install or upgrade the Genius Digital Diagnostics System. A site visit is required to install the SecureLink software.

The procedure describes how to enable authorized Hologic support personnel to access your Genius Digital Diagnostics System remotely if SecureLink software has been installed.

Remote Access Session for the Genius Image Management Server

1. Contact Hologic Technical Support. Refer to “Service Information” on page 6.1.
2. From the **Settings** menu of a Review Station, select **Remote Access** (available only to administrators. Slide the **SecureLink Access to Image Management Server** toggle to the right to enable the remote access.

   Note: The setting for a SecureLink connection to the Genius Image Management Server is restricted to users with an administrator role. If your lab does not have an any Review Station user with an administrator role, Field Service personnel trained by Hologic will need to set one up when SecureLink is installed.

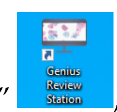
   An alert on the Review Station dashboard notifies that administrator that remote access with the SecurelLink software is enabled.

3. Field Service personnel trained by Hologic perform the troubleshooting activities and informs personnel at the lab when the service is complete.
   While remote access to the Genius Image Management Server is enabled, Field Service personnel trained by Hologic have access to the Genius Image Management Server dashboard. The level of access that Field Service personnel have remotely to system performance data, with the ability to transfer files, reports, and logs, is the same as an in-person site visit.
4. The Field Service personnel trained by Hologic disconnects their access when the service is complete.

Note: If desired, after the Field Service personnel have finished, an administrator at a Review Station can manually disable the remote access. To manually disable the access, on the **Settings** menu of a Review Station, slide the **SecureLink Access to Image Management Server** toggle to the left.
However, if the administrator leaves the session running, access will automatically expire 3 hours after the session started. The time that the session will automatically end is displayed on the screen.
If an administrator manually disables remote access, an alert on the Review Station dashboard notifies that administrator that the remote access with the SecurelLink software has been disabled.

Note: An administrator can disable the access session at any time by sliding the **SecureLink Access to Image Management Server** slider to the left.

Remote Access Session for the Genius Review Station Computer

1. Contact Hologic Technical Support. Refer to “Service Information” on page 6.1.
2. From the Windows desktop, double-click on the icon for “Genius Review Station” 

, if it is not already running. The Review Station application launches.

Note: Any user with Windows credentials can enable a Remote Access session to the Review Station computer.

3. Click the SecureLink icon  .
4. In the dialog box for SecureLink Access to Review Station, click the **Enable** button to enable the remote access.
5. The Field Service personnel trained by Hologic perform the troubleshooting activities and informs personnel at the lab when the service is complete.
   While remote access to the Genius Review Station computer is enabled, Field Service personnel have access to the Genius Review Station computer, including access to the Genius Review Station application. The level of access that the Field Service personnel trained by

Hologic have remotely to system performance data, with the ability to transfer files, reports, and logs is the same as an in-person site visit.

6. The Field Service personnel trained by Hologic disconnects their access when the service is complete.

Note: If desired, a user at the Review Station can disable the access after the Field Service personnel trained by Hologic have finished. However, access will automatically expire 3 hours after the session started. The time that the session will automatically end is displayed on the screen.

SECTION D DIGITAL IMAGER INFORMATION VIEWED FROM THE REVIEW STATION

From the Review Station, a reviewer can generate reports of Slide Events from the Digital Imagers connected in the Genius Digital Diagnostics System network.

From the Review Station, a reviewer can also generate reports of Imager System Errors from the Digital Imagers connected in the Genius Digital Diagnostics System network.

In a report, to view a description of the error code, click on the code. All of the error codes are listed below.

The following is a list of Slide Events. The slide is not imaged when there is a slide event. Slide events and Imager errors are corrected at the Digital Imager not the Review Station.

Table 5.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E0001	**Slide was scanned previously**	The slide has been imaged.	The slide may undergo review at the Review Station.
		Duplicate slide accession ID.	Use the Slide Lookup query. Confirm if the ID is unique. If there is a duplicate, reconcile both patient records; re-label one and reprocess the slide.

Table 5.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E0002	**Slide barcode could not be read**	Wrong kind of slide or slide label.	Check that the Digital Imager is configured to read the barcode format or OCR format used in your lab.
		Wrong accession ID format. Slide ID misprint.	Check the condition of the label and that the ID is in a format that the Digital Imager can read.
		Slide not loaded in slide carrier correctly.	Load the slide into the slide carrier with the label face up and away from the slide carrier handle.
		Possible malfunction at the macro station.	Attempt to process the slide again. If the error persists, contact Technical Support.
E0003	**Slide fiducial verification failed**	The wrong case type was selected.	Select a case type that is not the Gyn case type.
		The ThinPrep Pap test is on the wrong type of slide.	ThinPrep Imaging System slides are required for ThinPrep Pap tests analyzed by the Genius Cervical AI algorithm. Check that the slide is a ThinPrep Imaging System microscope slide.
		The ThinPrep Imaging System slide is missing one or more fiducial marks.	Check that the fiducial marks on the ThinPrep Imaging System microscope slide are not scratched or marred.
E0005	**No matching case types found for slide**	When the Digital Imager software compared the slide ID to the barcode rules, the slide ID did not match any custom Case Type.	Instead of using the "Auto" Case Type selection at the Digital Imager, load the slide into a slide carrier with slides of the same, desired case type and manually select the case type to image the slide. Reconfigure the barcode rules for custom Case Types at the Review Station.
E0006	**Multiple matching case types found for slide**	Two or more custom Case Types use barcode rules that are not distinct enough for the "Auto" Case Type to determine which case type to use.	Instead of using the "Auto" Case Type selection at the Digital Imager, load the slide into a slide carrier with slides of the same, desired case type and manually select the case type to image the slide. Reconfigure the barcode rules for custom Case Types at the Review Station so that the barcode rules for one case type are distinct from the barcode rules for another case type.

Table 5.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E0007	**Slide imaging failed due to focus QC**	Slide label extending beyond the slide label area, causing the slide to not sit properly in the imaging stage	Check that the slide label is applied properly, without overhang. Correct the label and attempt to image the slide again.
		The slide or coverslip may be scratched.	Check if the slide or coverslip is scratched. Attempt to image the slide again.
		There may be debris on the slide or on the imaging stage.	Check for debris. Remove any debris from the slide. If there is debris on the imaging stage, clean the imaging station slide holder.
		Possible instrument slide scanning issue	Attempt to process the slide again. If the error persists, contact Technical Support.
E0009	**Slide imaging failed due to oversaturated frames**	Possible issue with imaging frequency or illumination during imaging.	Attempt to process the slide again. If the error persists, contact Technical Support.
E0010	**Slide imaging failed due to an imaging stage disturbance**	The stage moved or was disturbed during imaging.	During operation, the Digital Imager is sensitive to vibrations. It should be placed on a sturdy flat surface away from centrifuges, vortexors or any equipment that may cause vibrations. Keep away from other environmental activity, such as constant foot traffic, proximity to elevators or doors that are frequently open and shut. Attempt to process the slide again. If the error persists, contact Technical Support.
E0012	**Image analysis failed**	The software attempted image analysis, and the analysis failed.	Attempt to process the slide again. If the error persists, contact Technical Support.
E0013	**Barcode contains invalid characters**	The barcode for the slide ID has characters that are not accepted by the Digital Imager for that barcode type.	Label the slide with the correct ID format.
E0014	**Failed to grip at macro. Slide manually removed by operator**	The slide gripper failed to properly grip a slide, or the slide was manually removed by the operator.	If the slide was manually removed by the operator, process the slide again. Check that the slide is properly coverslipped and labeled. If the error persists, contact Technical Support.

Table 5.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E0015	**Failed to parse barcode**	The ID printed on the slide label cannot be used by the Genius Digital Diagnostics System. The ID printed on the slide label is correct and the Accession ID Settings are wrong.	The Accession ID Settings on the Digital Imager are too long or too short for the slide. Change the Accession ID Settings.
		The Accession ID Settings are correct and the ID printed on the slide label is wrong (too long, too short, does not use a specified character).	Check that the ID printed on the slide label is in the correct format for your lab. Label the slide with the correct ID format.
E0016	**Slide imaging failed due to cell focus error**	Sample collection or slide preparation issue causing the scan area to be blank or very faint.	Make sure the proper specimen collection procedures and slide preparation procedures are followed. For cytology samples, refer to the instructions in the ThinPrep processor operator's manual.
		An issue with the Digital Imager has the slide in a position that is difficult to image.	Attempt to process the slide again. If the error persists, contact Technical Support.
E0004, E0008, E0017–E0024	**Slide processing events**	---	Attempt to process the slide again. If the error persists, contact Technical Support.

Table 5.2 Imager Error Codes

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E0500 through E0512, E0515	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E0514	**An error was detected while running periodic check.**	Imager conducted a self-check that did not pass.	Power cycle the system. If the error persists, contact Technical Support.
E0516	**The error carrier is full.**	Error carrier contains 40 slides.	Replace the full slide carrier in position 10 with an empty slide carrier.
E0517	**Error during light calibration.**	Unable to focus on the v-chip.	Clean the verification chip.
E4519	**Illumination uniformity across the image is not within specification.**	Illumination is misaligned with the objective, or the V-Chip is damaged, dirty or out of position.	Clean the verification chip.
E1001, E1002, E1004, E1005, E1006	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E1003	**The door or window was found open during start unexpectedly.**	Door or window lock failed; user opened door or window.	The Digital Imager cannot operate with the door or window open. Close the door or window.
E1007	**The door or window was found open during resume unexpectedly.**	Door or window lock failed; user opened door or window.	The Digital Imager cannot operate with the door or window open. Close the door or window.
E1008 through E1012, E1014 through E1017	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.

Table 5.2 Imager Error Codes

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E1013	**The door or window was found open during periodic check unexpectedly.**	Door or window lock failed; user opened door or window.	The Digital Imager cannot operate with the door or window open. Close the door or window.
E1018	**Unexpected door opening.**	Lock failed to prevent user from opening the door.	The Digital Imager cannot operate with the door or window open. Close the door or window.
E1019	**Unexpected window opening.**	Lock failed to prevent user from opening the window.	The Digital Imager cannot operate with the door or window open. Close the door or window.
E1200-E1203, E1206	**Imager error**	Error during POST with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E1204, E1205	**Debris found in the macro slide path.**	A slide has been left on the macro station or the macro station is dirty.	Clean the macro station. If the cleaning does not resolve the issue the first time, the Digital Imager instructs the operator to clean the macro station a second time. If the second cleaning does not resolve the issue, power cycle the system. If the error persists, contact Technical Support.
E1500 through E1504	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E2000	**An error occurred while starting the process image task.**	The camera fails to produce frames; the stage fails to move.	Power cycle the system. If the error persists, contact Technical Support.
E2001	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E2002	**An error occurred during processing a swath.**	An ImageProcessor component threw an exception.	Power cycle the system. If the error persists, contact Technical Support.
E2003	**An error occurred while waiting for the ending swath.**	Camera failed to produce frames. FocalMerger timed out while merging.	Power cycle the system. If the error persists, contact Technical Support.

Table 5.2 Imager Error Codes

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E2004	**An error occurred while ending a swath.**	An image processing component threw an exception. Image compression failure.	Power cycle the system. If the error persists, contact Technical Support.
E2005	**An error occurred while waiting for the image processing task to complete.**	An image processing component threw an exception.	Power cycle the system. If the error persists, contact Technical Support.
E2007 through E4000	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E4001	**A slide was found in the gripper at startup.**	The instrument was powered off with a slide in the gripper.	Power cycle the system. After the re-start, follow instrument prompts to remove the slide from the slide gripper. If the error persists, contact Technical Support.
E4003	**The slide handler failed to home.**	Motor move error caused by mechanical obstruction.	Power cycle the system. If the error persists, contact Technical Support. When the instrument is powered down, remove any obstruction.
E4004	**A move to a carrier location failed.**	Mechanical interference with one or more axes.	A recovery dialog is displayed at the Digital Imager.
E4005	**A move to the thumbnail location failed.**	Mechanical interference with one or more axes.	A recovery dialog is displayed at the Digital Imager.
E4006	**A move to the macro location failed.**	Mechanical interference with one or more axes.	A recovery dialog is displayed at the Digital Imager.
E4007	**A move to the queue location failed.**	Mechanical interference with one or more axes.	A recovery dialog is displayed at the Digital Imager.
E4008	**A move to the imaging stage location failed.**	Mechanical interference with one or more axes	A recovery dialog is displayed at the Digital Imager.
E4009	**A move to the safe location failed.**	Mechanical interference with one or more axes.	A recovery dialog is displayed at the Digital Imager.
E4010	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.

Table 5.2 Imager Error Codes

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E4011	**A multiple-axis concurrent motor move failed.**	Mechanical interference with one or more axes.	Power cycle the system. If the error persists, contact Technical Support.
E4012	**The slide handler was not able to pick a slide from the carrier.**	The slide was not present in the slot or was incorrectly inserted in the slot.	The system will move to the next slide to pick.
E4013	**The slide handler was not able to pick a slide from the macro stage.**	The slide on the macro was dropped, or incorrectly placed.	A recovery dialog is displayed at the Digital Imager.
E4014	**The slide handler was not able to pick a slide from the queue station.**	The slide on the queue was dropped or incorrectly placed	A recovery dialog is displayed at the Digital Imager.
E4015	**The slide handler was not able to pick a slide from the imaging stage.**	The slide on the imaging stage was not in the expected location, or the stage was not in the loading position.	A recovery dialog is displayed at the Digital Imager.
E4016	**Placing a slide in a carrier failed.**	The value for the place location in the carrier was incorrectly calculated.	A recovery dialog is displayed at the Digital Imager.
E4017	**Placing a slide in the macro nest failed.**	One or more axis movements failed, or the gripper failed to open.	A recovery dialog is displayed at the Digital Imager.
E4018	**Placing a slide in the queue failed.**	One or more axis movements failed, or the gripper failed to open.	A recovery dialog is displayed at the Digital Imager.
E4019	**Placing a slide in the imaging stage failed.**	One or more axis movements failed, or the gripper failed to open.	Power cycle the system. If the error persists, contact Technical Support.
E4020	**The inventory carrier operation failed.**	One or more motor axis movements failed, or the inventory sensor read failed.	A recovery dialog is displayed at the Digital Imager.
E4021 through E4513	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.

Table 5.2 Imager Error Codes

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E4514, E4520, E4521, E4522	**An error occurred during auto-calibration.**	Incorrectly configured V-Chip positions.	Power cycle the system. If the error persists, contact Technical Support.
E4515, E4523	**Particle defect found during auto-calibration.**	Particles on the V-Chip or lens. Incorrectly configured V-Chip position.	Clean the verification chip. If the error persists, contact Technical Support.
E4516 through 4518	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E5000	**The low-level hardware failed to initialize.**	CAN bus communication failure. Hardware failure.	Check that the system has a power connection. Power cycle the system. If the error persists, contact Technical Support.
E5002	**The gripper failed to home.**	The gripper motor move operation failed.	Power cycle the system. If the error persists, contact Technical Support.
E5003	**The gripper failed to open.**	The gripper motor move operation failed.	Power cycle the system. If the error persists, contact Technical Support.
E5001, E5004, E5005, E5007 through E6001	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E5006	**A motor move failed to complete successfully.**	Mechanical error with a motor.	A recovery dialog is displayed at the Digital Imager.
E6002	**Failed to connect to post scan service.**	Post Scanning Service is disconnected.	Power cycle the system. If the error persists, contact Technical Support.
E6005, E6006	**Imager error**	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E6500	**The Image Management Server is offline.**	The Image Management Server is down, IIS in Workflow is not running, or Imager Service in Workflow is not running.	Contact your laboratory's system administrator to power cycle the Image Management Server. Power cycle both the Digital Imager system and the Image Management Server. If the error persists, contact Technical Support.

Table 5.2 Imager Error Codes

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E6501	**The Image Management Server storage is full.**	The Image Management Server repository storage disk has insufficient space to upload slide data sets.	The Image Management Server must have sufficient storage capacity available in order for the Digital Imager to transmit data to it. Slide management and archiving criteria are set by a manager or administrator at the Genius Review Station. Ensure that slide management and archiving methods are in place and operational.

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6. Service Information

Chapter Six

Service Information

Corporate Address

Hologic, Inc.

250 Campus Drive

Marlborough, MA 01752 USA

Europe, UK, Middle East

Technical Solutions Cytology can be reached:

Mon-Fri : 08.00 – 18.00 CET

TScytology@hologic.com

And via the toll-free numbers below:

Finland	0800 114829
Sweden	020 797943
Ireland	1 800 554 144
United Kingdom	0800 0323318
France	0800 913659
Luxembourg	8002 7708
Spain	900 994197
Portugal	800 841034
Italy	800 786308
Netherlands	800 0226782
Belgium	0800 77378
Switzerland	0800 298921
EMEA	00 800 800 29892

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7. Ordering Information

Chapter Seven

Ordering Information

Europe, UK, Middle East

Technical Solutions Cytology can be reached:

Mon-Fri : 08.00 – 18.00 CET

TScytology@hologic.com

And via the toll-free numbers below:

Finland	0800 114829
Sweden	020 797943
Ireland	1 800 554 144
United Kingdom	0800 0323318
France	0800 913659
Luxembourg	8002 7708
Spain	900 994197
Portugal	800 841034
Italy	800 786308
Netherlands	800 0226782
Belgium	0800 77378
Switzerland	0800 298921
EMEA	00 800 800 29892

Mailing Address

Hologic, Inc.

250 Campus Drive

Marlborough, MA 01752 USA

Remittance Address

Hologic, Inc.

PO Box 3009

Boston, MA 02241-3009 USA

Warranty

A copy of Hologic's limited warranty and other terms and conditions of sale may be obtained by contacting Customer Service at the numbers listed above.

Protocol for Returned Goods

For returns on warranty-covered Genius Review Station accessory items, contact Technical Support.

Table 7.1 Reordering Supply Items for the Review Station

Item	Description	Quantity	Part Number
Review Station Operator's Manual	Additional operator's manual	ea.	MAN-11700-001

Table 7.2 Optional Accessories

Item	Description	Quantity	Part Number
Barcode scanner	Barcode scanner with USB connection	ea.	MEL-00970

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Part 2

Part 2.

Review of ThinPrep™ Pap Tests with the Genius™ Cervical AI Algorithm

There are three parts to this operator's manual.

- Part 1 describes installation, general use, and care of the Genius Review Station.
- Part 2 contains information specific to the review of ThinPrep Pap tests with the Genius Cervical AI algorithm.
- Part 3 contains information specific to the review of digital whole slide images.

Your system configuration may not have all of the options described in this manual. Contact your Hologic representative for more information.

Revision History

Revision	Date	Description
AW-32338-001 Rev. 001	7-2025	Initial release of instructions exclusive to the review of ThinPrep Pap tests using the Genius Cervical AI algorithm.

Document Number: AW-32338-001 Rev. 001

7-2025

Table of Contents

Table of Contents

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1. Introduction

Chapter One

Introduction

SECTION A OVERVIEW, CERVICAL CANCER SCREENING

For cervical cancer screening of gynecological samples prepared on ThinPrep Imaging System slides, an artificial intelligence image analysis algorithm within the product identifies Objects of Interest (OOIs) and presents a gallery of these images to aid a CT or pathologist in quickly and accurately reviewing the slide.

The CT or pathologist views the gallery by selecting the case ID from a list. A set of high-resolution images from the slide's cell spot is presented in the gallery. The image of the entire cell spot is also available.

Intended Use/Intended Purpose, Genius Digital Diagnostics System with the Genius Cervical AI Algorithm

The Genius Review Station is one component of the Genius Digital Diagnostics System.

The Genius™ Digital Diagnostics System, when used with the Genius™ Cervical AI algorithm, is a qualitative, *in vitro* diagnostic device indicated for assisting in cervical cancer screening of ThinPrep™ Pap test slides, for the presence of atypical cells, cervical neoplasia, including its precursor lesions (Low Grade Squamous Intraepithelial Lesions, High Grade Squamous Intraepithelial Lesions), and carcinoma, as well as all other cytological categories, including adenocarcinoma, as defined by as defined by *The Bethesda System for Reporting Cervical Cytology*[1].

The Genius Digital Diagnostics System includes the automated Genius Digital Imager, the Genius Image Management Server, and the Genius Review Station. If using the Genius Cervical AI algorithm, it must be used alongside the other components to the Genius Digital Diagnostics System. The system is for the creation and viewing of digital images of scanned ThinPrep glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy. It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using this system.

1. Nayar R, Wilbur DC. (eds), *The Bethesda System for Reporting Cervical Cytology: Definitions, Criteria, and Explanatory Notes.* 3rd ed. Cham, Switzerland: Springer: 2015

1 INTRODUCTION

Patient population

The Genius Digital Diagnostics System uses gynecological specimens from women, collected during routine screening (including initial screening and referral population) and gynecological specimens collected from women with a previous cervical abnormality.

For professional use.

SECTION B THE GENIUS DIGITAL DIAGNOSTICS SYSTEM PROCESS FOR CERVICAL CANCER SCREENING

Slides that have been prepared for screening are loaded into slide carriers which are placed into the Digital Imager. The operator uses a touch screen on the Digital Imager to interact with the instrument via a graphic, menu-driven interface.

A slide ID reader scans the slide's accession ID and locates the position of the cell spot. Then the Digital Imager scans the entire ThinPrep cell spot, creating an in-focus, whole slide image.

For ThinPrep Pap test patient sample slides, the system identifies objects of interest found on the slide. The objects classified as most clinically relevant are presented in a gallery to a cytologist (CT) or pathologist for review in a gallery of images. The slide image data, the slide ID and its associated data record are transmitted to the Image Management Server, and the slide is returned to its slide carrier.

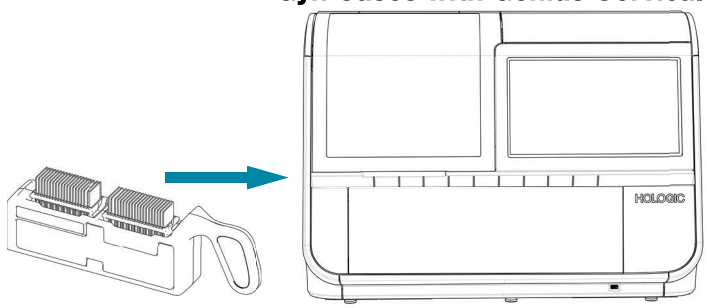
The Genius Digital Diagnostics System is a version of ThinPrep Imaging System.

The Image Management Server acts as the central data manager for the Genius Digital Diagnostics System. As slides are imaged by the Digital Imager and reviewed at the Review Station, the server stores, retrieves and transmits information based on the case ID. The Digital Imager, the Image Management Server and the Review Station are connected by a network, but they may be in different locations.

The CT or pathologist reviews cases at the Review Station. The Review Station is a computer running a Review Station software application, with a monitor suitable for diagnostic review of objects of interest and/or whole slide images. The Review Station is connected to a keyboard and mouse. When a valid case accession ID has been identified at the Review Station, the server sends the images for that ID. The CT or pathologist is presented with a gallery of images of objects of interest for that slide.

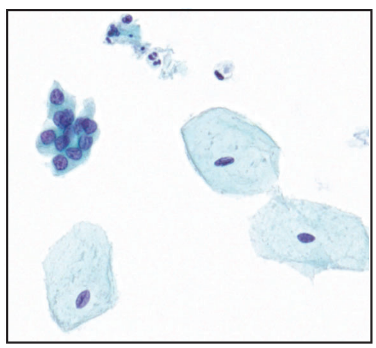
When any image is being reviewed, the CT or pathologist has the option to electronically mark objects of interest and include the marks in the slide review. The reviewer always has the option to move and zoom through a view of the whole slide image, which provides complete freedom to move any portion of the cell spot into the field of view for examination.

Genius Digital Diagnostics System Process,
Gyn Cases with Genius Cervical AI



Prepared ThinPrep slides are loaded into a slide carrier, which is loaded into the Digital Imager.

The cell spot is imaged.

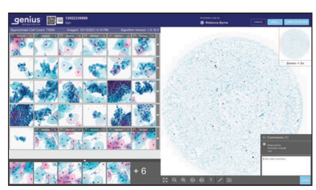


The Digital Imager scans the entire cell spot. The Genius Cervical AI algorithm identifies objects of interest found on the slide.

Case data and images, including objects of interest, are stored on the Image Management Server.

During review, the Review Station presents a gallery of images with the objects of interest to the reviewer.

Case review by the cytologist or pathologist



Cells and other objects of interest may be electronically marked by the reviewer. The case is marked as reviewed.

At completion, case data is updated with any marked areas as well as information on the review session.

The case is available to subsequent reviewers at the Review Station.

Figure 2-1-1 Genius Digital Diagnostics System Process with Genius Cervical AI

2. User Interface

Chapter Two

User Interface

This chapter provides detailed information on reports that are unique for reviewing ThinPrep Pap Tests on the Genius Digital Diagnostics System with the Genius Cervical AI algorithm. Additional information on the user interface screens, including other reports, is available in Part 1 of this manual.

This chapter includes:

SECTION A — REPORTS FOR GYN CASES

CT Reviews Report

The CT Reviews Report lists individual accession IDs reviewed at the Review Station during a period of time. A manager or an administrator can select more than one reviewer to include in the report. For labs using access control filters, a manager selects from reviewers within the manager's access control filter, and an administrator selects from the users of all of the Review Stations connected to the same Image Management Server. When a reviewer runs the report, the data only includes that one reviewer.

1. Choose the time period for the report data.
   Select a review time from the available options of:
   - All (all of the data in the server's database)
   - Today
   - Yesterday
   - Last 7 days
   - Last 30 days

- Custom

2. A manager or an administrator must also choose which reviewers to include in the report data.
    - Select one or more reviewers by clicking on the name of the reviewer in the list, or
    - All (all of the reviewers in the server's database)

   When a reviewer runs this report, that reviewer's name is preselected and is the only available option.

   Note: Each completed review of a case is considered a review by the Review Station. For example, an initial review by a CT, a subsequent review for quality control and a review by a pathologist, are each considered a review by the Review Station.

3. If access control filters are used, choose the access control filter(s) that will be included in the report data.
    - Select one or more access control filter by clicking on name(s) of the filter in the list, or
    - All (cases from all of the access control filters in the server's database)
4. Choose the category that will be used to sort the data in the report. Choose from:
    - Reviewer
    - Accession ID
    - Review time (date and time)
    - Review marks
5. Choose the order in which the data will appear:

- Sort the results in ascending or descending order.

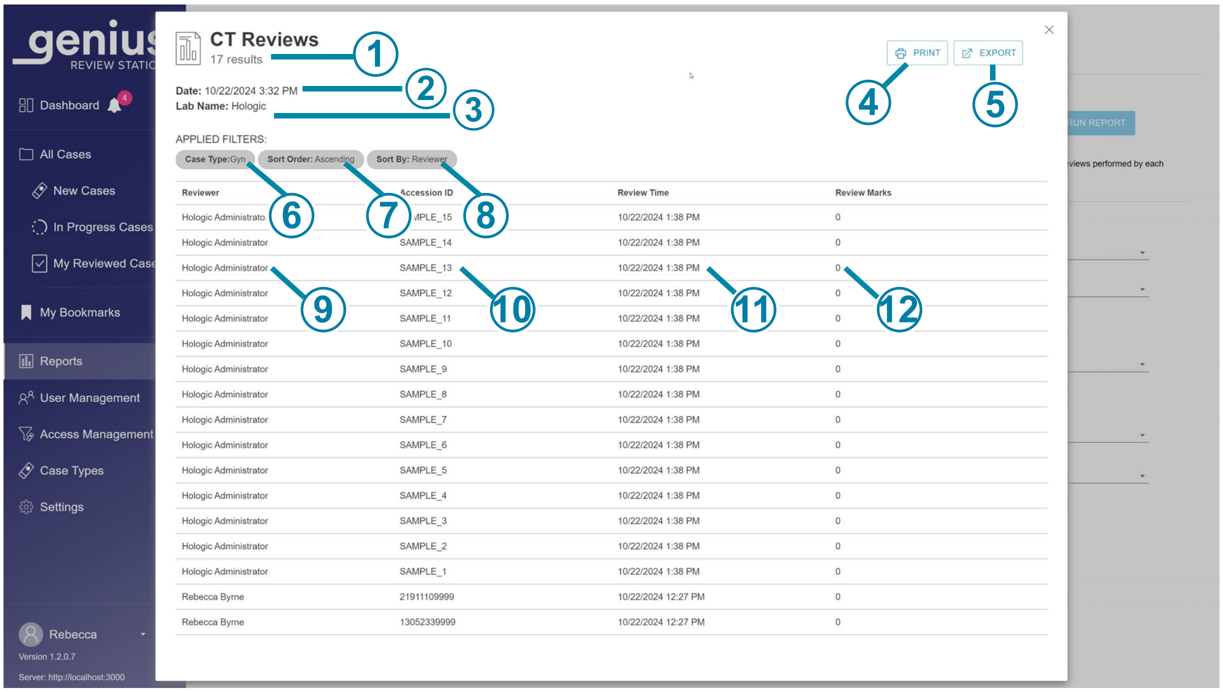


Figure 2-2-1 CT Reviews Report, example

Key to Figure 2-2-1	
1	Total number of reviews during the time period for the report ***Note:*** For any report, if there is no data that meets the report criteria, the report will list “0 results” in the header.
2	Date the report is run (today’s date)
3	Lab name
4	Print to PDF
5	Export the data as a CSV file

Key to Figure 2-2-1	
6	The Case Type is listed. The Case Type is always Gyn for this report.
7	The sorting order for the data in the report.
8	The sorting criteria for the data in the report.
9	The name of the CT. For users with the reviewer role, all of the data is for that person.
10	The Accession ID for each case reviewed by this CT during this time period
11	The date and time that the case review was completed
12	The number of marks saved on that case

CT Workload History

The CT Workload History Report lists the total number of reviews completed by a Review Station user (reviews per person) during a period of time. A manager can select more than one reviewer to include in the report. For labs using access control filters, a manager selects from reviewers within the manager's access control filter, and an administrator selects from the users of all of the Review Stations connected to the same Image Management Server. When a reviewer runs the report, the data only includes that one reviewer.

Note: The CT Workload History Report separates out the workload by a time interval over a period of time. For example, the CT Workload History Report can show the number of reviews each week for a month.

1. Choose the time period for the report data.
   Select a review time from the available options of:
   - All (up to one year of data on the server, starting at the current date)

- Today
- Yesterday
- Last 7 days
- Last 30 days
- Custom

2. A manager or an administrator must also choose which reviewers to include in the report data.
    - Select one or more reviewers by clicking on name of the reviewer(s) in the list, or
    - All (all of the reviewers in the server's database)

   When a reviewer runs this report, that reviewer's name is preselected and is the only available option.
3. Chose a time interval. This determines the level of detail for the data in the report. Select from the available options of:
    - All (this selects the largest interval, which is by the calendar year)
    - Hour
    - Day
    - Week (the start of each reviewer's week in the report is the day of the week that the first review by that reviewer was completed. In the report, the week may or may not start on a Sunday or a Monday.)
    - Month
    - Year
4. If access control filters are used, choose the access control filter(s) that will be included in the report data.
    - Select one or more access control filter by clicking on name(s) of the filter in the list, or
    - All (cases from all of the access control filters in the server's database)
5. Choose the category that will be used to sort the data in the report. Choose from:
    - Reviewer
    - Review count
6. Choose the order in which the data will appear:
- Sort the results in ascending or descending order.

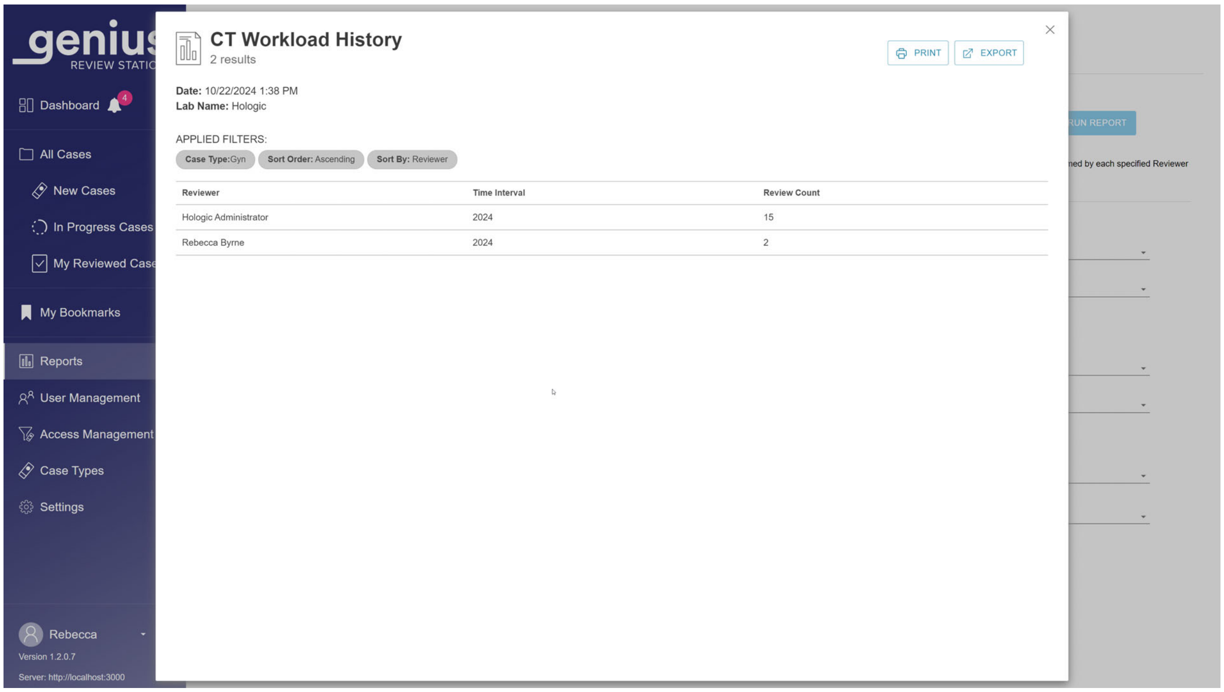


Figure 2-2-2 CT Workload History Report, example

CT Workload Summary

The CT Workload Summary lists how many reviews were done by each reviewer over a specific time period. When a manager runs the CT Workload Summary Report in a lab the does not use access control filters, the report includes all reviewers in the database. For labs using access control filters, the report run by a manager includes reviewers within the manager's access control filter, and a report run by an administrator includes all of the users of all of the Review Stations connected to the same Image Management Server. When a reviewer runs the report, the data only includes that one reviewer.

Note: The CT *Workload Summary Report* summarizes the workload over a period of time (for example, the total number of reviews completed by a reviewer in a particular month). By contrast, the CT *Workload History Report* includes a "segment" for the period of time (for example, the total number of reviews completed by a reviewer each week in a particular month).

1. Choose the time period for the report data.
   Select a review time from the available options of:
   - All (all of the data in the server's database)
   - Today
   - Yesterday

- Last 7 days
- Last 30 days
- Custom

2. A manager or an administrator must also choose which reviewers to include in the report data.
   - Select one or more reviewers by clicking on the name of the reviewer(s) in the list, or
   - All (all of the reviewers in the server's database)

   When a reviewer runs this report, that reviewer's name is preselected and is the only available option.
3. The Case Type is always Gyn for this report.
4. If access control filters are used, choose the access control filter(s) that will be included in the report data.
   - Select one or more access control filter by clicking on the name of the filter(s) in the list, or
   - All (cases from all of the access control filters in the server's database)
5. Choose the order in which the data will appear:
   - Sort the results by the reviewers' names.
   - Sort the results by Review count (the number of reviews completed at the Review Station).
6. Choose the order in which the data will appear:

- Sort the results in ascending or descending order.

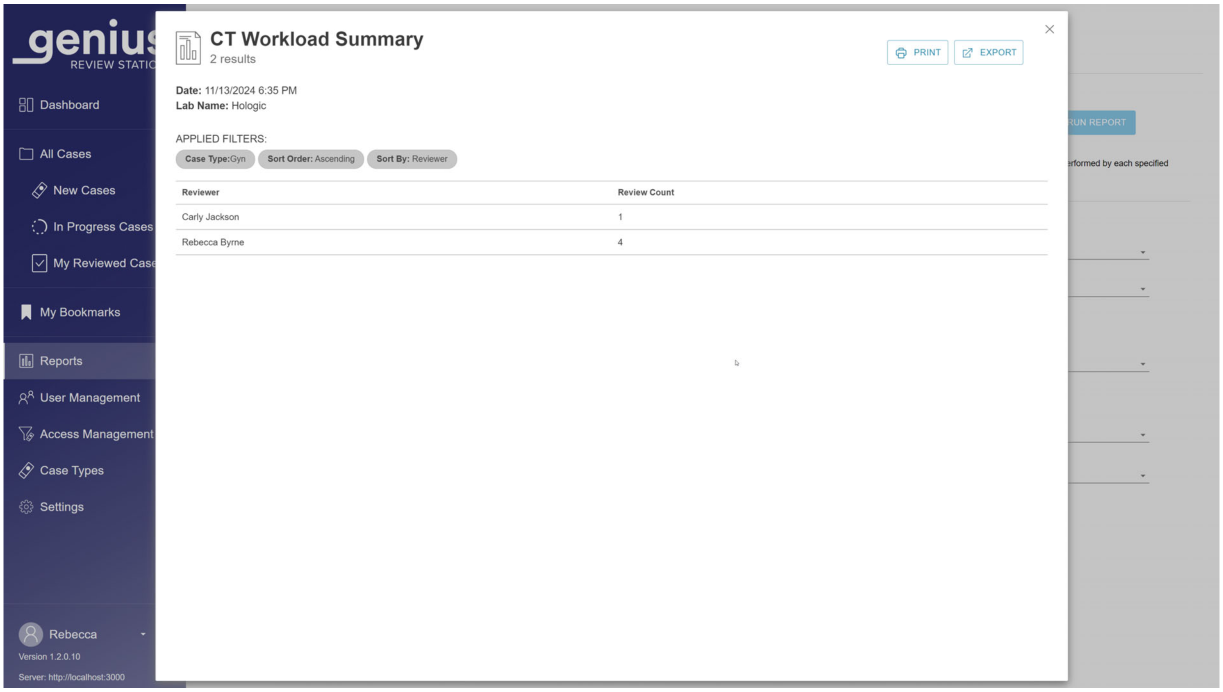


Figure 2-2-3 CT Workload Summary Report, example

Informational Message History Report

The Informational Message History Report lists any informational messages, over a specific time period, for slides imaged on Digital Imagers connected to the same Genius Image Management Server. For labs using access control filters, when a manager, reviewer or lab tech runs the report, the slide data is from accession IDs within the manager, reviewer or lab tech's access control filter. When an administrator runs the report, all of the slide data on the Image Management Server is eligible for the report.

The report includes data for all slides imaged in the specified time period, including slides without any informational message.

Note: If a case with an informational message is deleted, the data for that case is not included in the Informational Message History Report.

The Informational Message History Report lists the accession ID, the date and time that the slide was imaged, any tags applied the case, the message code, and the message associated with that code.

Note: In the report, "No Message" means that the Genius Cervical AI algorithm did not generate an informational message when it generated the gallery.

1. Choose the time period for the report data.
   Select an imaged time from the available options of:

- All (all of the data in the server's database)
- Today
- Yesterday
- Last 7 days
- Last 30 days
- Custom

2. Choose which tags to include in the report. Select any of the tags, or select **All**.
3. Choose which message codes to include in the report. Select any of the individual messages, or select **All**.
4. Choose the category that will be used to sort the data in the report. Choose from:
    - The accession ID
    - The slide image time (date and time)
    - Tag names
    - The message code number
    - The description (the message itself)

5. Choose the order in which the data will appear. Sort the results in ascending or descending order.

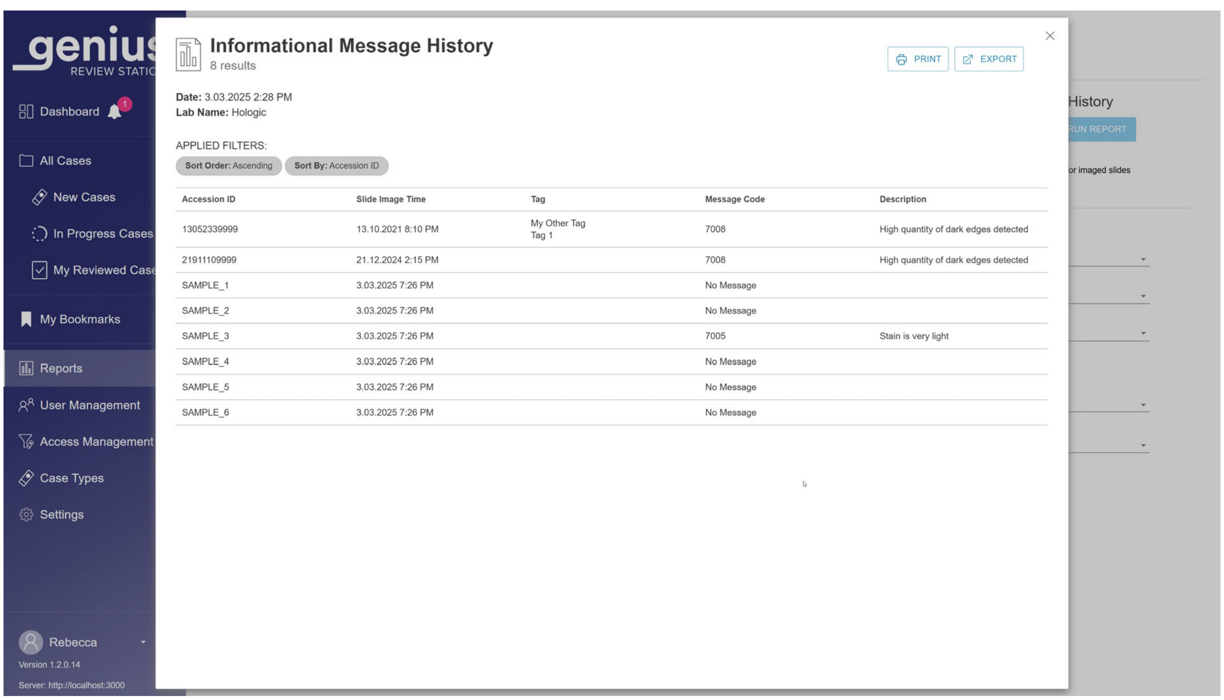


Figure 2-2-4 Informational Message History Report, example

Informational Message Usage Report

The Informational Message Usage Report lists the total number of informational messages for cases imaged during a period of time. The Informational Message Usage Report lists the total number of cases displaying a particular message or no message, and tallies a total for the number of slides described in the report.

Note: If a case with an informational message is deleted, the data for that case is not included in the Informational Message Usage Report.

For labs using access control filters, when a manager, reviewer or lab tech runs the report, the slide data is from accession IDs within the manager, reviewer or lab tech's access control filter. When an administrator runs the report, all of the slide data on the Image Management Server is eligible for the report.

Note: In the report, "No Message" means that the Genius Cervical AI algorithm did not generate a message when it generated the gallery.

1. Choose the time period for the report data.
   Select an imaged time from the available options of:
   - All (all of the data in the server's database)
   - Today
   - Yesterday
   - Last 7 days
   - Last 30 days
   - Custom
2. Choose which message codes to include in the report. Select any of the individual messages, or select **All**.

   Note: The total at the end of the Informational Message Usage Report counts all of the data displayed in the report. A report with **All** selected for the Informational Message Codes tallies all of the slides imaged during that time period, with no message displayed *and* with messages displayed.
3. Choose the category that will be used to sort the data in the report. Choose from:
   - Message code
   - Description (the message itself)
   - Message count (the number of times the message appeared in that time period)

4. Choose the order in which the data will appear. Sort the results in ascending or descending order.

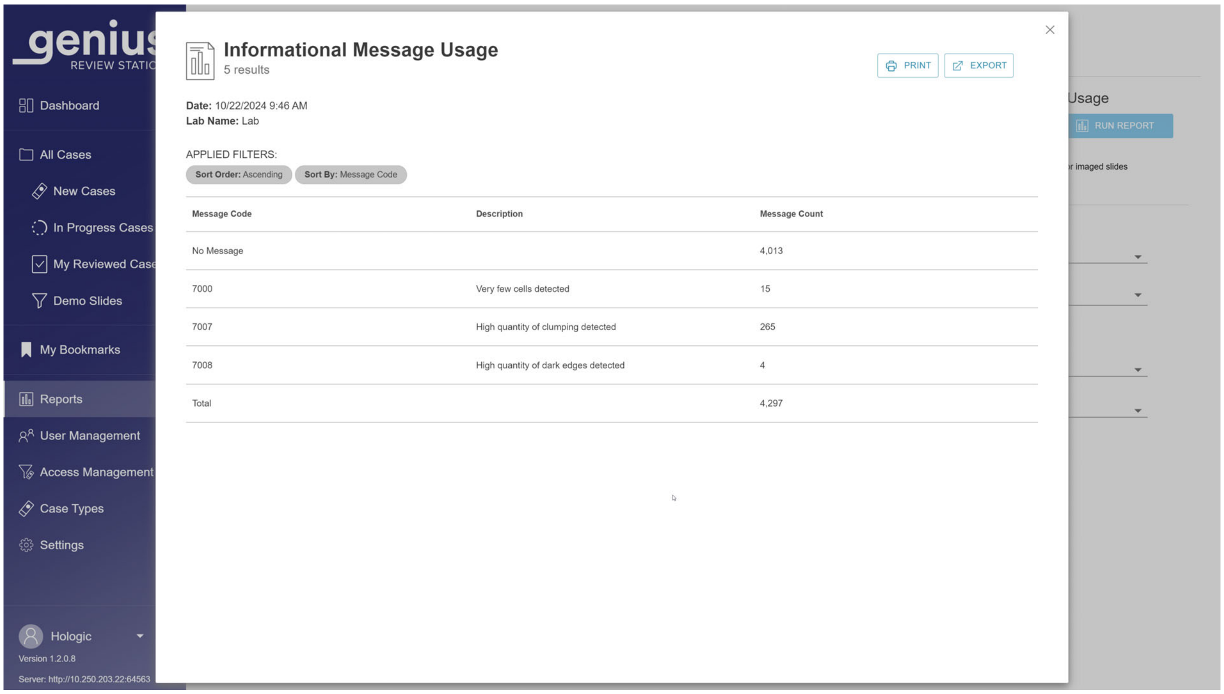


Figure 2-2-5 Informational Message Usage History Report, example

Note: The Informational Message *Usage* Report summarizes the messages generated over a period of time (for example, the total number of cases where a message about light stain appeared in a particular month). By contrast, the Informational Message *History* Report is a detailed view, listing the accession ID and tag(s) for the period of time.

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3. Operation

Chapter Three

Operation

SECTION A OVERVIEW, GYN CASES USING GENIUS CERVICAL AI

The Genius Review Station is used to review digital images created in the Genius Digital Diagnostics System for cytological specimens.

The images are reviewed by a cytologist (CT) or pathologist. The same images may be reviewed by additional cytologists and pathologists. During review, the reviewer can mark objects of interest, and the marks are available to anyone reviewing the same case later.

For cervical cancer screening of ThinPrep Pap test slides imaged and analyzed by the Genius Cervical AI algorithm, the Review Station presents a gallery of images, additional images, and an image of the whole cell spot.

For all case types, the Review Station presents an image of the whole slide image. A reviewer can adjust the zoom of the whole slide image. A reviewer has the option to download a jpeg image (screenshot) of the image to the Review Station computer.

The Review Station can transmit event information related to cases. The event data can integrate with a compatible Laboratory Information System (LIS). Additional integration activities by the laboratory or the LIS provider are required.

The instructions in Part 1 of this manual must also be followed for proper use of the Review Station.

Case Review, Gyn Cases Using Genius Cervical AI

The Review Station organizes case information by Accession ID. Case data for the cases on the Genius Image Management Server are available from any Review Station in the network, and access can be restricted using access control filters. A reviewer opens a case and only one reviewer at a time can mark an image of cells, add comments on images, tag the case, and complete a review of a case.

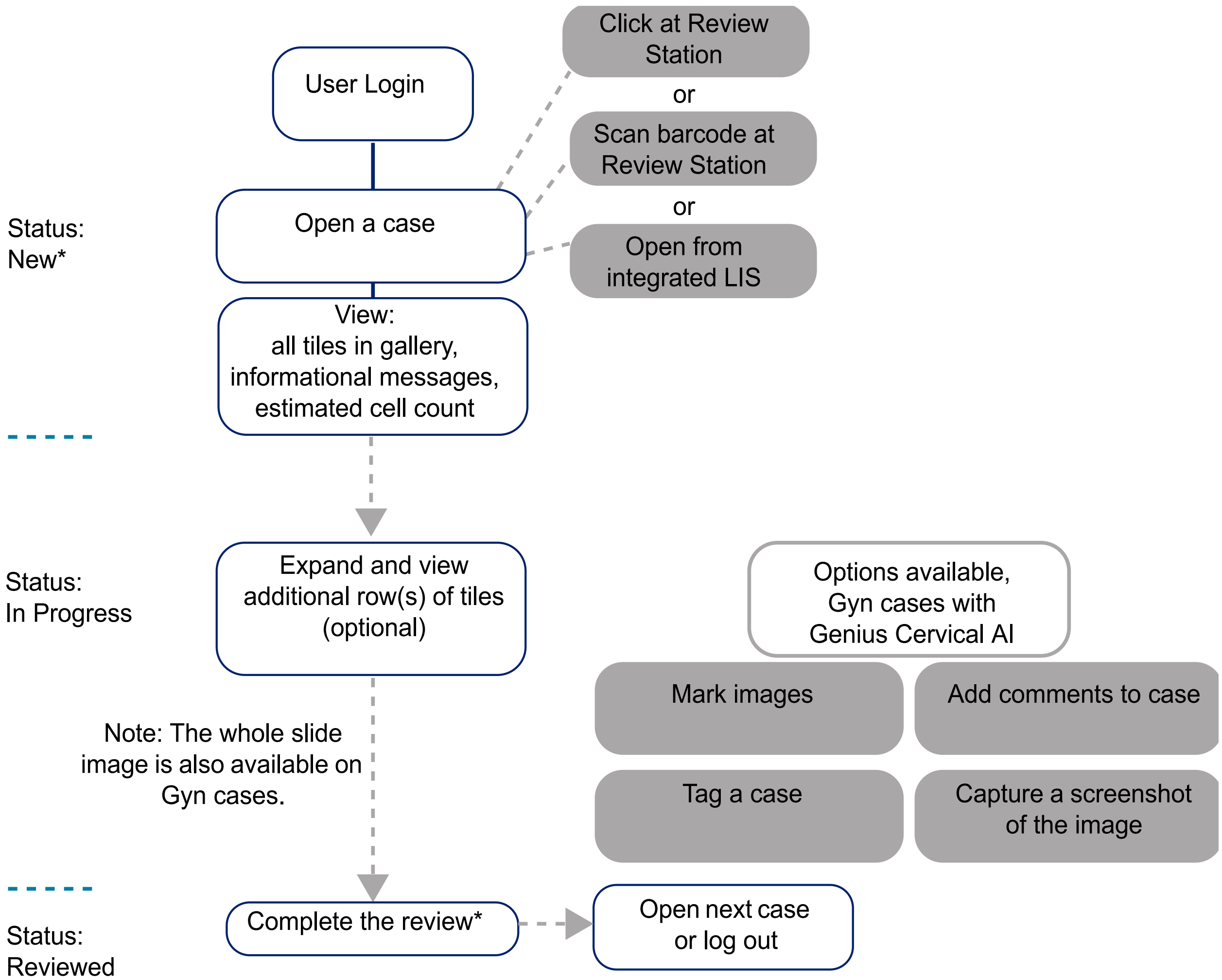
Once a reviewer changes the status of a case to "In Progress" and again when the reviewer changes the status of a case to complete the review, the case data record is updated and stored on the Image Management Server, available to other reviewers in the Review Station network.

If another reviewer opens a case whose review has been completed, the marks and comments made by previous reviewer(s) are displayed. The subsequent reviewer can add marks and comments, and save their review to the data record stored on the Image Management Server. A subsequent reviewer cannot delete marks or comments saved by an earlier reviewer. The marks and comments are available the next time the case is opened by a reviewer in the Review Station network. The name of the reviewer(s) and the date(s) of review are stored data in the case data record.

Case Data Record

The case data record is the accumulation of all imaging and review activity for the case. The reports are generated from data that is in the case data record. A case data record is generated when a valid slide ID is accepted into the Image Management Server's database. Items that are associated with the case data record include:

- Date/time stamp when imaging ended
- Serial number of the Digital Imager that imaged the slide
- High resolution images of the cell spot
- A macro image of the entire slide, including the slide label area
- Date/time stamp when slide review ended (including subsequent reviews)
- Name of the reviewer for each review of the slide (including subsequent reviews)
- Electronic marks and comments



*A reviewer can also open a case that is in the "Reviewed" status and review it again. And, a reviewer can opt to save a case to continuing reviewing later.

Figure 2-3-1 Typical case review processes, Gyn cases

SECTION B MATERIALS REQUIRED PRIOR TO OPERATION

- Slide data on the Genius Image Management Server from imaged glass microscope slides. For ThinPrep Pap test cases using Genius Cervical AI, ThinPrep Imaging System slides are required.
- Genius Review Station

Important Operational Notes

- For Gyn samples, examine the gallery of tiles, the five rows with six tiles per row, initially displayed at the Review Station.
- The case images are digitally marked and/or saved as screenshots by the CT or pathologist. Follow your laboratory's guidelines for marking objects of interest in case images. Follow all applicable guidelines and regulations for handling downloaded images.

SECTION C REVIEW A CASE

For Gyn cases, a gallery of images from the slide's cell spot is presented to the reviewer. Additional images of the case are also available for viewing. A reviewer can mark the images and comment on the case. The images presented in the gallery are used to interpret the case.

The image of the entire cell spot is also available.

Open a Case

There are several ways to open a case on the Review Station.

From a Case List:

- Click on an accession ID to open the case. Use cases lists in the menu bar (All Cases, New Cases, In Progress Cases or any custom filters) and filters on the displayed columns to show particular kinds of cases in the Case List.
- Or, type in the accession ID using the keyboard or, with the cursor in the "Search by Accession ID" field, scan the accession ID from your laboratory records with the optional barcode scanner. Then, press Enter on the keyboard or click on the search icon (magnifying glass) to search.

From the Dashboard, in the **Open a Case** section, type in the accession ID using the keyboard or, with the cursor in the Accession ID field, scan the accession ID from your laboratory records with the optional barcode scanner. Select **Open Case**, and the review screen displays.

Note: If your facility uses the optional settings on the Genius Digital Imager to exclude characters in the slide label or add a time stamp of the imaging time, consider that the accession ID in the Genius Digital Diagnostics System for the cases specified by your lab may not be an exact match with the accession ID on the slide label or your facility's information systems. Maintain the chain of custody for all samples to ensure the integrity and reliability of test results. Ensure compliance with all applicable quality control procedures, regulations, and policies.

And, in product configurations where your laboratory has integrated an interface between the Genius Event Bridge Messaging and your laboratory's LIS, follow your laboratory's process for using the Accession ID in the LIS to open a case at the Review Station.

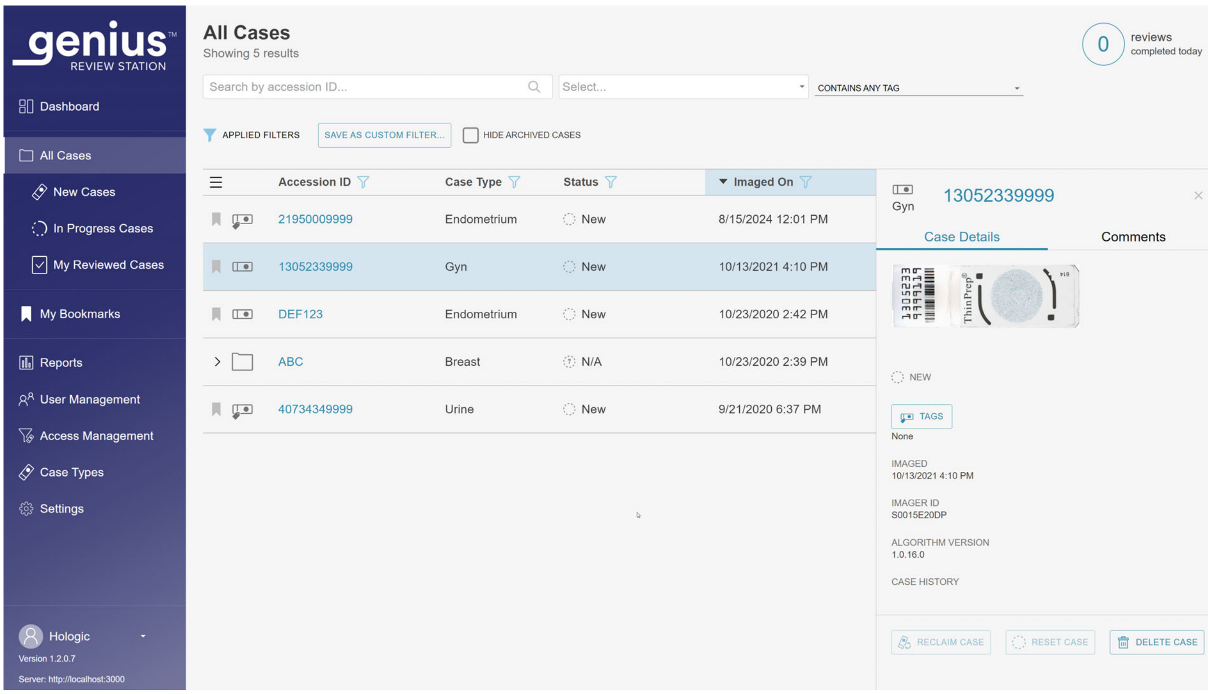


Figure 2-3-2 Case List - Click Accession ID to Open Case, example

Only one reviewer can review a case at a time. If a reviewer attempts to open a case that is already open, the reviewer can choose a read-only mode to view the images. In read-only mode, the reviewer sees the images, the current marks, and the existing comments, but cannot complete a review of that case, cannot change the marks, and cannot add comments. In read-only mode, above the reviewer's name the Review Station says "viewing as" rather than "reviewing as". The **Complete Review** button is unavailable, and a **Back** button returns the reviewer to the Case List screen rather than the **Cancel** button.

The data displayed in the Case List is refreshed once per minute by the Genius Digital Diagnostics System. The entries and their position in the Case List may change as other reviewers review cases and as additional slides are imaged. If two users attempt to review the same case, when the first reviewer changes the status or saves any marks or comments, the second reviewer is notified that the case is in-progress by the other reviewer.

The review screen for Gyn cases with Genius Cervical AI differs from the review screen for whole slide images without Genius Cervical AI. Refer to Part 3 of this manual for instructions for reviewing whole slide images.

Review Images for a Gyn Case with Genius Cervical AI

The review screen for Gyn cases has a gallery of images on the left and the whole slide image (WSI) on the right. The tiles in the gallery display at 20x magnification and the whole slide image displays images at <2x magnification initially.

Note: The magnification values displayed on the Review Station are intended as digital equivalents of the magnification when glass slides are viewed through a microscope objective.

Each tile in the gallery on the left is an object of interest in the whole slide image shown on the right.

The heading of the review screen shows:

- An image of the slide including its label
- The Accession ID
- A QR code of the Accession ID
- The Case Type (Gyn in this example)
- Your name “Reviewing Case As”
- **Cancel** button
- **Tags...** button
- **Complete Review** button

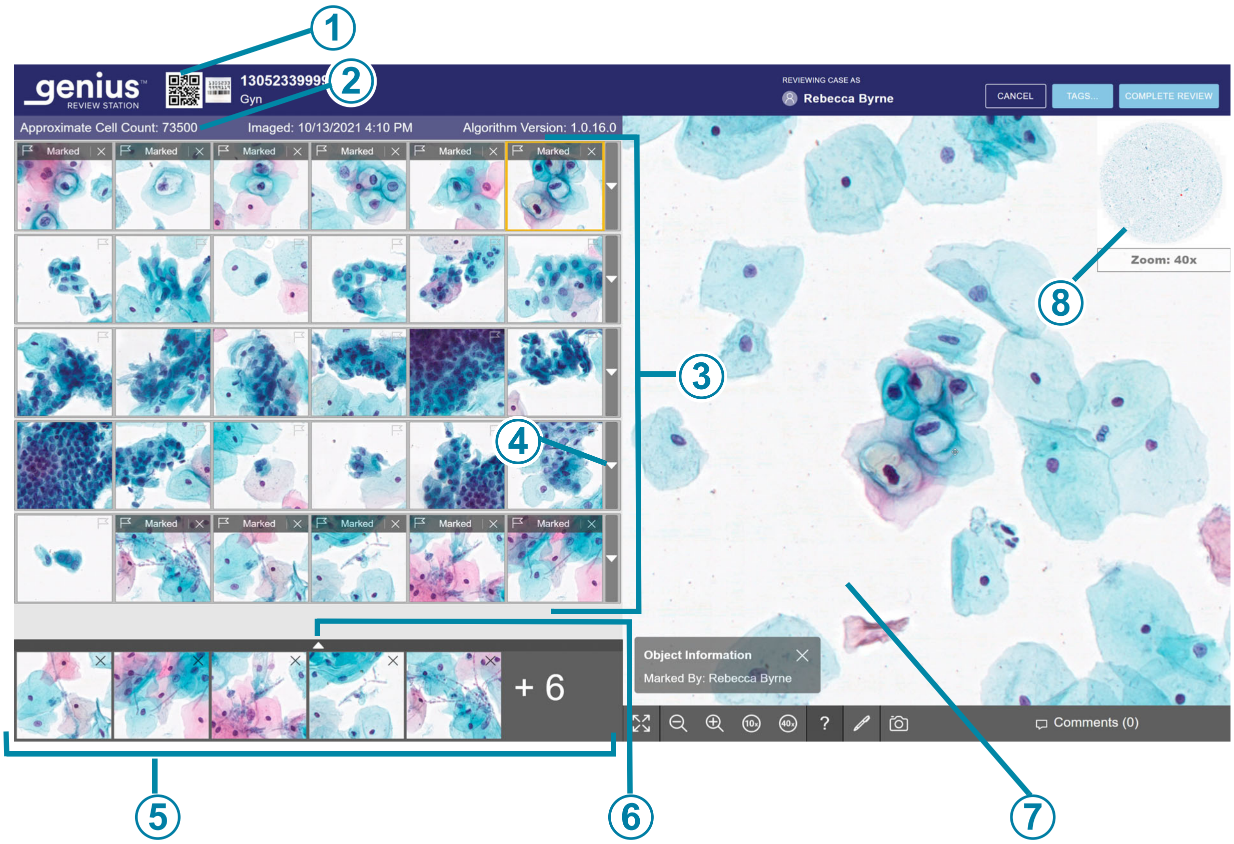


Figure 2-3-3 Gyn case - new case opened for review, example

Key to Figure 2-3-3	
1	Accession ID and macro image of the slide label area The Review Station displays the Accession ID as text and as a QR code. To see the macro image of the slide, click on the macro image of the slide label area. Refer to Figure 2-3-4. To see a larger image of the QR code, click on the QR code. To scan the Accession ID with an optional barcode scanner, scan the macro image of the slide, the smaller QR code of the Accession ID, or the larger image of the QR code.
2	Above the gallery, the approximate cell count, date the slide was imaged, and algorithm version display. Refer to “Cell count, date and algorithm version” on page 3.12 for more details.
3	The gallery of 30 tiles: five rows of six tiles. For Gyn cases only. Refer to “Review the Gallery of Objects of Interest (OOIs), Gyn Case” on page 3.11 for more details.

Key to Figure 2-3-3	
4	Arrow to show or hide additional rows in the gallery. Refer to “The Genius Cervical AI Gallery, Gyn Case” on page 3.12 for more details.
5	“Shortlist” of marked cells. Refer to “About Shortlists of marked objects” on page 3.24 for more details.
6	Arrow to show or hide additional rows in the Shortlist. Refer to “About Shortlists of marked objects” on page 3.24 for more details.
7	Whole Slide Image and tools for navigating the whole slide image. Refer to “The Whole Slide Image, Gyn Cases” on page 3.17 for more details.
8	Inset macroscopic view of the cell spot

The accession ID used by the Genius Digital Diagnostics System and the ID printed on the slide label are shown in the macro image of each case.

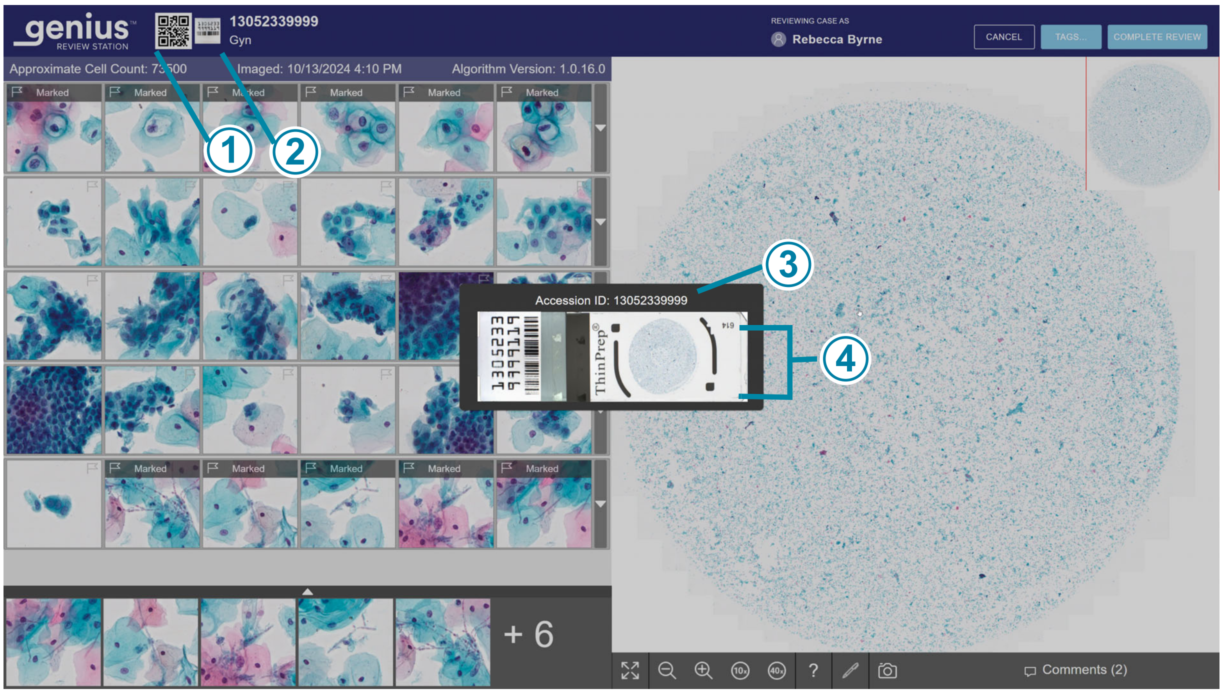


Figure 2-3-4 Macro image shows slide label area, example of a case with Genius Cervical AI

Key to Figure 2-3-4	
1	The QR code represents the Accession ID used by the Genius Digital Diagnostics System.
2	When a case is open for review, to see the accession ID, click to the left of the Accession ID to view the macro image of the slide.
3	The Accession ID used by the Genius Digital Diagnostics System appears above the macro image of the slide.
4	The macro image itself also shows what is printed on the slide label.

Review the Gallery of Objects of Interest (OOIs), Gyn Case

The Genius Cervical AI algorithm in the Genius Digital Diagnostics System analyzes the images of the whole cell spot on a Gyn case to identify diagnostically relevant objects. These objects of interest are presented on the Review Station at 20x magnification as a gallery of images. There are 30 tiles in the gallery. The gallery consists of the five rows with six tiles per row, initially displayed at the Review Station.

The Genius Cervical AI algorithm categorizes and organizes the OOIs as rows in the gallery. For some cases, one or more tiles could be empty.

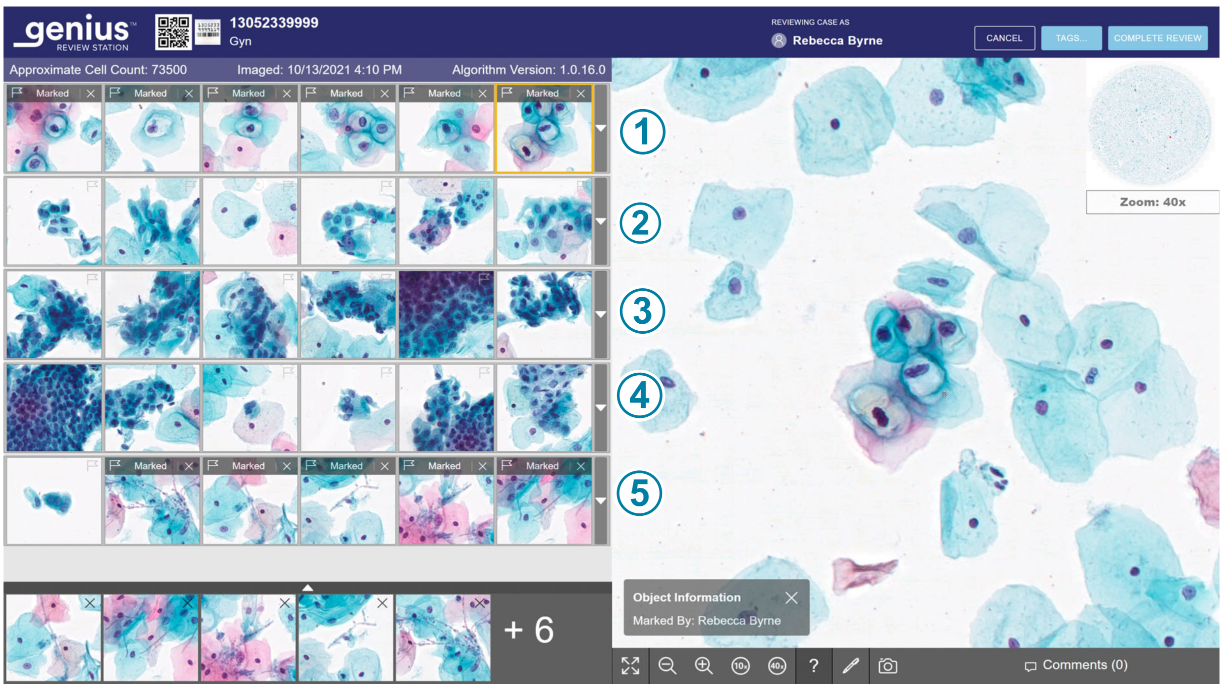


Figure 2-3-5 Genius Cervical AI gallery characteristics, example

Key to Figure 2-3-5	
1	Row 1 of the gallery displays objects of interest that the Genius AI algorithm has identified as having a lower NC ratio and, if present, cells with enlarged nuclei such as ASCUS or LSIL and/or the morphology of koilocytes.
2	Row 2 of the gallery displays objects of interest that the Genius AI algorithm has identified as having a higher NC ratio and, if present, enlarged nuclei.
3	Row 3 of the gallery displays objects of interest that the Genius AI algorithm has identified as having distorted, elongated and/or spindled morphology.

Key to Figure 2-3-5	
4	Row 4 of the gallery displays objects of interest that the Genius AI algorithm has identified as having glandular and/or cluster morphology.
5	Row 5 of the gallery displays objects of interest that the Genius AI algorithm has identified as having morphology representing infectious organisms.

1. Review each of the 30 tiles in the gallery. A reviewer can mark an OOI.
   If additional information is necessary to diagnose the case or determine specimen adequacy, optional rows of tiles in the gallery and the whole slide image to the right of the gallery are available. Refer to "The Genius Cervical AI Gallery, Gyn Case" on page 3.12 and "The Whole Slide Image, Gyn Cases" on page 3.17 for more information. The Review Station also provides the option of adding comments to a case. Refer to "Adding Comments" on page 3.17.
2. When a reviewer finishes reviewing a case, from the review screen, click on the **Complete Review** button in the upper right.
3. Next, click on **Confirm Review**.
   All marks and any comments made by the reviewer are saved in the case.
   In the Case List, the status for the case changes to "Reviewed". A case in the "Reviewed" status can be reviewed by one or more subsequent reviewers.

The Genius Cervical AI Gallery, Gyn Case

Cell count, date and algorithm version

Approximate cell count: The Genius Cervical AI algorithm provides an estimate of the squamous cell count that may be used to assist in assessing specimen adequacy. The system does not determine specimen adequacy; use your standard lab protocol.

To generate the approximate cell count, the system locates all potential cell nuclei in the whole slide image, classifies those objects, and counts the number which are deemed to be squamous cell types.

The count includes the entire cell region. It is not based on a partial sampling. This count is rounded off to provide an estimate. Refer to the Instructions for Use for the performance characteristics of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm.

The date the slide was imaged and the algorithm version display near the approximate cell count.

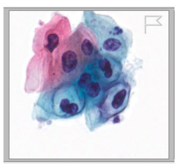
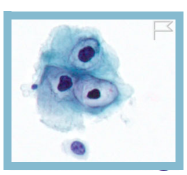
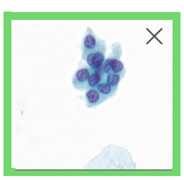
Due to environmental factors such as fading, drying, lighting, and system variability, re-imaging a ThinPrep Pap test slide with Genius Cervical AI may not produce a gallery of Objects of Interest (OOIs) identical to the original gallery. Refer to the Instructions for Use for the performance characteristics of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm.

Maintain the chain of custody for all samples to ensure the integrity and reliability of test results. Ensure compliance with all applicable quality control procedures, regulations, and policies.

Tiles of objects of interest

A reviewer reviews the objects of interest presented in the tiles.

The color coding around a tile helps indicate position while navigating the gallery of tiles.

	A tile that has not been clicked on is surrounded by a grey box.
	The tile currently selected is surrounded by a yellow/ orange box.
	After a tile has been selected, the tile is surrounded by a light blue box.
	After a tile is marked, when the tile is selected from the Shortlist of marked images, the tile in the gallery is surrounded by a green box.

There are different options for navigating through the tiles in the gallery with the mouse and keyboard. And, there are different options for marking images in the tiles with the mouse and keyboard. A reviewer can switch between the mouse and keyboard at all times.

Navigate the gallery and mark objects with a mouse

When the gallery opens, the tile in the upper left is ready to be selected. The image in the whole slide image is shown at <2x. Click on a tile, and the image in the whole slide image changes to 40x, presenting the area of the whole slide image that corresponds to the tile.

To move to the next tile in the gallery, click the mouse on the next tile.

To mark an image of a cell in a tile in the gallery with the mouse, click on the flag icon  .
The marked tile is added to the “Shortlist” of tiles at the bottom of the gallery.
To delete a mark, click on the “x” icon near the flag icon.

Note: A mark made during an earlier, completed review of the case cannot be deleted. The “x” to delete is not available.

To see an additional row of six more tiles in the gallery that are similar to a row, click the down-arrow at the right edge of each row. To hide the additional row of similar tiles, click on the up arrow.

Navigate the gallery and mark objects with the keyboard

The first step for navigating the gallery with the keyboard requires the use of a mouse. When the gallery opens, the image in the whole slide image is shown at <2x. Click with a mouse to select any tile in the gallery, and the image in the whole slide image changes to 40x, presenting the area of the whole slide image that corresponds to the tile.

To move to the next tile in the gallery, use the arrow keys or the A, W, S, D keys on the keyboard. On a keyboard with the AZERTY layout, use the arrow keys or the Q, D, Z, S keys on the keyboard.

To mark an image of a cell in a tile in the gallery with the keyboard, navigate to that tile and press the space bar.
The marked tile is added to the “Shortlist” of tiles at the bottom of the gallery.
To delete a mark, navigate to that tile and press the space bar.

Note: A mark made during an earlier, completed review of the case cannot be deleted.

To see an additional row of six more tiles in the gallery that are similar to a row, press the enter key on the keyboard when a tile is selected. To hide the additional row of similar tiles, press the enter key again.

Informational Messages from the Genius Cervical AI Algorithm

For some Gyn cases, the Genius Cervical AI algorithm provides additional information, which may assist a reviewer. When additional information is available, the bar over the top row of the gallery is pink.

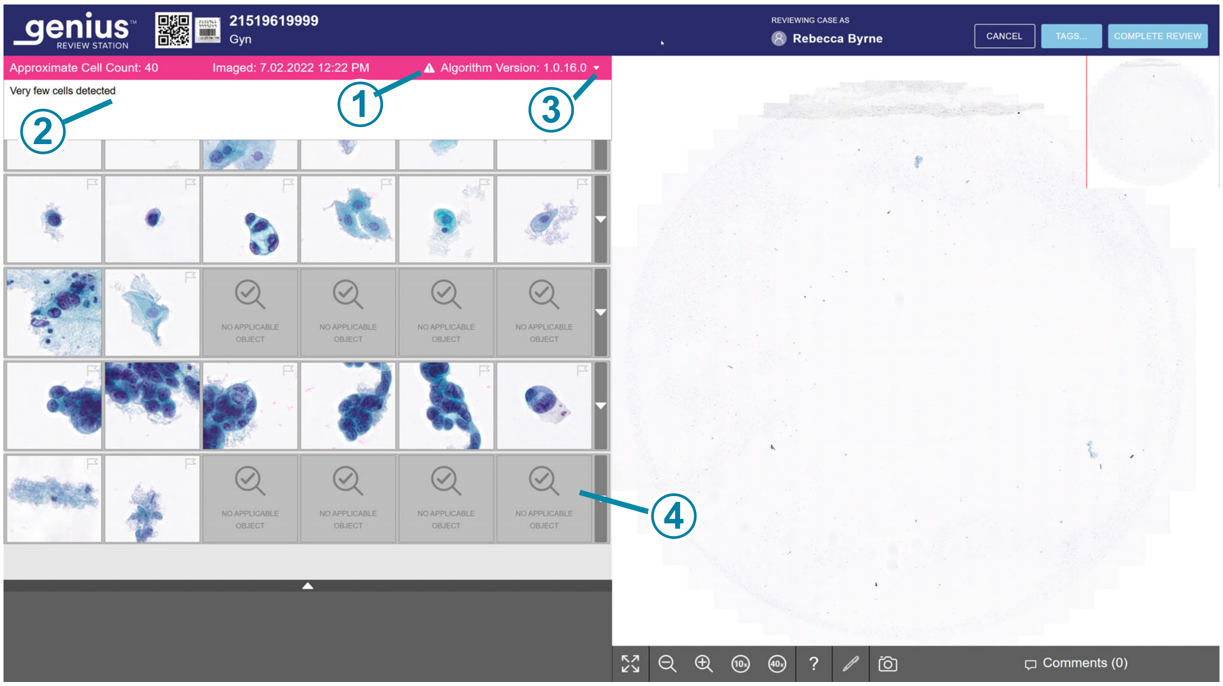


Figure 2-3-6 Gyn case with an informational message, text displayed, example

Key to Figure 2-3-6	
1	Informational Message bar. The pink color and exclamation point indicate the case has a notification.
2	Informational message.
3	When the case opens, the message's text is not visible. No action is required by the reviewer, but the reviewer can click on the arrow to display or close the message text window.
4	The "no applicable object" tile displays if the algorithm has no further objects to display. This is not an error. A reviewer can continue to review the gallery and may opt to also check the whole slide image.

To read the informational message, click on the down-arrow at the right edge of the pink bar. The messages are informational, intended as supplemental information that may help the reviewer review the case. A reviewer can review the gallery of images and may opt to also check the whole slide image.

For information on the reports that the Review Station can generate for informational messages, refer to "Informational Message History Report" on page 2.8 and "Informational Message Usage Report" on page 2.10.

Follow your laboratory's procedures or standard practices for interpreting cases with these notifications.

Table 3.1 Informational Messages

Message for Gyn Case	Possible Cause	Suggested Next Steps
Very few cells detected	The case has very low number of objects.	Review gallery. Check WSI. Check slide preparation.
Large amount of dark content	Something obscured part of the slide or part of the camera during slide imaging.	Review gallery. Check WSI. Check slide preparation.
High quantity of debris detected	The objects on the slide are mostly debris or other artifacts, not cells.	Review gallery. Check WSI. Check slide preparation.
Out of focus objects detected	The images of the case are focused well enough to be presented, but the image also includes some objects that are out of focus.	Review gallery. Check WSI. Check slide preparation.
Stain is very light	The nuclei are very light.	Review gallery. Check WSI. Check slide preparation.
Stain is very dark	The nuclei are very dark.	Review gallery. Check WSI. Check slide preparation.

Table 3.1 Informational Messages

Message for Gyn Case	Possible Cause	Suggested Next Steps
High quantity of clumping detected	The case has clumped objects. These could be the result of a biological event where the sample may contain abundant clumpy inflammation or bacteria. The clumped objects could include blood, lysed blood cells, mucus, and lubricant. Typically there is some detectable background material in the clumps.	Review gallery. Check WSI. Check slide preparation.
High quantity of dark edges detected	The case may have air bubbles, material retracted under the coverslip on the slide, or other hard-edged content, such as long strands of debris.	Review gallery. Check WSI. Check slide preparation.

The Whole Slide Image, Gyn Cases

For Gyn cases, the whole slide image is on the right of the display.

Note: The magnification values displayed on the Review Station are intended as digital equivalents of the magnification when glass slides are viewed through a microscope objective.

Under the whole slide image, the Review Station offers a set of tools for changing the view and adding marks.

Adding Comments

While a reviewer has a case open, the reviewer can add comments.

1. Click on the **Comments** tool 

in the lower right, under the whole slide image.
2. A comments box opens. Any comments added to the case previously, by you or another reviewer, are visible.

3. Type in a comment, if any.

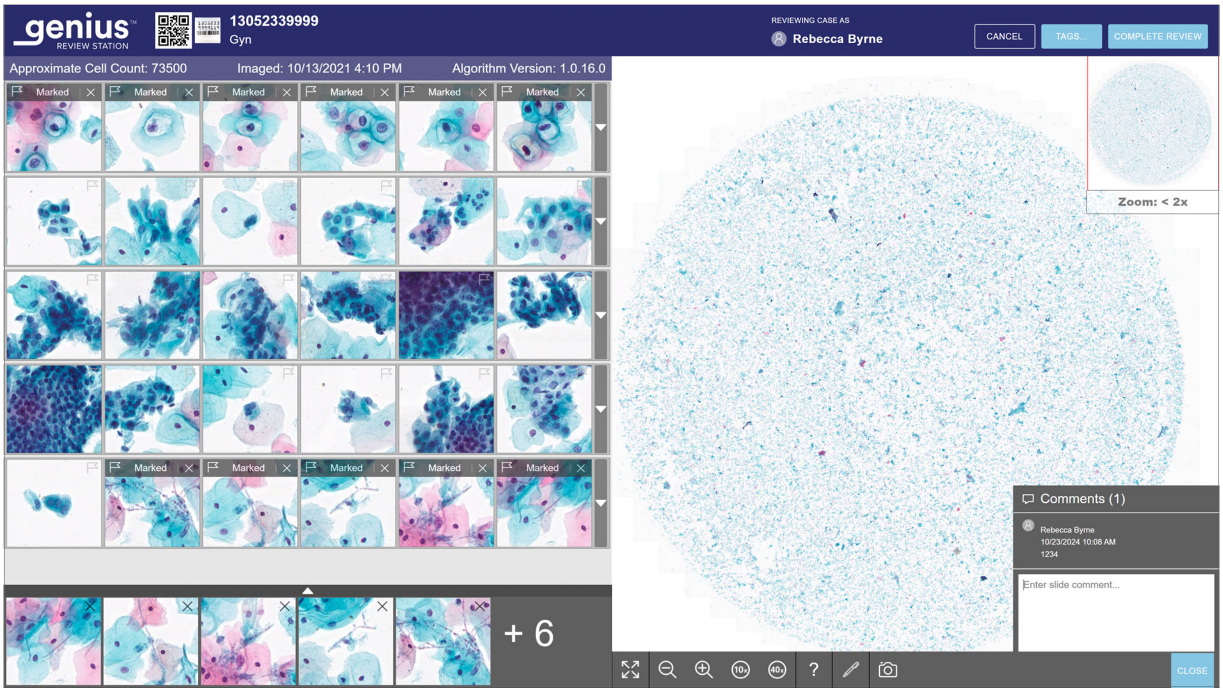


Figure 2-3-7 Add comments, view existing comments, Gyn example

4. Click on the **Close** button beneath the comment. The comment is associated with the case, and visible to other users who view or review the case.
5. Click in the gallery of tiles to continue navigating through the tiles with the keyboard or mouse.

Navigate the Whole Slide Image and Mark Objects with a Mouse

There are different options for navigating through the whole slide image with the mouse and keyboard. And, there are different options for marking images with the mouse and keyboard. A reviewer can switch between the mouse and keyboard at all times.

When the case opens, the image in the whole slide image is shown at <2x.

The toolbar under the whole slide image has several tools.

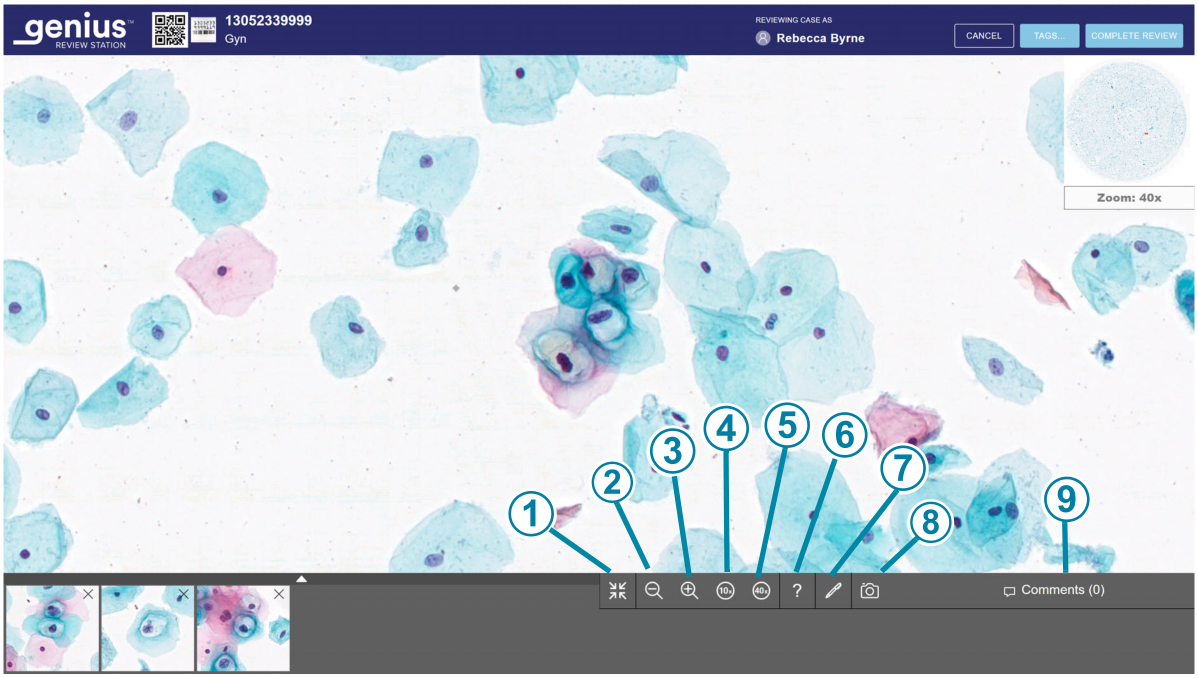
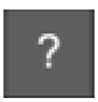


Figure 2-3-8 Toolbar under the whole slide image, example

Key to Figure 2-3-8	
1	 Expand to full screen (available only when a gallery is present) Select the icon to change the screen display so that the whole slide image fills the entire display area. To return to the gallery view and contract the view of the whole slide image, click the tool again.
2	 Zoom out Click the mouse as many times as desired on the - button to zoom out.

Key to Figure 2-3-8	
③	 Zoom in Click the mouse as many times as desired on the + button to zoom in. The maximum zoom is 40x.
④	 Zoom to 10x Click on the 10x button and the magnification zooms to the 10x view.
⑤	 Zoom to 40x Click on the 40x button and the magnification zooms to the 40x view.
⑥	 Object Information Click on the Object Information tool (the question mark) to select the tool. Then, click on a marked object in the Shortlist of tiles to see the name of the reviewer who made the mark.
⑦	 Mark Click on the mark tool (the pen) to select the tool. Then, click on the cell to mark in the whole slide image.
⑧	 Snaphot Click on the snapshot tool to save a jpeg graphic file of the whole slide image window to the Downloads folder of the Review Station computer.

Key to Figure 2-3-8	
9	 **Comments** Click the comments button to read existing comments or to add new comments. The number of comments already in the case appears in parentheses.

Zoom and move the view in the whole slide image

In addition to the tools in the toolbar, the mouse allows the reviewer to move the view through the whole slide image.

To zoom in with the mouse, click anywhere in the whole slide image and roll the mouse scroll wheel up (clockwise).

To zoom out with the mouse, click anywhere in the whole slide image and roll the mouse scroll wheel down (counter-clockwise).

To move the view of the whole slide image up, down, left, or right, click anywhere in the whole slide image and drag the mouse.

To move the view in the whole slide image, click in the macro image of the whole slide image. The view in the whole slide image moves to the area clicked in the macro image.

Add marks

To mark an image of a cell, click on the mark tool  .

Click an image of a cell.

The marked object is added to the "Shortlist" of tiles at the bottom of the display.

To delete a mark, click on the "x" icon in that tile in the Shortlist.

Note: The magnification on the whole slide image must be 10x or greater to add a mark.

Capture the screen image (Snapshot tool)

To capture an image of the whole slide image, click on the snapshot tool  .

The Review Station software creates a jpeg file of the review screen. The resolution of the screenshot is 1920 x 1997, equivalent to 96 ppi.

A dialog box for the file name of the snapshot opens. The default name for the snapshot is the accession ID for the slide. To change the file name, type in the file name field. If more than one snapshot is taken of the same case, a sequential number is added in parentheses to the end of the file name. To save the jpeg file to the "Downloads" folder of the Review Station computer, click **Continue**, or click **Cancel** to discard the snapshot.

Add a tag

Cases in a lab with a common attribute can be tagged, and then any reviewer in the lab can search for all of the cases that have been tagged with the same tag. A tag is a keyword set up by the lab manager or an administrator. The use of tags is optional. Follow your lab's policy for using tags.

Note: On the Review Station, a bookmark lets one reviewer have cases with that bookmark readily available to that *one reviewer.* Cases with the same tag are available to *all reviewers* at Review Stations connected to the same Image Management Server.

1. A tag must be set up by a manager or an administrator before the tag can be associated with a case. A manager or an administrator can set up a tag using the Settings menu. Refer to Part 1 of this manual for more information.
   Or, a manager or an administrator can set up a new tag from the **Tags...** button in a Case Review screen.

2. After the tag is set up, as a reviewer is reviewing a case, click the **Tags...** button to select a tag.

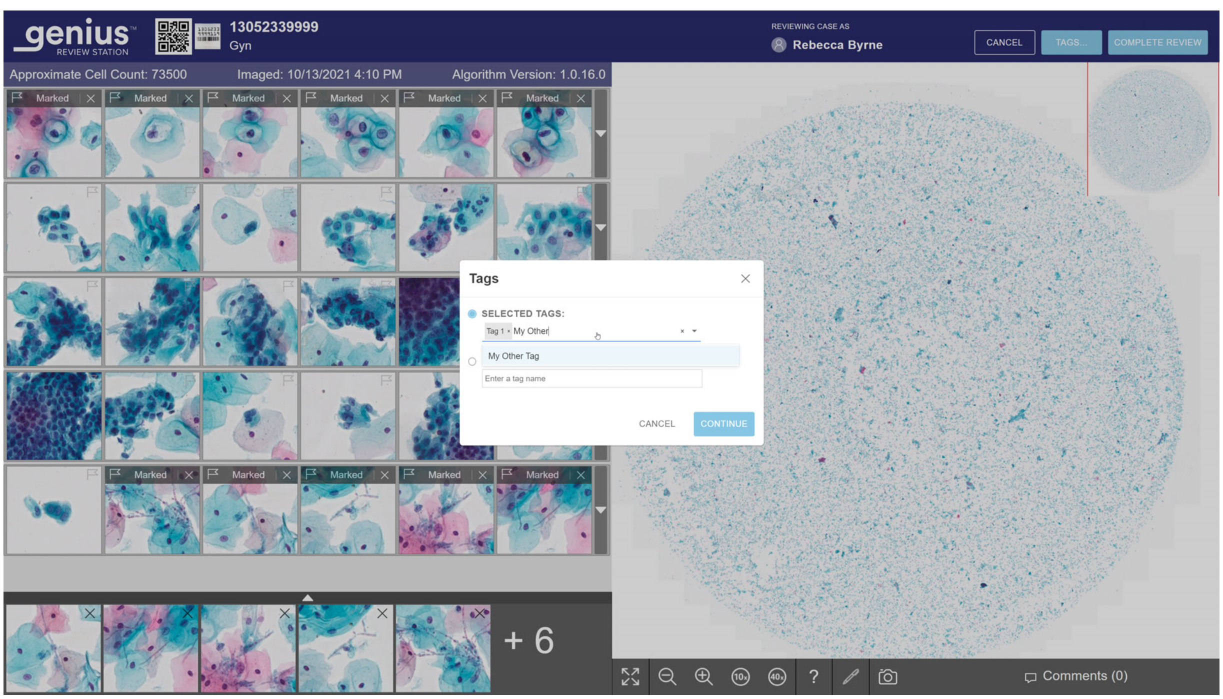


Figure 2-3-9 Tags, manager role shown

3. In the box that appears on the screen, select the name of the tag from the available options in the drop-down list, or type in the first few characters of the name of the tag to navigate to and select the tag in the list. The tags' names are listed in alphabetical order in the drop-down list.

Note: A manager or an administrator can also create a new tag from this screen.

4. Click **Continue** to tag the case, or click **Cancel** to return to the review screen without tagging the case.

After a case is tagged the icon on the case list screen changes to the Tagged Case icon, and the name of the tag is on the case details section for that case.

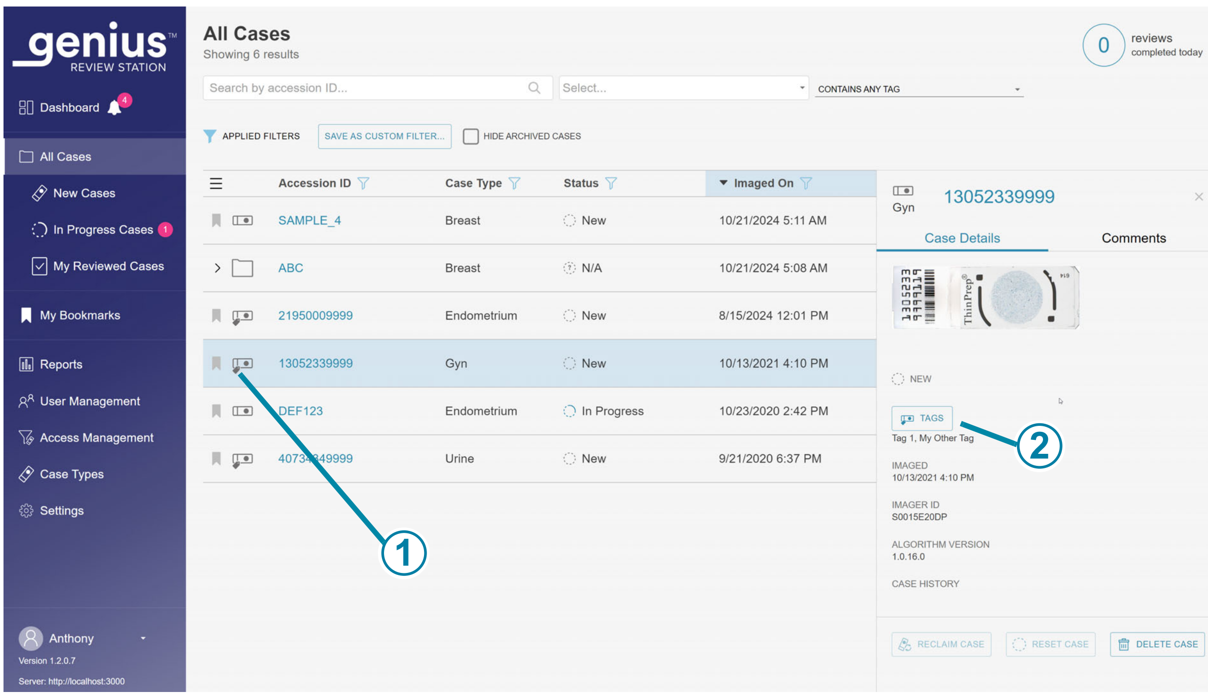


Figure 2-3-10 Case Details screen for a case with a tag

Key to Figure 2-3-10	
1	The tagged case icon shows in the Case List.

Key to Figure 2-3-10	
②	**Tags** button in the Case Details screen The name of the tag (or tags) associated with the case appear in the Case Details section. A reviewer can click the **Tags** button to add or remove a tag from the case. The steps are the same as using **Tags** button on the Case Review screen. If a manager or an administrator changes the name of a tag, the name of the tag updates in the case details screen. If a manager or an administrator deletes a tag from the Review Station network, that tag will no longer appear in the Case Details screen for a case.

More than one tag can be applied to the same case.

After a case is tagged, that case and all of the cases with the same tag can be found by using the **Search by tag...** feature on the Case List. Refer to Part 1 of this manual for more information.

Remove a tag

A tag can be removed from a case in the Case Review screen and in the Case Details screen.

1. As a reviewer is reviewing a case, click the **Tags...** button. Or navigate to the Case Details screen and click the **Tags** button.
2. In the box that appears on the screen, scroll to the name of the tag to remove from the available options in the drop-down list, or type in the first few characters of the name of the tag.
3. Click the "x" to the right of the name of the tag to remove that tag from the case.
4. Click **Continue** to remove the tag from this case, or click **Cancel** to return to the review screen without removing the tag.

Navigate the Whole Slide Image and mark objects with the keyboard

To zoom in with the keyboard, first click the mouse anywhere in the whole slide image and then press the + key (plus key) as many times as desired.

To zoom out with the keyboard, first click the mouse anywhere in the whole slide image and then press the - key (minus key) as many times as desired.

To move the view of the whole slide image up, down, left or right, first click the mouse anywhere in the whole slide image and then press the arrow keys as many times as desired. The A, W, S, D keys on the keyboard also navigate left, up, down, and right. On a keyboard with the AZERTY layout, use the arrow keys and the Q, D, Z, S keys on the keyboard.

About Shortlists of marked objects

Marked images are added to a new section of tiles, a "Shortlist".

The Shortlist is a gallery of marked tiles. For Gyn cases, the Shortlist is below the gallery. When a mark is added to a tile in the gallery, a flag icon is added to the tile in the gallery. Refer to "The Genius Cervical AI Gallery, Gyn Case" on page 3.12.

When the Shortlist exceeds six tiles, the sixth tile changes to a number. For example, "+9" means marks have been made on nine tiles that are not immediately in view.

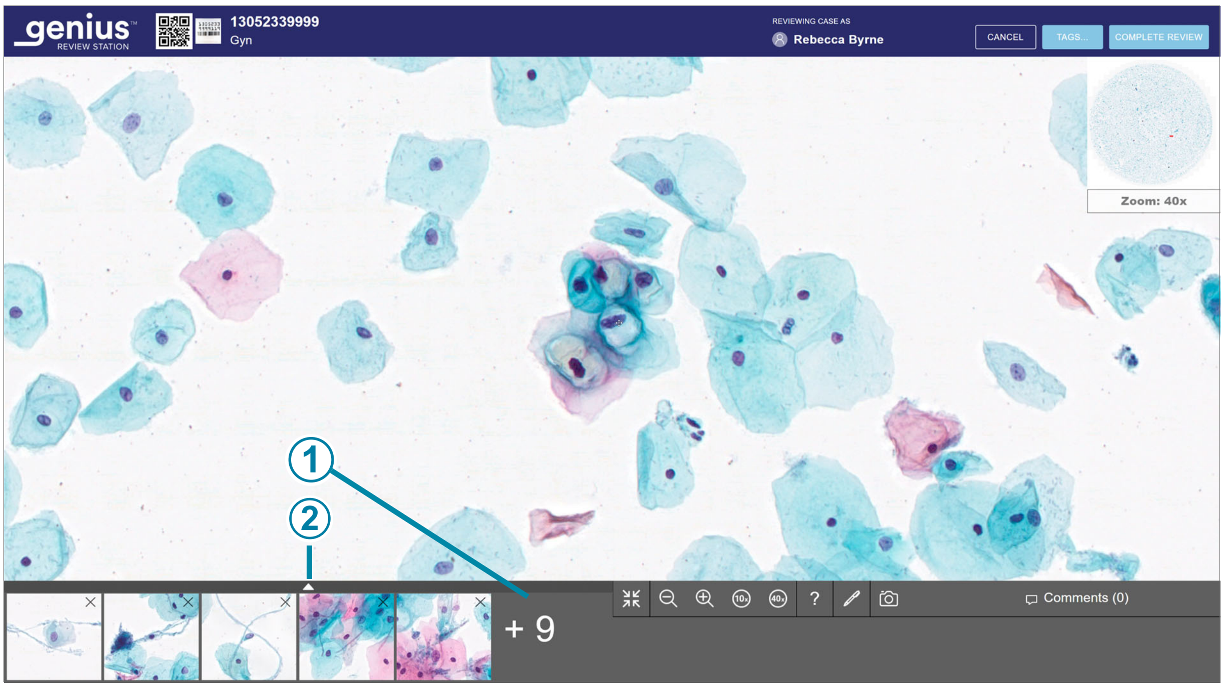


Figure 2-3-11 Shortlist of marked objects

Key to Figure 2-3-11	
1	The number indicates a longer Shortlist. In this example, nine tiles are not immediately in view.
2	To expand the view to see all tiles, click the up arrow. Click the down arrow in the marked Shortlist to return to the six-tile view.

To scroll through a large set of tiles with the keyboard, use the arrow keys or the ASWD keys. Or, use the mouse to click on any tile.

Keep a Case In Progress (optional)

A case can be reviewed and completed in one session. Once a reviewer opens a case from the Case List, that reviewer is the only one who can add marks, make comments, or complete the review. In the event that a reviewer cannot complete a review in one session before logging out, the Review Station also offers the option of keeping the review of a case in progress.

To change the status to In Progress, from the review screen click on the **Cancel** button in the upper right.

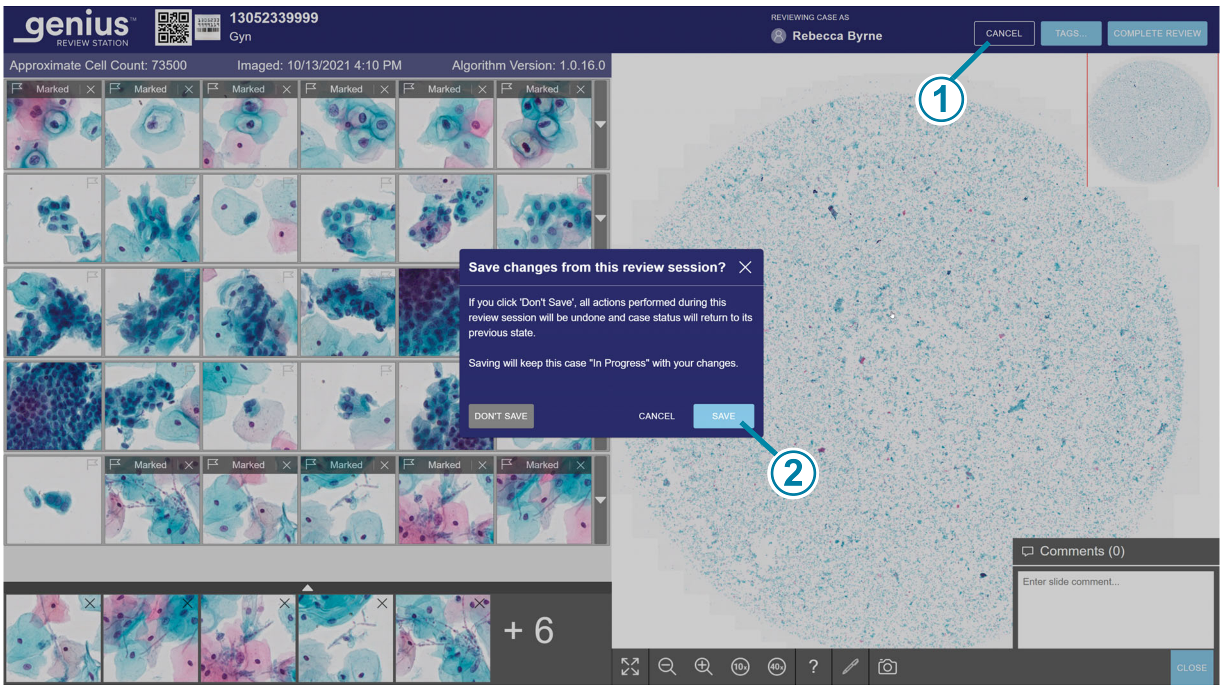


Figure 2-3-12 Save a case as In Progress, Gyn example

Key to Figure 2-3-12	
①	Click **Cancel**.
②	Click **Save**.

A dialog box appears with the option to save changes from the review session. To cancel the review, undo any new marks or comments, and keep the case in the “New Cases” status, select “Don’t Save”.

To save changes from this review session and change the status for the case to In Progress, select **Save**.

The dialog box also has a **Cancel** button which closes the dialog box.

While a case is in progress, a reviewer can add, edit, and remove new comments. While a case is in progress, a reviewer can add and remove marks. Once the review is complete, the comments and marks are permanently associated with the case.

Complete a review of a case

When a reviewer is ready to complete the review of the case, click the **Complete Review** button in the upper right of the review screen.

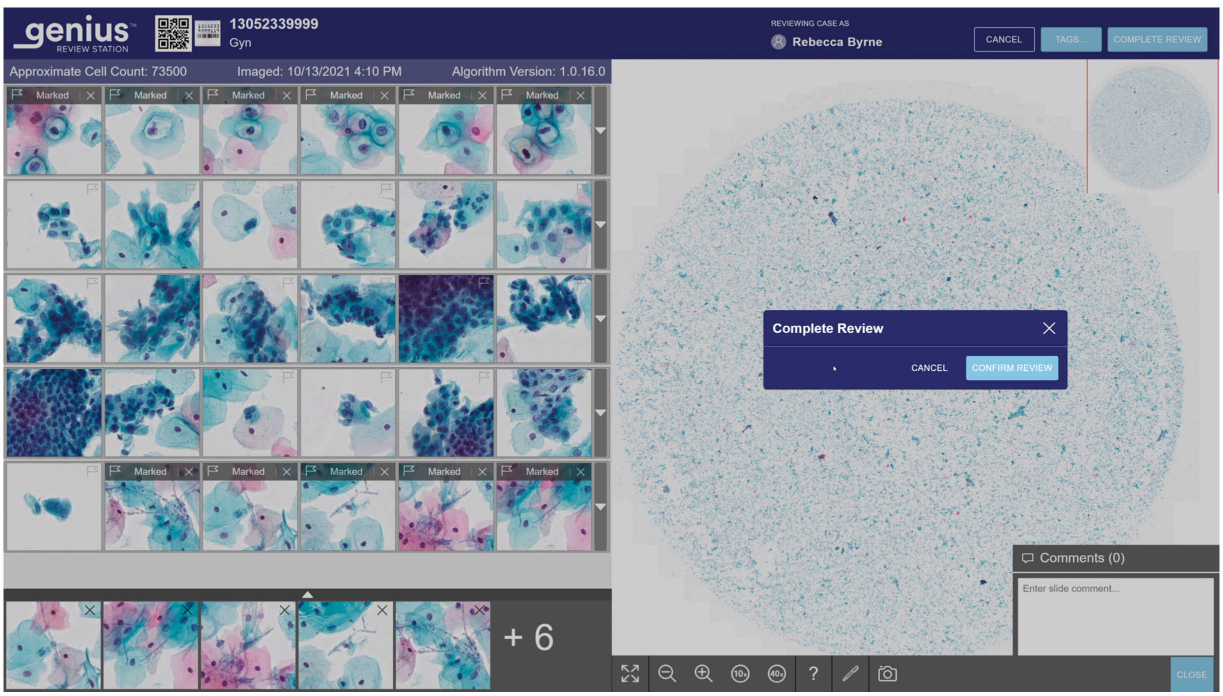


Figure 2-3-13 Complete the review of a case

5. A confirmation message appears to confirm that you want to complete the review.
   - Click **Confirm Review** to confirm. The status for this Accession ID will change to "Complete". The case now appears with the status "Reviewed" in Case Lists, including the "My Reviewed" Case List for the reviewer. Any comments and marks made during the review are saved with the case. Comments cannot be edited.
   - Click **Cancel** to keep the case at its current state.

Table 3.2 Hotkeys and Mouse Clicks

	With the mouse	On the keyboard
In the gallery		
Select the next tile in the gallery	Click on the tile	Left arrow - move left Right arrow - move right Up arrow - move up Down arrow - move down A - move left (Q on AZERTY keyboards) D - move right W - move up (Z on AZERTY keyboards) S - move down
Mark an image on a tile	With the tile selected, click on the flag icon 	With a tile selected, press the space bar
Show optional additional row of tiles	Click on the down-arrow along the right edge of that row	With a tile selected, press enter
Hide optional additional row of tiles	Click on the up-arrow along the right edge of that expanded row	With a tile selected, press enter
In the whole slide image ***Note:*** These hotkeys are also available when a tile in the gallery is selected.		
Zoom in, in small increments	Click zoom in button as many times as desired: 	+ (plus key) - zoom in

	With the mouse	On the keyboard
Zoom out, in small increments	Click the zoom out button as many times as desired: 	- (minus key) - zoom out
Zoom in, in a larger increment	Click and scroll the wheel on the mouse up (clockwise)	+ (plus key) - zoom in
Zoom out, in a larger increment	Click and scroll the wheel on the mouse down (counter-clockwise)	- (minus key) - zoom out
Zoom to 10x magnification	Click the 10x button: 	1 - 10x magnification
Zoom to 20x magnification	Not available	2 - 20x magnification
Zoom to 40x magnification	Click the 40x button: 	4 - 40x magnification
Pan to the left	Click and drag right	Left arrow - move left A - move left (Q on an AZERTY keyboard)
Pan to the right	Click and drag left	Right arrow - move right D - move right
Pan up	Click and drag down	Up arrow - move up W - move up (Z on an AZERTY keyboard)
Pan down	Click and drag up	Down arrow - move down S - move down

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Part 3

Part 3

Part 3.

Reviewing Whole Slide Images

There are three parts to this operator's manual.

- Part 1 describes installation, general use, and care of the Genius™ Review Station.
- Part 2 contains information specific to the review of ThinPrep™ Pap tests with the Genius Cervical AI algorithm.
- Part 3 contains information specific to the review of digital whole slide images.

Your system configuration may not have all of the options described in this manual. Contact your Hologic representative for more information.

Revision History

Revision	Date	Description
AW-32337-001 Rev. 001	7-2025	Initial release of instructions exclusive to the review of digital whole slide images.

Document Number: AW-32337-001 Rev. 001

7-2025

Table of Contents

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1. Introduction

Chapter One

Introduction

SECTION A

OVERVIEW, REVIEW OF WHOLE SLIDE IMAGES

Intended Use/Intended Purpose, Genius Digital Diagnostics System, Genius Digital Imager and Genius Review Station

The Genius Review Station is one component of the Genius Digital Diagnostics System.

The Genius Digital Diagnostics System is a PC-based and automated imaging and review system. The Genius Digital Diagnostics System includes the automated Genius Digital Imager, the Genius Image Management Server (IMS), and the Genius Review Station and is intended for *in vitro* diagnostic use as an aid to the pathologist or cytologist to review and interpret digital images of scanned non-gynecological cytology slides and surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue that would otherwise be appropriate for manual visualization by conventional light microscopy. The system is not intended for frozen section and non-FFPE hematopathology specimens.

It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using this system.

Patient Population

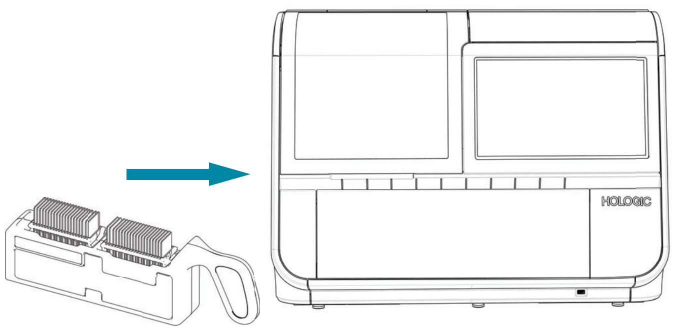
Specimens for use on the Genius Digital Diagnostics System may be acquired from any patient population.

For professional use.

SECTION B

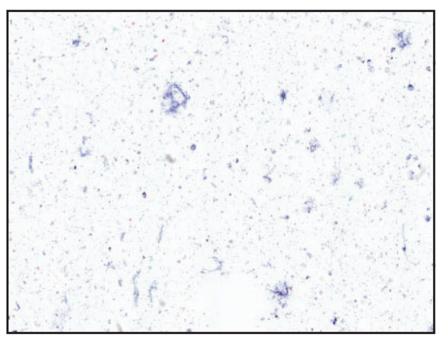
THE GENIUS DIGITAL DIAGNOSTICS SYSTEM PROCESS

Genius Digital Diagnostics System Process, Whole Slide Image



Prepared slides are loaded into a slide carrier, which is loaded into the Digital Imager.

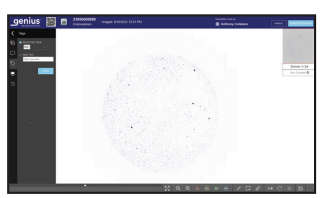
The slide is imaged.



The Digital Imager scans the slide.

Case data and images are stored on the Image Management Server.

Case review by the cytologist or pathologist



During review, the Review Station presents a whole slide image to the reviewer.

Review and annotation of the image is conducted. The case is marked as reviewed.

At completion, case data is updated with any annotated areas as well as information on the review session.

The case is available to subsequent reviewers at the Review Station.

Figure 3-1-1 Genius Digital Diagnostics System Process, Custom Case Types

2. User Interface

Chapter Two

User Interface

SECTION A

OVERVIEW

This chapter provides detailed information on features that are unique for reviewing whole slide images on the Genius Digital Diagnostics System. Additional information on the user interface screens is available in Part 1 of this manual.

This chapter includes:

SECTION B

CUSTOM CASE TYPES

A Case Type is a combination of the settings that are used to image slides on the Digital Imager. Custom Case Types are set up by users at the Review Station. Part 1 of this manual provides an introduction to custom Case Types.

The four parameters that comprise a Case Type are:

Name: This is the name for the Case Type. The name will appear in the carrier selection area of the Genius Digital Imager touch screen, in Case Lists at the Review Station and in Reports run from the Review Station. Use the keyboard at the Review Station to type a name. The name can be up to 20 characters long.

Note: At the Digital Imager, long names will display in smaller type than shorter names.

The name must be unique; two Case Types in a Genius Digital Diagnostics System connected to the same Genius Image Management Server cannot have same name. A new Case Type cannot have the same name as a Case Type that has been inactivated.

Scan Profile: The scan profile is the fixed set of instructions that the Genius Digital Imager uses to scan an area of a slide. The scan profiles for Genius Digital Diagnostics System use volumetric imaging to capture up to 14 layers of the glass slide, and merge focusing to create a focused image.

Status: A custom Case Type can be active or inactive. The Case Type must be active to image slides at the Digital Imager. If a custom Case Type is inactivated after cases were imaged, users at the Review Station can review case information that Case Type. A reviewer can choose to hide or show inactivated cases in the view of the Case List.

Note: In the event that a Case Type is created and never used to image slides, a Case Type can be deleted at the Review Station.

Barcode rules: An optional feature that sets up the Digital Imager to use data from the label on each slide in a slide carrier to automatically determine the Case Type for the slide.

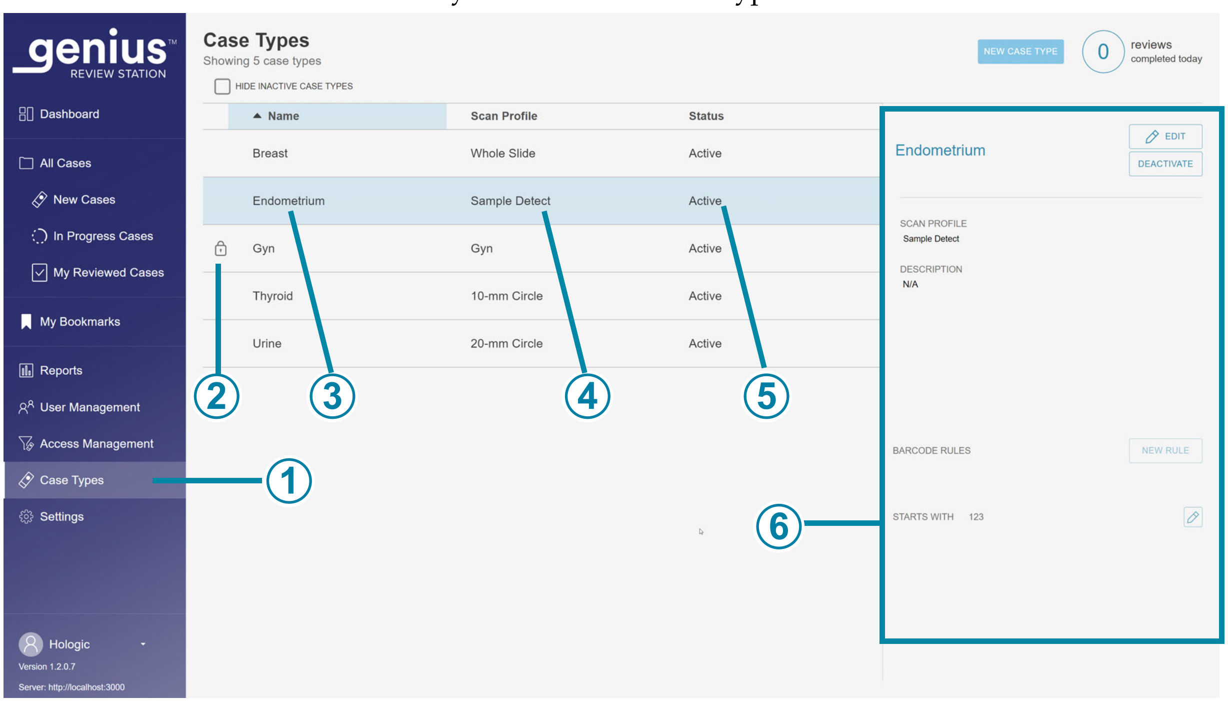
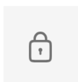


Figure 3-2-1 Case Types, example

Key to Figure 3-2-1	
1	The lighter color in the menu bar indicates that **Case Types** is selected.
2	 The settings for the Gyn case type are locked and cannot be changed.
3	**Name** The name that your laboratory establishes for a case type at the Genius Review Station appears in the carrier selection options at the Genius Digital Imager. The name of the case type also appears in several reports.
4	**Scan Profile** The list of case types shows the scan profile for each case type.
5	**Status** The list of case types shows the status for each case type. A case type must be in the active status in order to image slides.
6	This panel shows more information about existing case types. Use this panel to create a new case type, edit an existing case type, or change the status of an existing case type.

Create a Custom Case Type

A user with the administrator role or the lab tech role can create a new Case Type. After a new Case Type is created, every Digital Imager connected to the same Genius Image Management Server network can use that Case Type. To create a new Case Type:

1. Select Case Types in the menu bar. The Case Types screen appears.
2. Type the name for the new Case Type in the **Case Type Name** field.
3. Set the scan profile for this Case Type.
   Select a scan profile from the available options using the drop-down menu. The options are:
   - 20-mm circle
   - 10-mm circle
   - Sample Detect
   - Whole Slide

4. Type a description for this case type. (Optional). The description is visible to all administrators and lab techs in the Review Station network. The default description is “N/A”.
5. Set barcode rules for the accession ID for this case type. (Optional) Refer to “Barcode Rules” on page 2.7.
6. Click **Save** to save the new Case Type, or click **Cancel** to discard the changes.

The new Case Type appears in the list of Case Types at the Review Station and in the carrier selection menu at the Digital Imager.

An administrator or a lab tech can sort the list of Case Types by the name of the case type, by the scan profile, and by the status.

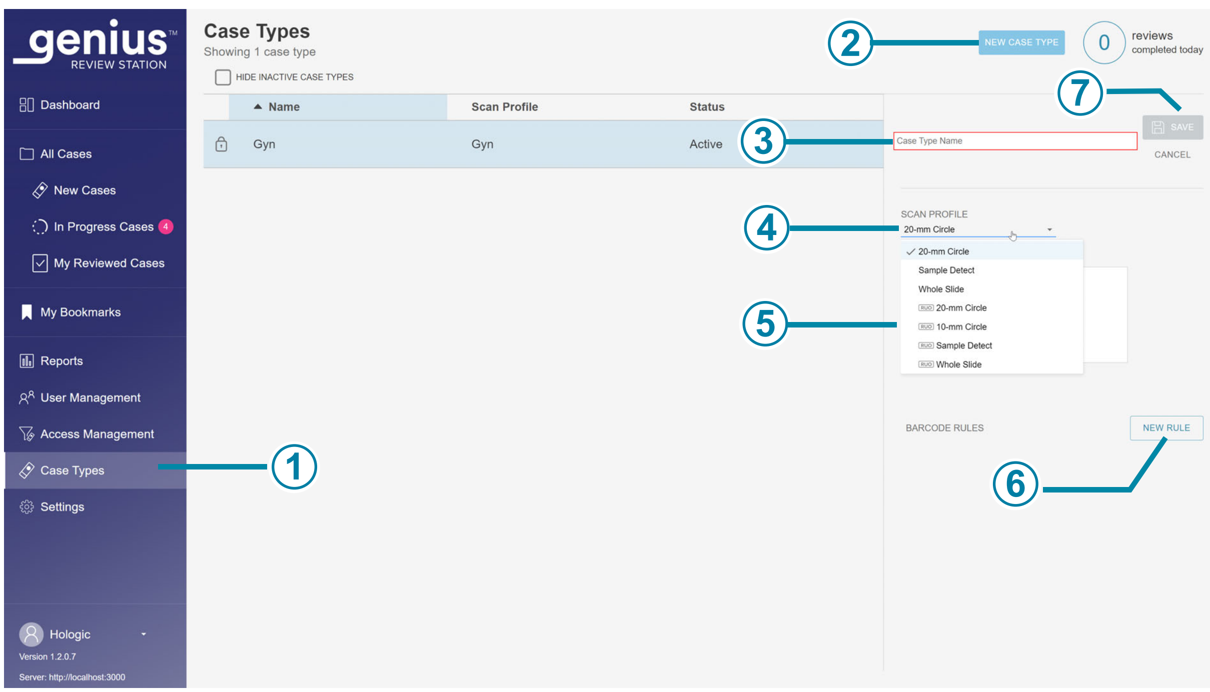


Figure 3-2-2 Create a new case type

Key to Figure 3-2-2	
1	The lighter color in the menu bar indicates that **Settings** is selected.

Key to Figure 3-2-2	
2	The **New Case Type** button is available to administrators and lab techs.
3	**Case Type Name** To create a new case type, type a name.
4	**Scan Profile** To set the scan profile for the new case type, select from the available options.
5	**Description** (optional), below the Scan Profile selection.
6	**Barcode rules** (optional, for using Auto carrier selection at the Digital Imager)
7	Click **Save** to add the new Case Type to the list of Active Case Types, or click **Cancel** to leave the Case Types as they are.

Change a Custom Case Type

Once a custom Case Type is set up, it may never need to be modified. However, the Review Station allows an administrator or a lab tech can change the status of a Case Type and to change other attributes for a Case Type.

Deactivate a Case Type

If a particular Case Type is no longer needed, the Case Type can be made inactive.

All of the data for cases imaged before the Case Type was deactivated are available at the Review Station and in reports. An inactive Case Type is not shown in the menu for carrier selection at the Digital Imager.

Note: There is an option to hide inactive Case Types in the list of Case Types. All Case Types, active and inactive, are available to view in case lists, reports and widgets. Use the filters in case lists, reports, and widgets to show or hide cases imaged with inactive Case Types.

A new case type with a different name can be created with the same criteria as an inactive Case Type.

Edit a Case Type

It is possible to change the name, scan profile, description and barcode rules for a custom Case Type. If slides have already been imaged with a custom Case Type, it is recommended that the names and scan profiles are not changed. Consider deactivating a Case Type rather than changing its name or scan profile.

Slides imaged after a Case Type is changed will use the new criteria.

Slides imaged before the name of a Case Type changed appear in the Case List and in Reports with the new Case Type name.

Slides imaged before the scan profile for the Case Type changed remain in the tally in the Scan Profile Usage History Report, but there is no other record of the scan profile that was in effect at the time the slide was scanned.

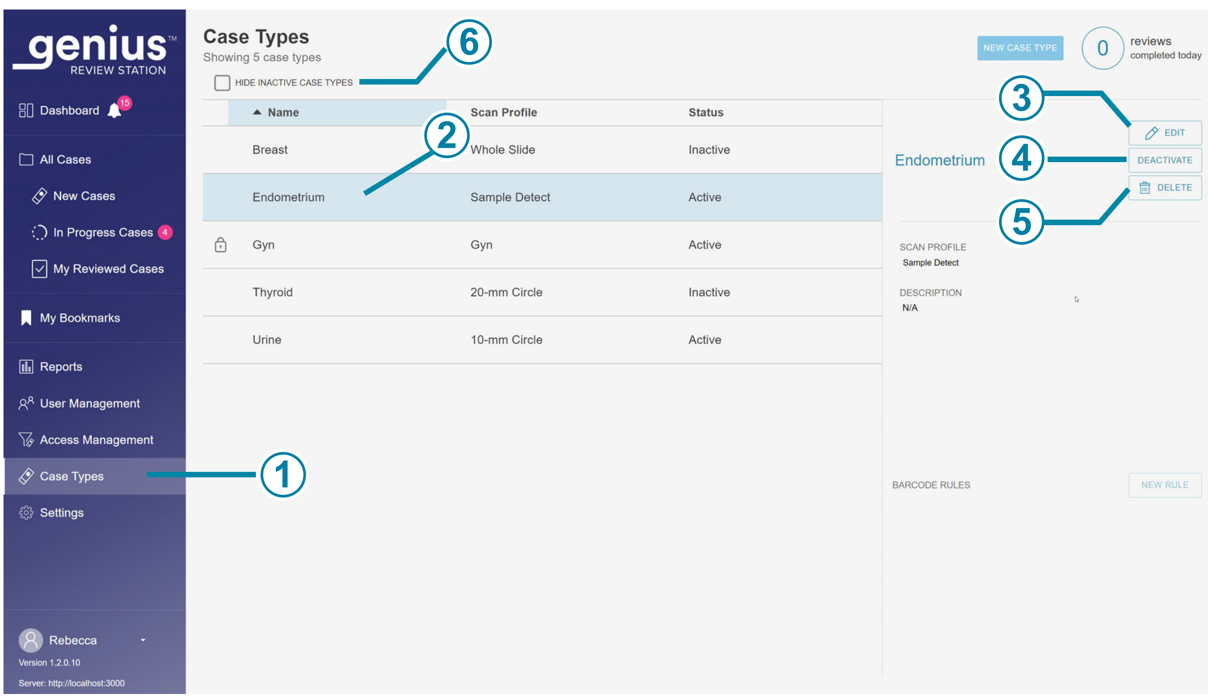


Figure 3-2-3 Change criteria for a case type

Key to Figure 3-2-3	
1	The lighter color in the menu bar indicates that **Case Types** is selected.

Key to Figure 3-2-3	
②	Select a Case Type from the list
③	**Edit** Use the edit button to change the name, scan profile or the description for the Case Type, or to add barcode rules to the Case type. The **Edit** button changes to a **Save** button. To save the changes, press the **Save** button.
④	**Activate/Deactivate** Use this button to change the status of the selected Case Type.
⑤	**Delete** If no slides were imaged using a Case Type, the **Delete** button is displayed. Use this button to delete a Case Type. (For example, if a duplicate Case Type was created by mistake.) On the confirmation screen, click **Continue** to continue with the deletion, or click **Cancel** to keep the Case Type.
⑥	**Hide Inactive Case Types** The reviewer can specify whether the list of Case Types should show or hide inactive case types. Data for imaged cases is stored in the Genius Digital Diagnostics System database, regardless of whether the Case Type is currently active. A Case Type must be active to use that Case Type to image slides.

Barcode Rules

With custom Case Types, a lab has the option to set up the Genius Digital Diagnostics System so that the Digital Imager identifies the Case Type based on characters in the Accession ID for the slide. Setting up barcode rules for a Case Type at the Genius Review Station allows operators at Genius Digital Imagers, connected to the same Genius Image Management Server, to use an automatic setting (Auto) for carrier selection. The Genius Digital Imager Operator’s Manual has more information about using “Auto” slide carriers on the Digital Imager.

Setting barcode rules at the Genius Review Station and using the Auto carrier selection at the Genius Digital Imager are optional. The Auto carrier selection cannot be used before barcode rules are set.

Note: The “Auto” carrier type is not for use with Gyn samples. To image ThinPrep Pap tests on the Genius Digital Diagnostics System, the carrier must be selected as “Gyn” and all of the slides in the carrier must be ThinPrep Pap tests on ThinPrep Imaging System microscope slides.

When barcode rules for Case Types are set and the Auto carrier is used, the Digital Imager reads the barcode on a slide label and compares the accession ID to the barcode rules. If the characters on the label match characters in the barcode rule for a cutom Case Type, then that custom Case Type will be used to scan the slide.

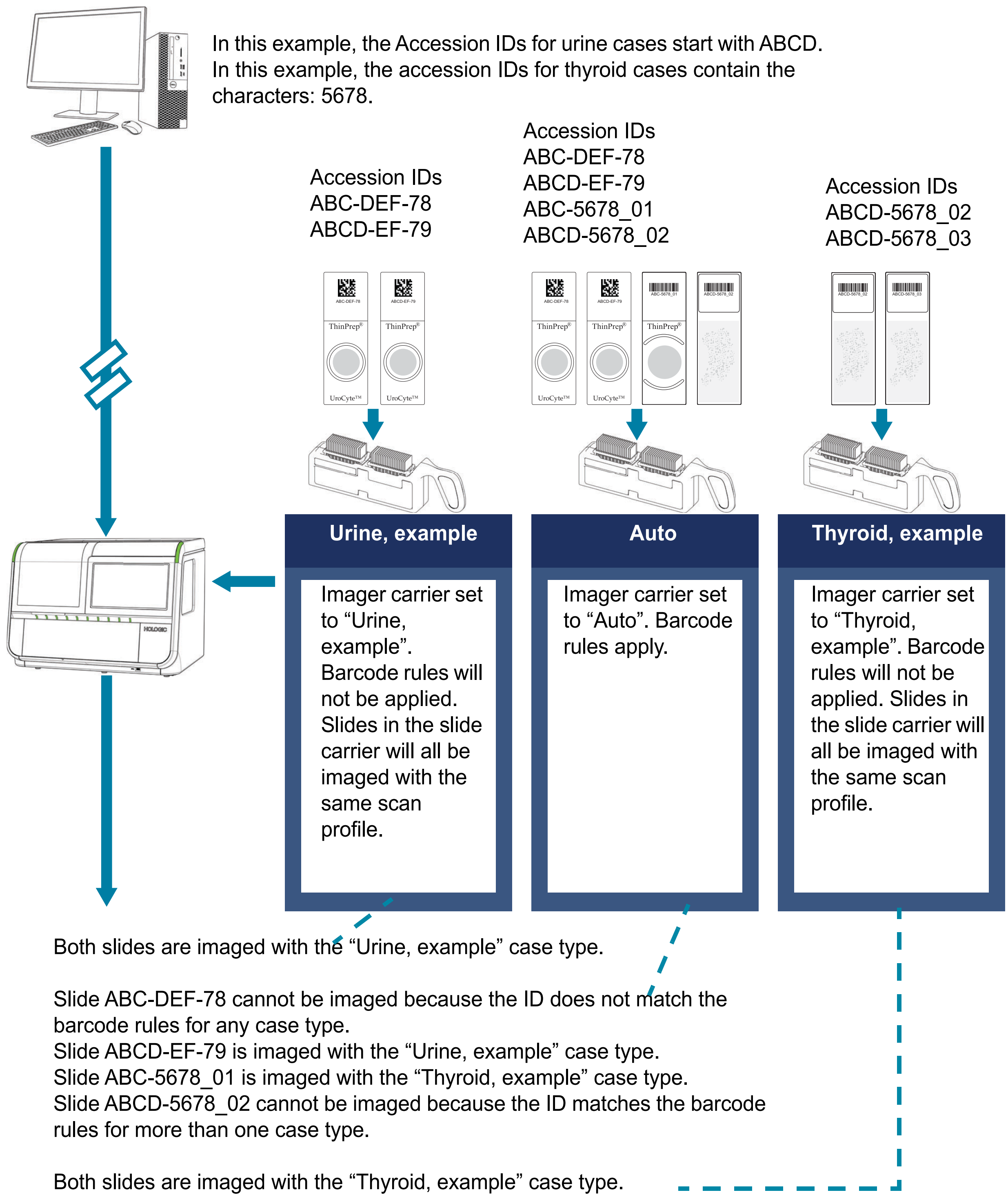


Figure 3-2-4 Barcode Rules Set at the Review Station for Auto Carrier at Digital Imager, example

A user with the administrator role or the lab tech role can add or change a barcode rule for a custom Case Type. The barcode rule comes into effect immediately when the administrator or lab tech saves the Case Type at the Review Station and the **Start** button or the **Refresh** button is pressed at each Digital Imager connected to the same Genius Image Management Server.

With the "Auto" carrier type, the Digital Imager software searches every accession ID for a match with the barcode rules. If the case type cannot always be determined from the barcode rule, the Digital Imager cannot determine which case type to use.

Note: Barcode rules can be added or changed after slides have been imaged. The new or changed barcode rules do not apply to case data already in the Genius Digital Diagnostics System. The new or changed rules only apply to slides imaged after the rule is added or changed.

If the "Auto" carrier type is used, but the barcode rules for a custom Case Type have not been set up or the barcode rules are ambiguous, then the Digital Imager cannot determine which custom case type to use. If the Digital Imager cannot determine what Case Type to use, a slide event will be reported and the slide will not be imaged.

To add or change a barcode rule:

1. In the details pane (right side) of the **Case Types** screen, in the **Barcode Rules** area, click on the **New Rule** button.

   Note: If a Case Type is not already selected, first navigate to the Case Types screen, select a Case Type, and then select **Edit**.

2. On the **Add Rule** window, set the criteria that are unique for slide IDs for this Case Type. A barcode rule controls how slides are imaged based on the accession ID for the case. The barcode rule feature searches for accession IDs that start with, end with, or contain certain characters.

   A. Select a **Search Type** from the available options in the drop-down menu:

   - Starts with: all accession IDs that start with the character(s) typed in the "search value" field will be imaged with the selected custom Case Type. The characters and the number of characters are determined by your laboratory.
   - Contains: all accession IDs with the character(s) typed in the "search value" field will be imaged with the selected custom Case Type. The characters and the number of characters are determined by your laboratory.
   - Ends with: all accession IDs that end with the character(s) typed in the "search value" field will be imaged with the selected custom Case Type. The characters and the number of characters are determined by your laboratory.

   Note: The characters used as Case Type criteria must be consecutive in the accession ID. For example, if a Case Type barcode rule is set up to identify slides labels that contain "ABCD", then a case with an accession ID of "123ABCD456" will use that Case Type, and a case with a an accession ID of "123A-BCD456" will not use that Case Type.

   Note: Uppercase letters and lowercase letters are considered the same characters in barcode rules. For example, one Case Type cannot use "LAB" as a barcode rule if another Case Type uses "lab" as a barcode rule.

B. Type in the search value. The search value is the group of characters that are unique for slide IDs of this Case Type.

3. Click **Save** to add the barcode rule to the selected Case Type, or click **Cancel** to discard the changes.
4. To add more barcode rules to the same Case Type, click on the **New Rule** button and begin the steps again.

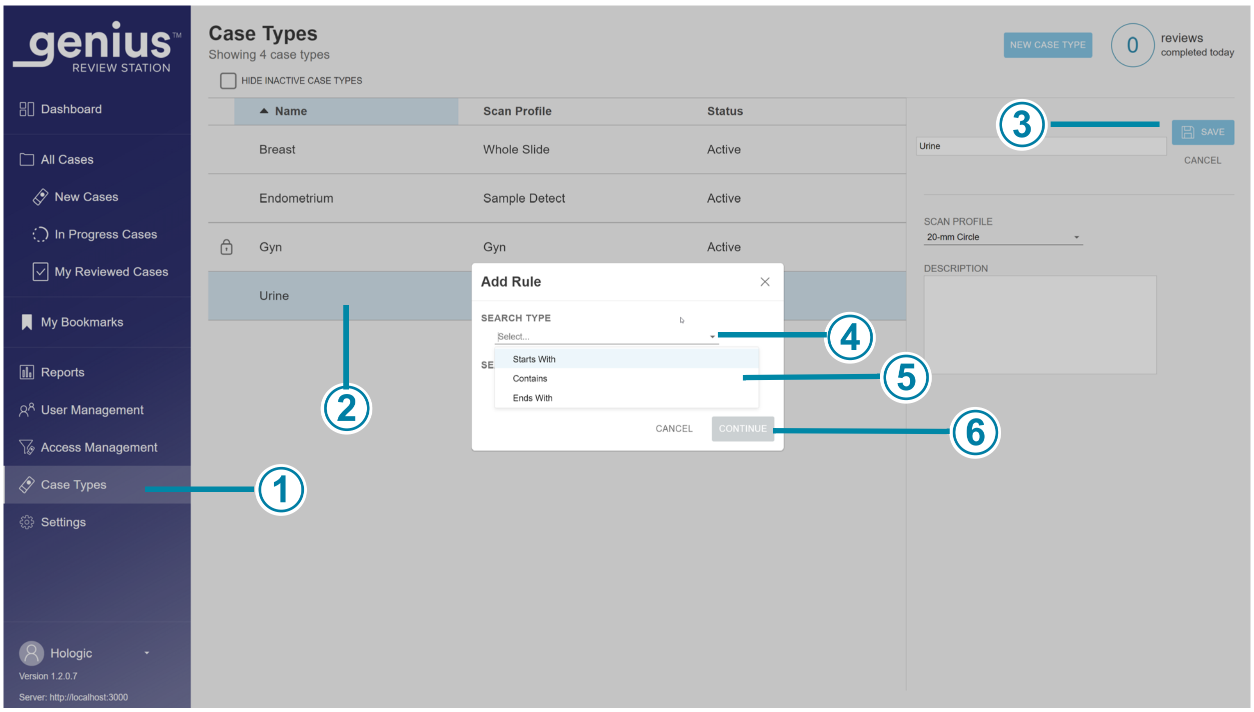


Figure 3-2-5 Add a barcode rule to a custom Case Type, example

Key to Figure 3-2-5	
1	The lighter color in the menu bar indicates that **Case Types** is selected.
2	**Case Type** Click on an existing Case Type to select it.

Key to Figure 3-2-5	
③	**Edit/Save** Click on the **Edit** button to start making changes. The **Edit** button changes to a **Save** button.
④	**Search Type** Click on the arrow to select from the drop-down menu. Then, click to select one of the options.
⑤	Type in the search value. The search value is the group of characters that are unique for slide IDs of this Case Type.
⑥	Click **Save** to add the barcode rule to the Case Type, or click **Cancel** to leave the barcode rules as they are.

Note: To use the "Auto" carrier type at the Digital Imager, barcode rules must be set up for the custom Case Types in your lab whose slides will go in the "Auto" carrier. With the "Auto" carrier type, the Digital Imager software searches every accession ID for a match with the barcode rules. If there is no match, which can be caused by no rule being set up, the Digital Imager cannot automatically determine which case type to use.

Note: The values used in Barcode rules must be unique in order to use the "Auto" carrier type at the Digital Imager. This applies to barcode rules within the same Case Type and barcode rules for separate Case Types. With the "Auto" carrier type, the Digital Imager software searches every accession ID for a match with the barcode rules.
For example, if one case type has a barcode rule of "starts with 123" and a different case type has a barcode rule of "contains 123", the Digital Imager cannot automatically determine the case type for a slide whose accession ID includes the characters "123".

Note: Barcode rules cannot overlap in order to use the "Auto" carrier type at the Digital Imager. This applies to barcode rules within the same Case Type and barcode rules for separate Case Types.
For example, if one case type has a barcode rule of "starts with 1123" and a different case type has a barcode rule of "contains 123", the Digital Imager cannot automatically determine the case type for a slide whose accession ID includes the characters "123".

Note: The Digital Imager software has an option for labs to only use a portion of the ID printed on the slide label as the Accession ID in the Genius Digital Diagnostics System. The barcode rules set at the Review Station are used by the Digital Imager after the Digital Imager uses Accession ID settings. Consider the Accession ID settings set at the Digital Imager when setting barcode rules at the Review Station.
For example, if a slide is labeled as 12345678 and the Digital Imager Accession ID is set to start at the fourth character, the Accession ID read by the Digital Imager will be 45678. In a lab

that uses “Auto” carriers, the barcode rules for custom Case Types should be based on the Accession ID of 45678 instead of the printed slide label ID of 12345678, in this example.

Note: The Digital Imager software has an option for labs to add the date and time to the end of Accession IDs. The barcode rules set at the Review Station are used by the Digital Imager before the Digital Imager software adds the date and time to the Accession ID. There is no need to consider the date and time ending, if used, when setting Barcode rules at the Review Station.

Note: “Barcode” rules also apply to slides that use an OCR format for the accession ID.

3. Operation

Chapter Three

Operation

SECTION A

OVERVIEW, CUSTOM CASE TYPES

The Genius Review Station is used to review digital images created in the Genius Digital Diagnostics System. The images are reviewed by a cytologist (CT) or pathologist. The same images may be reviewed by additional cytologists and pathologists. During review, the reviewer can annotate and comment on the case, and the annotations and comments are available to anyone reviewing the same case later.

For cases imaged with a custom case type, the Review Station presents a digital whole slide image. A reviewer can adjust the zoom of the whole slide image. A reviewer has the option to download a jpeg image (screenshot) of the image to the Review Station computer.

The Review Station can transmit event information related to cases. The event data can integrate with a Laboratory Information System (LIS). Additional integration activities by the laboratory or the LIS provider are required.

The instructions in Part 1 of this manual must also be followed for proper use of the Review Station.

This chapter includes:

Case Review

The Review Station organizes case information by Accession ID. Case data for the cases on the Genius Image Management Server are available from any Review Station in the network, and access can be restricted using access control filters. A reviewer opens a case and only one reviewer at a time can annotate images, mark areas on images, add comments on images, tag the case, and complete a review of a case. Secondary reviewer(s) who open the same case are able to navigate the image, but are not permitted to edit the image while the image is being viewed by the primary reviewer.

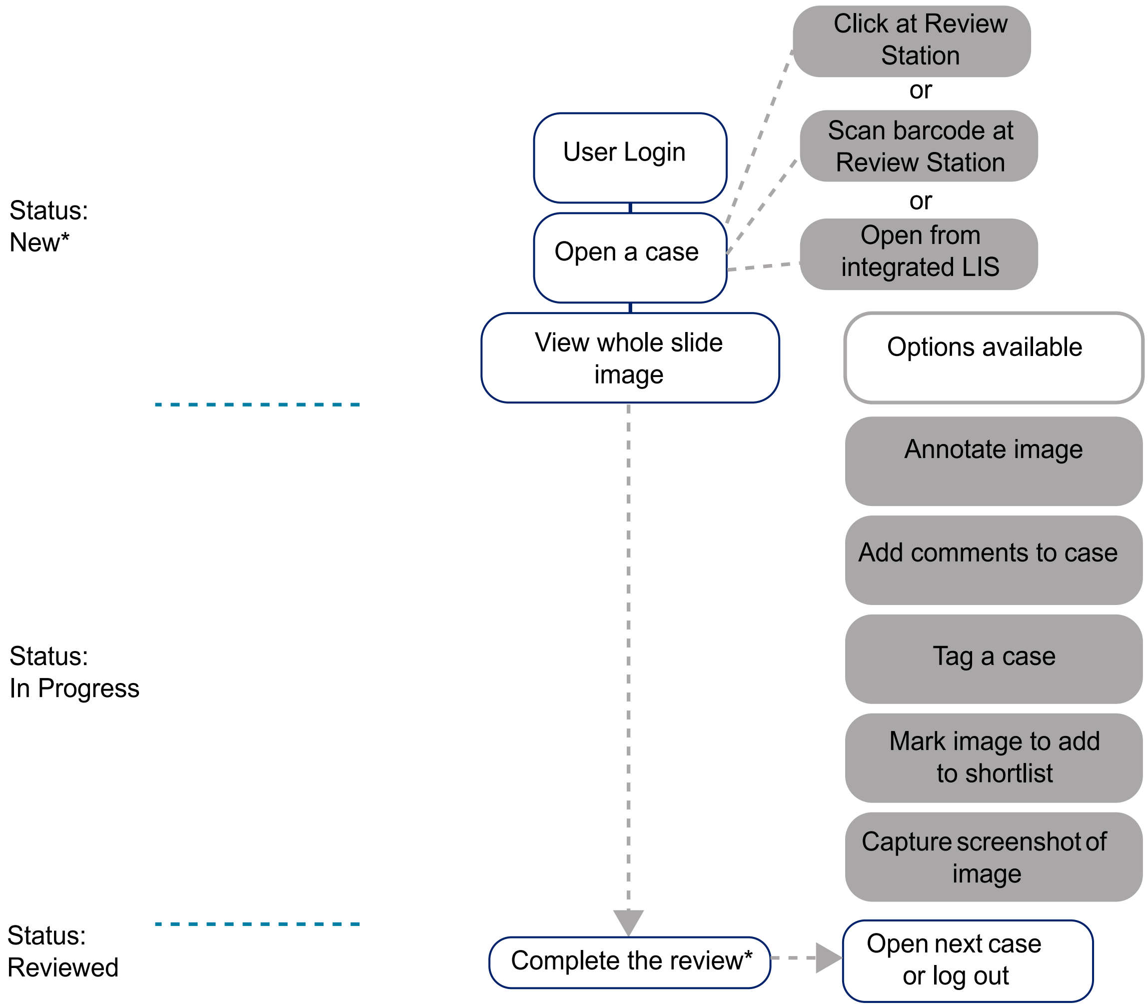
Once a reviewer changes the status of a case to "In Progress" and again when the reviewer changes the status of a case to complete the review, the case data record is updated and stored on the Image Management Server, available to other reviewers to review in the Review Station network.

If another reviewer opens a case whose review has been completed, the annotations, comments and marks made by previous reviewer(s) are displayed on the image. The subsequent reviewer can add annotations, comments and marks, and save their review to the data record stored on the Image Management Server. A subsequent reviewer cannot delete annotations, comments or marks saved by an earlier reviewer. The annotations, comments and marks are available the next time the case is opened by a reviewer in the Review Station network. The name of the reviewer(s) and the date(s) of review are stored data in the case.

Case Data Record

The case data record is the accumulation of all imaging and review activity the case encounters. The reports are generated from data that is in the case data record. A case data record is generated when a valid slide ID is accepted into the Image Management Server's database. Items that are associated with the case data record include:

- Date/time stamp when slide imaging ended
- Serial number of the Digital Imager that imaged the slide
- High resolution image of the specimen
- A macro image of the entire slide, including the slide label area
- Date/time stamp when slide review ended (including subsequent reviews)
- Name of the reviewer for each review of the slide (including subsequent reviews)
- Electronic annotations, comments and marks



*A reviewer can also open a case that is in the "Reviewed" status and review it again. And, a reviewer can opt to save a case to continuing reviewing later.

Figure 3-3-1 Typical Case Review Processes, Custom Case Types

SECTION B

MATERIALS REQUIRED PRIOR TO OPERATION

- Slide data on the Genius Image Management Server from imaged glass microscope slides.
- Genius Review Station

Important Operational Notes

- Case images are digitally annotated, marked, and/or saved as screenshots by the CT or pathologist. Follow your laboratory's guidelines for adding annotations and marking objects of interest in case images. Follow all applicable guidelines and regulations for handling downloaded images.

SECTION C REVIEW A CASE

For cases which have been scanned using a scan profile of a 10-mm circle, 20-mm circle and whole slide, one whole slide image of the slide is presented to the reviewer. A reviewer can add annotations, comments and marks.

Open a Case

There are several ways to open a case on the Review Station.

From a Case List:

- Click on an accession ID to open the case. Use cases lists in the menu bar (All Cases, New Cases, In Progress Cases or any custom filters) and filters on the displayed columns to show particular kinds of cases in the Case List.
- Or, type in the accession ID using the keyboard or, with the cursor in the “Search by Accession ID” field, scan the accession ID from your laboratory records with the optional barcode scanner. Then, press Enter on the keyboard or click on the search icon (magnifying glass) to search.

From the Dashboard, in the **Open a Case** section, type in the accession ID using the keyboard or, with the cursor in the Accession ID field, scan the accession ID from your laboratory records with the optional barcode scanner. Select **Open Case**, and the review screen displays. See Figure 3-3-3 on page 3.9.

Note: If your facility uses the optional settings on the Genius Digital Imager to exclude characters in the slide label or add a time stamp of the imaging time, consider that the accession ID in the Genius Digital Diagnostics System for the cases specified by your lab may not be an exact match with the accession ID on the slide label or your facility’s information systems. Maintain the chain of custody for all samples to ensure the integrity and reliability of test results. Ensure compliance with all applicable quality control procedures, regulations, and policies.

And, in product configurations where your laboratory has integrated an interface between the Genius Events Bridge Messaging and your laboratory’s LIS, follow your laboratory’s process for using the Accession ID in the LIS to open a case at the Review Station.

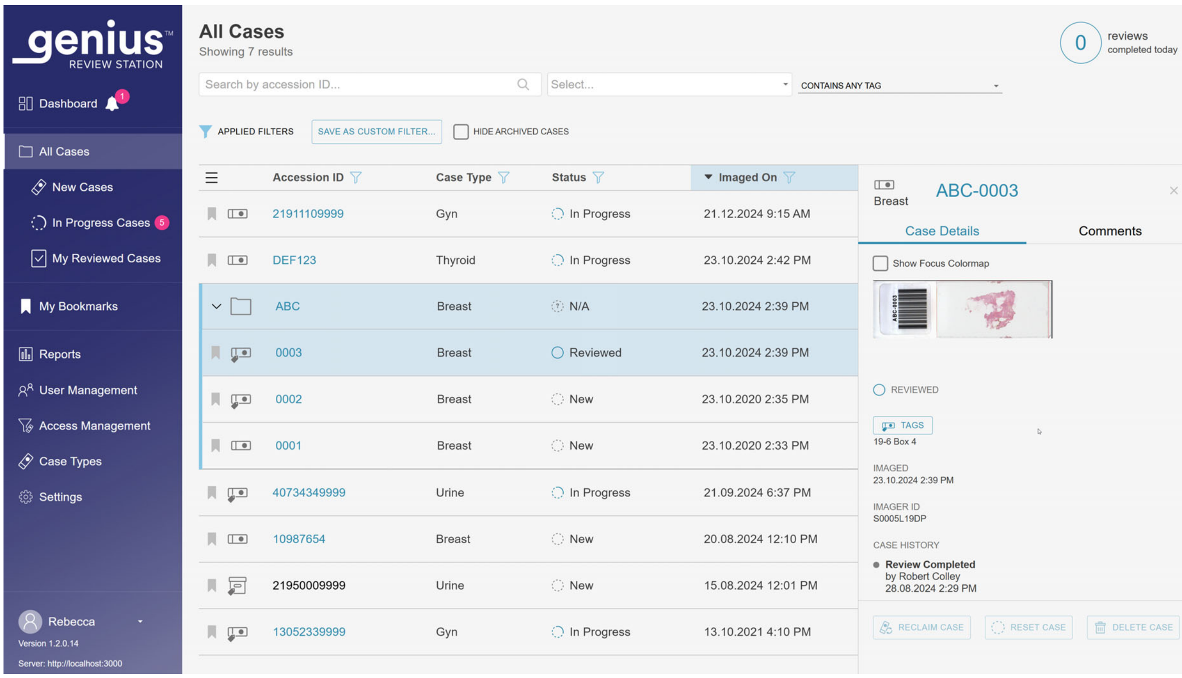


Figure 3-3-2 Case List - Click Accession ID to Open Case

Note: For cases comprised of multiple slides grouped together with a primary ID, the accession ID in the Case List represents the group of slides. Click the arrow to the left of the primary ID or click anywhere in the blue shaded line to see the accession ID for each of the slides in that case. If the Digital Imager was not configured to group several slides from the same case together, then each slide for a case is listed as a separate case.

Only one reviewer can review a case at a time. If a reviewer attempts to open a case that is already open, the reviewer can choose a read-only mode to view the images. In read-only mode, the reviewer sees the images, the current annotations, the existing comments, and the current marks, but cannot complete a review of that case, cannot annotate, cannot add comments, and cannot add comments. In read-only mode, above the reviewer's name the Review Station says "viewing as" rather than "reviewing as". The **Complete Review** button is unavailable, and a **Back** button returns the reviewer to the Case List screen rather than the **Cancel** button.

The data displayed in the Case List is refreshed once per minute by the Genius Digital Diagnostics System. The entries and their position in the Case List may change as other reviewers review cases and as additional slides are imaged. If two users attempt to review the same case, when the first reviewer changes the status or saves any annotations, marks or comments, the second reviewer is notified that the case is in-progress by the other reviewer.

The review screen for Gyn cases with Genius Cervical AI differs from the review screen for custom Case Types. Refer to Part 2 of this manual for instructions for reviewing Gyn cases with Genius Cervical AI.

The Whole Slide Image

For 10-mm circle, 20-mm circle and whole slide cases, the whole slide image is centered on the display.

Note: The magnification values displayed on the Review Station are intended as digital equivalents of the magnification when glass slides are viewed through a microscope objective.

The heading of the review screen shows:

- An image of the slide including its label
- The Accession ID
- A QR code of the Accession ID
- The Case Type
- Your name "Reviewing Case As"
- **Cancel** button
- **Complete Review** button

Due to environmental factors such as fading, drying, lighting, and system variability, re-imaging a slide may not produce an identical image. Refer to the Instructions for Use for the performance characteristics of the Genius Digital Diagnostics System. Maintain the chain of custody for all samples to ensure the integrity and reliability of test results. Ensure compliance with all applicable quality control procedures, regulations, and policies.

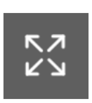
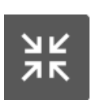
Navigate the whole slide image with a mouse

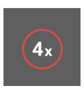
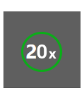
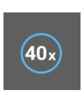
There are different options for navigating the whole slide image with the mouse and keyboard. And, there are different options for annotating and marking images with the mouse and keyboard. A reviewer can switch between the mouse and keyboard at all times.

When the case opens, the image in the whole slide image is shown at <2x. The reviewer can change the magnification at which the whole slide image is displayed.

Under the whole slide image, the Review Station offers a set of tools for changing the view and annotating the image. To the left of the whole slide image, the Review Station offers a panel of Case Control options.

Figure 3-3-3 initial view of the review screen, example

Key to Figure 3-3-3	
①	Case Control Panel
②	 Expand to full screen Select the icon to change the screen display so that the whole slide image fills the entire display area. To return to the view with the Case Control Panel and toolbar, click the contract icon  .

Key to Figure 3-3-3	
3	 Zoom out Click the mouse as many times as desired on the - button to zoom out.
4	 Zoom in Click the mouse as many times as desired on the + button to zoom in. The maximum zoom is 40x.
5	 Zoom to 4x Click on the 4x button and the magnification zooms to the 4x view.
6	 Zoom to 10x Click on the 10x button and the magnification zooms to the 10x view.
7	 Zoom to 20x Click on the 20x button and the magnification zooms to the 20x view.
8	 Zoom to 40x Click on the 40x button and the magnification zooms to the 40x view.
9	Inset macroscopic view of the whole slide image
10	Image Sync When a whole slide image displays on the Review Station monitor, the Review Station software checks that all of the image data is loaded for the best image focus. The message “Data syncing...” changes to “Sync complete” when the image loading is finished.

Zoom and move the view in the whole slide image

In addition to the tools in the toolbar, the mouse allows the reviewer to move the view through the whole slide image.

To zoom in with the mouse, click anywhere in the whole slide image and roll the mouse scroll wheel up (clockwise).

To zoom out with the mouse, click anywhere in the whole slide image and roll the mouse scroll wheel down (counter-clockwise).

To move the view of the whole slide image up, down, left, or right, click anywhere in the whole slide image and drag the mouse.

To move the view in the whole slide image, click in the inset macro image of the whole slide image in the upper right. The view in the whole slide image moves to the area clicked in the macro image.

Navigate the whole slide image with the keyboard

To zoom in with the keyboard, first click the mouse anywhere in the whole slide image and then press the + key (plus key) as many times as desired.

To zoom out with the keyboard, first click the mouse anywhere in the whole slide image and then press the - key (minus key) as many times as desired.

To zoom to the 4x magnification, press the ‘ key on a QWERTY keyboard (to the left of the 1 key) or the ú key on an AZERTY keyboard.

To zoom to the 10x magnification, press the 1 key.

To zoom to the 20x magnification, press the 2 key.

To zoom to the 40x magnification, press the 4 key.

To move the view of the whole slide image up, down, left or right, first click the mouse anywhere in the whole slide image and then press the arrow keys as many times as desired. The A, W, S, D keys on the keyboard also navigate left, up, down, and right. On a keyboard with the AZERTY layout, use the arrow keys and the Q, D, Z, S keys on the keyboard.

Change the View

The reviewer can adjust some attributes of how the whole slide image is displayed. Except for the Thumbnail Tracker, these changes are only in effect for the duration of the review and are not saved. If the case is opened for review by another reviewer or a subsequent reviewer, the case is displayed at the default setting.

Overlay options

In the Case Control Panel on the left of the review screen, the **Layers** panel gives a reviewer the option to show or hide information on the review screen.

- A reviewer can choose to show or hide any annotations made by this reviewer or by a previous reviewer. When a reviewer opens a case, the annotation overlay is visible by default.
- A reviewer can choose to show or hide the **Focus Colormap** for the slide. This is the same Focus Colormap displayed in the Case Details section of the Case List screen for slides scanned with a custom case type. When a reviewer opens a case, the default is to not show the Focus Colormap overlay.
- A reviewer can choose to show or hide the **Thumbnail Tracker** in the inset macroscopic image of the slide. When the whole slide image is viewed at 4x zoom or more, the Thumbnail Tracker identifies, in the inset image, the area of the whole slide image shown in the main window of the review screen. The Thumbnail Tracker is visible by default. If a reviewer chooses to turn off the Thumbnail Tracker, the Thumbnail Tracker will not show for any cases that this reviewer opens. A reviewer can change the setting at any time.

Other tools

The toolbar under the whole slide image has tools that give the reviewer the option to flip or rotate the view of whole slide image, to adjust the brightness during the case review, and to capture a snapshot of the image and save the snapshot to the Review Station computer.

- **Flip** - The whole slide image displays on the review screen in the orientation that has the slide label to the left of the glass microscope slide. During case review, the reviewer can chose to flip the image on its y-axis, showing the image with the slide label on the right.
- **Rotate** - A reviewer can rotate the view of the whole slide image.

  To rotate the view 90 degrees, 180 degrees, 270 degrees, or 360 degrees from the current view, click the arrow that curves clock-wise or the arrow that curves counter-clockwise. When the Rotate tool is open, pressing the **Enter** key on the keyboard also rotates the view 90 degrees clockwise from the current view.

  To rotate the view at a custom angle, anywhere between 0 and 360 degrees, in the **Rotate** tool, click in the blue arrow and drag the mouse to an angle.

  A reviewer can rotate the view clockwise or counter-clockwise.

  To return to the orientation that the case had when the slide was imaged, click the reset button.

  Note: If a reviewer rotates a whole slide image and then annotates an image, the annotations are at the rotated angle. When a subsequent reviewer opens the case, the whole slide image will be at the original orientation, and the annotations will be rotated.

- **Image Adjustment** - There are three adjustments that a reviewer can make from the **Image Adjustment** tool. The case opens with the Brightness, Gamma and Contrast values set to 0 (zero). Use the mouse to click the desired level, or, with the tool open, use the up or down arrows on the keyboard to change the level. The -5 to +5 ranges are scales that change each level as a percentage, from -50% to +50% of the original setting.

Gamma - A reviewer can click to select from a range of -5 to +5 to adjust the gamma brightness, the mid-tones between light and dark, to adjust the appearance of color in the whole slide image.

Brightness - A reviewer can click to select from a range of -5 to +5 to adjust the brightness to change the overall light in the whole slide image.

Contrast - A reviewer can click to select from a range of -5 to +5 to adjust the difference in luminosity between points in the whole slide image.

- **Snapshot** - (Capture the screen image)

  In instances where it may be useful to save an interesting or important portion of a whole slide image, the Snapshot tool allows a reviewer to download a jpeg image of the whole slide image window. Follow your lab's policy for downloading screen captures of a whole slide image.

A. To capture an image of the whole slide image, click on the snapshot tool  .

The Review Station software creates a jpeg file of the review screen. The resolution of the screenshot is 1920 x 1997, equivalent to 96 ppi.

B. A dialog box for the file name of the snapshot opens. The default name for the snapshot is the accession ID for the slide. To change the file name, type in the file name field. If more than one snapshot is taken of the same case, a sequential number is added in parentheses to the end of the file name.

C. To save the jpeg file to the "Downloads" folder of the Review Station computer, click **Continue**, or click **Cancel** to discard the snapshot.

Note: If the case has annotations on the whole slide image, the shapes and lines will be part of the jpeg. Annotation comments, measurements and annotation names are not part of the jpeg.

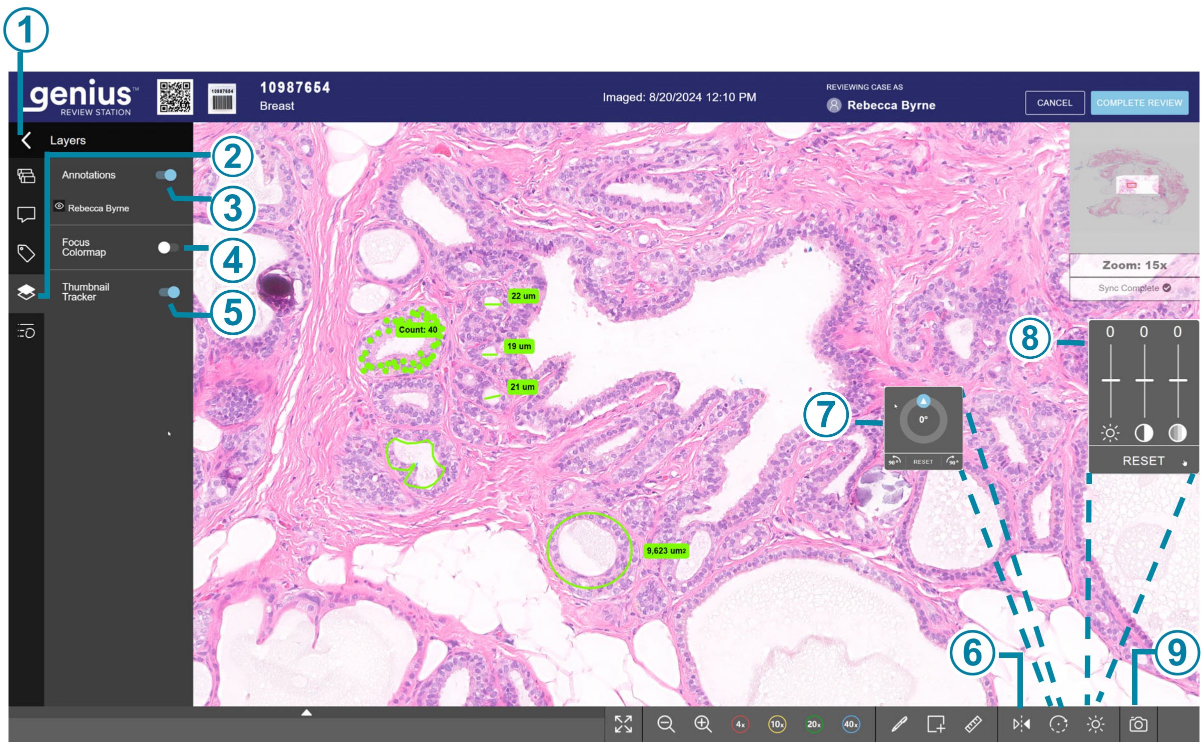
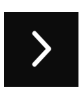
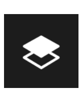
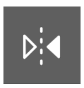


Figure 3-3-4 Session view tools for the whole slide image, example

Key to Figure 3-3-4	
1	 Use the arrow to show or hide the Case Control Panel. From the review screen, a reviewer can also show or hide the Case Control Panel by pressing the **Enter** key on the keyboard.
2	 Layers Click the Layers button to see the options for overlaying information on the image.
3	Display the Annotations. Refer to "Overlay options" on page 3.11.

Key to Figure 3-3-4	
④	Focus Colormap. Refer to “Overlay options” on page 3.11.
⑤	Thumbnail Tracker. Refer to “Overlay options” on page 3.11.
⑥	 Flip the view
⑦	 Rotate the view
⑧	 Image adjustments
⑨	 Snaphot tool

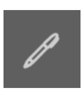
Annotations, Comments, Marks and Tags

The reviewer can add annotations to the whole slide image, add comments to the case review record, mark the image to add a tile in the shortlist, and the reviewer can add a tag to the case.

The annotations, marks, and comments are stored with the case review record and are visible to subsequent reviewers.

Figure 3-3-5 Annotation tools for the whole slide image, example

Key to Figure 3-3-5	
1	Use the arrow to show or hide the Case Control Panel. From the review screen, a reviewer can also show or hide the Case Control Panel by pressing the **Enter** key on the keyboard.
2	**Comments** Click the comments button to read existing comments or to add new comments to the case. The number of comments already in the case appears near the top of the Comments area. Refer to “Add comments to the case” on page 3.25.

Key to Figure 3-3-5	
③	 Tags Click on the Tags icon to add a tag to the case. Refer to “Add a tag” on page 3.27.
④	 Annotations details Use the tools in this panel to change the appearance of annotations. Refer to “Add annotations” on page 3.18.
⑤	 View/Hide shortlist of marked objects Click on the arrow to show or hide the shortlist of marked objects. Refer to“About Shortlists of marked objects” on page 3.26.
⑥	 Mark Click on the mark tool (the pen) to select the tool. Then, click on an object in the whole slide image to add that area of the whole slide image to the shortlist of marked objects. Refer to “Mark objects to the Shortlist” on page 3.26.
⑦	 Shapes Click on the Shapes tool to choose the type of annotation. Then, click on the image to add shapes or arrows to the whole slide image. Refer to “Annotation tools” on page 3.18.
⑧	 Measure Click on the Measure tool to choose a line or dots as annotations. Then, click on the image to add a measured line or a number of dots to the whole slide image. Refer to “Annotation tools” on page 3.18.

Add annotations

While a reviewer has a case open, the reviewer can “draw” an annotation on the whole slide image. Annotations drawn by one reviewer are available to subsequent reviewers. The palette of annotation tools and a menu of options for adjusting the annotations are on the case review screen.

The instructions for using the shapes annotation tools and the measure annotation tool are similar.

The reviewer annotates an image, then completes the drawing step for the annotation. Next, the reviewer has the option to adjust the annotation and choose which aspects of the annotation will be visible to other reviewers after the case review is complete.

The reviewer must complete the review of the case, or save the review as “in progress,” in order for the annotation to be visible to a subsequent reviewer. The Review Station allows a user to complete a review without annotating and image. Follow your lab’s best practices and requirements for using annotations.

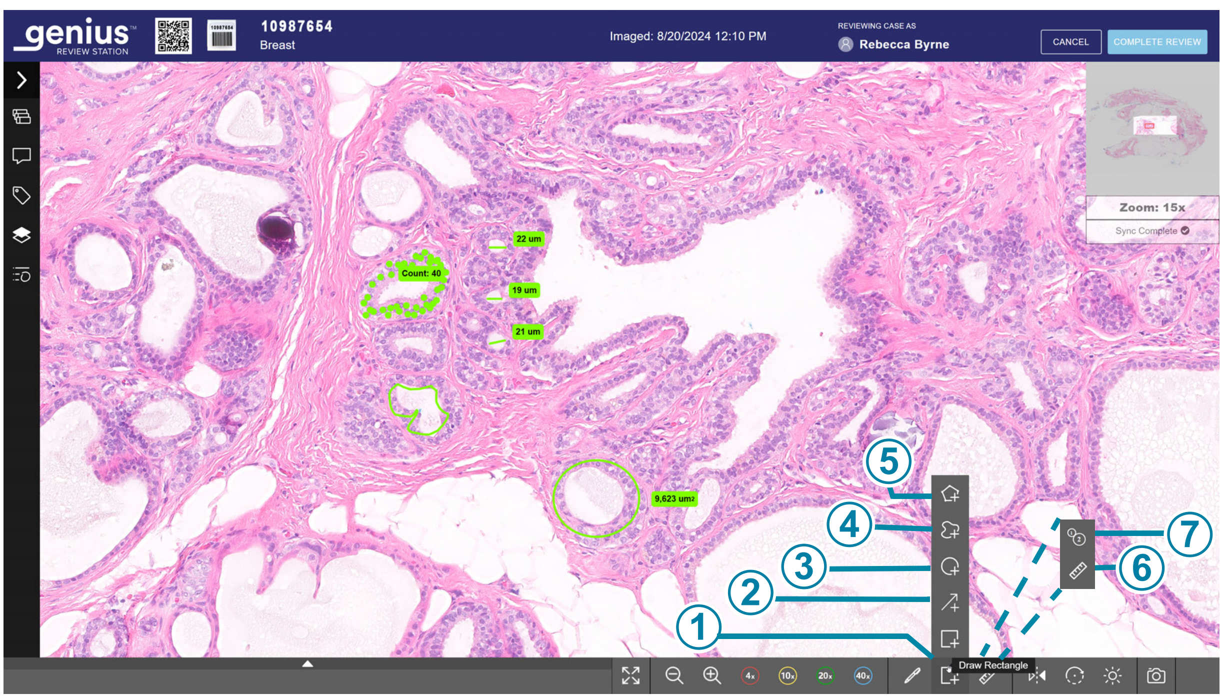


Figure 3-3-6 Annotation tools

Key to Figure 3-3-6	
1	The **Shapes** annotation tools. The rectangle is the default shape. Refer to Table 3.1 on page 3.21. Hover the mouse in the toolbar to expand the menu of shapes. In this example, the mouse is hovering over the rectangle annotation tool selection. Click to select a shape.
2	The arrow annotation tool. Refer to Table 3.1 on page 3.21.
3	The circle annotation tool. Refer to Table 3.1 on page 3.21.
4	The freeform (scribble) annotation tool. Refer to Table 3.1 on page 3.21.
5	The polygon annotation tool. Refer to Table 3.1 on page 3.21.
6	The **Measure** and counter annotation tools. The measuring tool (line) is the default shape. Refer to Table 3.1 on page 3.21. Hover the mouse in the toolbar to expand the menu to change between the measure and counter annotation tools. Click to make a selection.
7	The counter annotation tool. Refer to Table 3.1 on page 3.21.

1. Click on the **Shapes** tool  or the **Measure** tool  under the whole slide image to see the available options.
2. Click on the tool to select the tool.
   When a case is first opened for review, the default tools of the rectangle shape and the measure (line) display. If the reviewer selects a different tool, the button changes to show that tool. Refer to Table 3.1, "Shapes, Lines and Dots," on page 3.21.
3. To start drawing most annotations, click and drag the mouse in a selected portion of the whole slide image. To start drawing dots to be counted, click once to make a dot. Move the mouse and click again to make the next dot.

Note: When an annotation tool is active, the cursor changes appearance to look like that shape. When no annotation tool is active, the cursor can be used to select annotations on the whole slide image.

To move to another area of the whole slide image while an annotation tool is selected, either:

- Hold the spacebar on the keyboard and scroll with the mouse, or
- Center-click the mouse and scroll

To change the magnification while an annotation tool is selected, click on the navigation tools below the whole slide image (zoom in, zoom out, 40x, etc.).

Note: Each slide is scanned with a 40x objective. Images can be magnified on screen to 80x.

4. Click on an annotation tool to stop drawing that type of annotation, or to select a different type of annotation.
5. After an annotation is drawn, if desired, click on the annotation to move it.
6. Continue to draw as many annotations as appropriate.
   - To choose a different shape, select the other shape from the Shapes tool.
   - To choose the line to measure, select the measure tool.
   - To choose the counter tool, select the counter tool.
   - To start a new count for the counter tool (to start a new group of dots), with the counter tool selected, left-click the mouse, or click the **Add new count** button near the bottom of the whole slide image.
7. To stop the drawing session, either:
   - Click the **Complete** button
   - Right-click the mouse

Note: If the reviewer does not click the **Complete** button on the annotation menu, and the reviewer uses the mouse or keyboard in an attempt to scroll, a new annotation will be drawn on the whole slide image. If the new annotation is a mistake, use the delete icon (trash can) to delete the mistake. Refer to “Image Review Panel, line annotation, example” on page 3.31.

With the counter tool, the count is displayed on-screen near the first dot that the reviewer makes. If the reviewer pans or zooms such that the count is out of view, a reviewer could lose track of whether additional dots are part of a new count or adding to an existing count. To see the count for an annotation no matter the zoom or area of the slide shown on-screen, open that count in the Image Review Panel. Refer to “Edit and Organize Annotations” on page 3.30.

An annotation must be completed, with the **Complete** button or a right-click of the mouse, before the annotation details can be changed.

Table 3.1 Shapes, Lines and Dots

	Shape	Description
	Rectangle	Click and drag in the whole slide image to draw a rectangle. Release the mouse to stop drawing a rectangle. Click again to draw additional rectangles. To draw a square, hold the Shift key on the keyboard and click and drag the mouse. The area of the rectangle is displayed. The units may be micrometers, millimeters or centimeters, depending on the size of the rectangle. The area measurement is calculated by the Review Station software from a count of pixels in the image. The area measurement is accurate +/- 7.8%. To delete a rectangle, click on the rectangle tool to stop drawing and return to using the cursor. • Then, select the annotation with the cursor, and then click the trash can icon from the small menu near the annotation. • Or, select the annotation with the cursor, and press the Delete key on the keyboard.
	Circle (oval)	Click and drag in the whole slide image to draw a circle. Release the mouse to stop drawing a circle. Click again to draw additional circles. To draw a circle rather than an oval, hold the Shift key on the keyboard and click and drag the mouse. The area of the circle is displayed. The units may be micrometers, millimeters or centimeters, depending on the size of the circle. The area measurement is calculated by the Review Station software from a count of pixels in the image. The area measurement is accurate +/- 7.8%. To delete a circle, click on the circle tool to stop drawing and return to using the cursor. • Then, select the annotation with the cursor, and then click the trash can icon from the small menu near the annotation. • Or, select the annotation with the cursor, and press the Delete key on the keyboard.

Table 3.1 Shapes, Lines and Dots

	Shape	Description
	Polygon	Click to add the first point and additional points to the polygon, and drag in the whole slide image to change the size of the polygon. Release the mouse to stop drawing a polygon. Click again to draw additional polygons. To delete a polygon, click on the polygon tool to stop drawing and return to using the cursor. • Then, select the annotation with the cursor, and then click the trash can icon from the small menu near the annotation. • Or, select the annotation with the cursor, and press the Delete key on the keyboard.
	Freeform (Scribble)	Click and drag in the whole slide image to draw a line, curve or shape. Release the mouse to stop drawing. Click again to draw another freeform shape. To delete a freeform line or shape, click on the freeform tool to stop drawing and return to using the cursor. • Then, select the annotation with the cursor, and then click the trash can icon from the small menu near the annotation. • Or, select the annotation with the cursor, and press the Delete key on the keyboard.
	Arrow	Click and drag in the whole slide image to draw an arrow. Release the mouse to stop drawing. Click again to draw another arrow. To delete an arrow, click on the arrow tool to stop drawing and return to using the cursor. • Then, select the annotation with the cursor, and then click the trash can icon from the small menu near the annotation. • Or, select the annotation with the cursor, and press the Delete key on the keyboard.

Table 3.1 Shapes, Lines and Dots

	Shape	Description
	Measure (draw a line)	Click and drag in the whole slide image to draw a line and measure the line in micrometers, millimeters or centimeters, depending on the length of the line. The line measurement is calculated by the Review Station software from a count of pixels in the image. The line measurement is accurate +/- 3.9%. Release the mouse to stop the line. Click again to draw another line. To delete a measured line, click on the line tool to stop drawing and return to using the cursor. • Then, select the annotation with the cursor, and then click the trash can icon from the small menu near the annotation. • Or, select the annotation with the cursor, and press the Delete key on the keyboard.

Table 3.1 Shapes, Lines and Dots

	Shape	Description
	Counter (count a group of dots)	Click in the whole slide image to make a dot to include in the count. Click again to add another dot to the same group. A count of the dots (the number of dots) displays on the whole slide image. While the counting tool is active, the reviewer can continue to add dots to the current count by clicking in the image. Right-click stops adding dots. Click in the image again to continue to add dots to the current count. To make a new group of dots and start the counting again, click the **Add new count** button near the bottom of the whole slide image. While the counting tool is active, the reviewer can add more dots for inclusion in a count by opening this count annotation from the Image Review Panel. To delete one dot, click on the counter tool to stop drawing and return to using the cursor. • Select the dot with the cursor, and then click the trash can icon from the small menu near the annotation. • Or, select the dot with the cursor, and press the Delete key on the keyboard. The count lowers by one for this counter. To delete one group of dots, open the count in the Image Review Panel and delete the entire annotation. Refer to "More actions for counters" on page 3.24.

More actions for counters

There are two actions for the counter that a reviewer can take in the Image Review Panel: add dots to an existing counter and delete the entire counter annotation.

To add a dot:

1. To add one dot at a time to an existing counter annotation, select the existing counter. Select the existing annotation either by clicking on one of its dots in the whole slide image or by clicking on the down-arrow next to the name of that counter in the Image Review Panel.
2. Click the **Add** button 

.
3. Click where the new dot should be placed on the whole slide image.

4. The counter increases by one for this counter.

To delete a counter annotation:

1. To delete an existing counter annotation, deleting the entire group of dots, select the existing counter. Select the existing annotation either by clicking on one of its dots in the whole slide image or by clicking on down-arrow next to the name of that counter in the Image Review Panel.

2. Click the **Clear** button 

.

Add comments to the case

While a reviewer has a case open, the reviewer can add comments to the case.

1. Click on the **Comments** tool  in the Case Control Panel to the left of the whole slide image.
2. A comments box opens. Any comments added to the case previously, by you or another reviewer, are visible.
3. Type in a comment, if any.

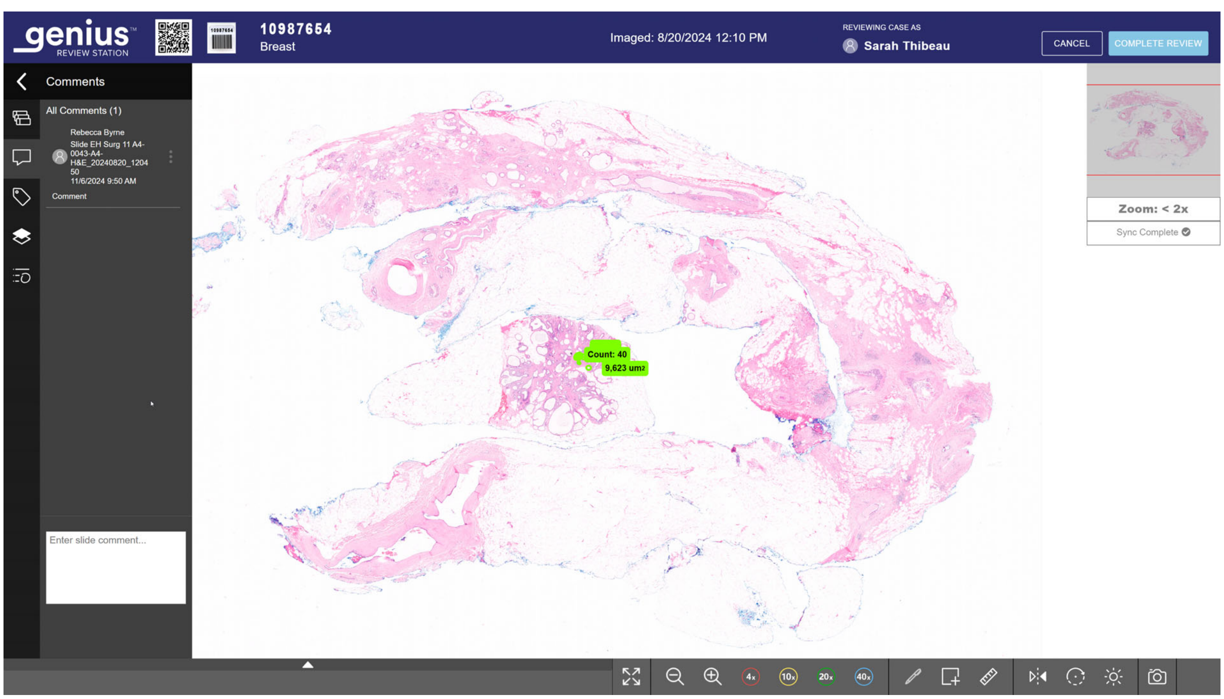


Figure 3-3-7 Add comments, view existing comments, example

4. Click on the **Close** button beneath the comment. The comment is associated with the case, and visible to other users who view or review the case.

Note: Comments made by a previous reviewer are locked.

About Shortlists of marked objects

Marked images are added to a new section of tiles, a "Shortlist" below the whole slide image. The Shortlist is a gallery of marked tiles. The top of the Shortlist appears below the whole slide image. To see the Shortlist, click the arrow above the list.

When the current reviewer or a subsequent reviewer clicks on a tile in the shortlist, the view of the review screen presents the area of the whole slide image shown in the tile at 40x magnification.

When the Shortlist exceeds six tiles, the sixth tile changes to a number. For example, "+10" means marks have been made on ten tiles that are not immediately in view.

Mark objects to the Shortlist

To mark an object, click on the mark tool  .

Click an image of an object within the whole slide image.

The marked object is added to the "Shortlist" of tiles at the bottom of the display.

To delete a mark and remove the tile from the Shortlist, click on the arrow to see the Shortlist (if not already displayed), and click on the "x" icon in that tile in the Shortlist.

Note: The magnification on the whole slide image must be 10x or greater to add a mark.

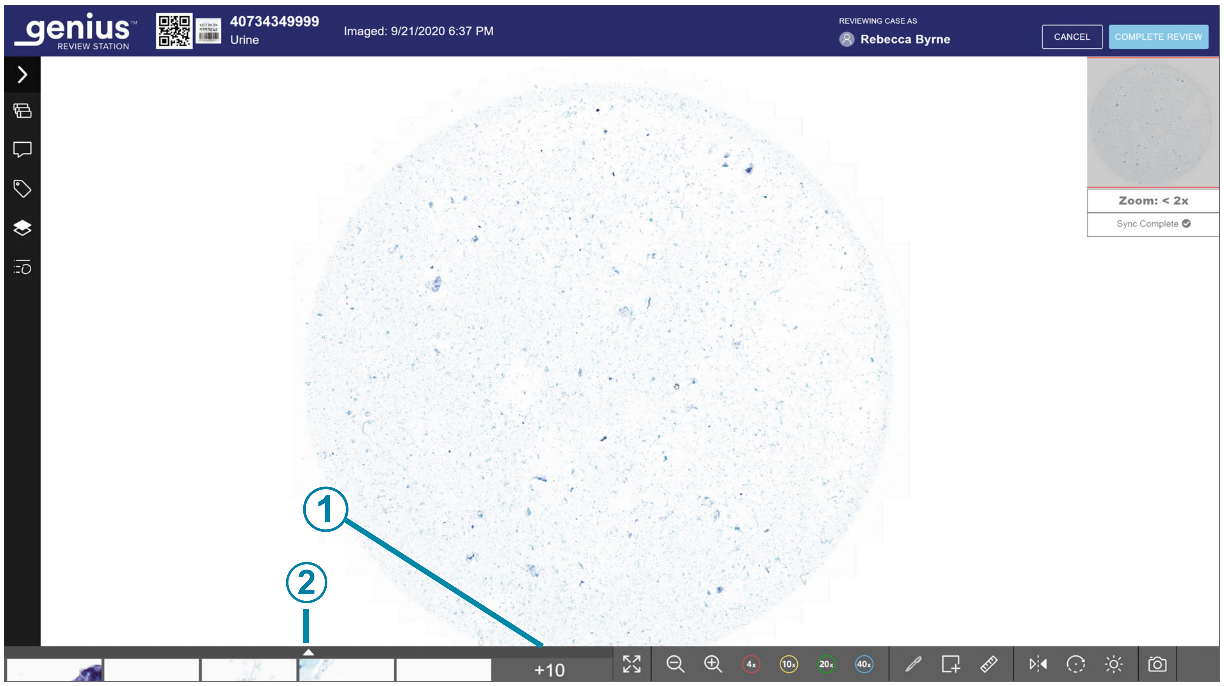


Figure 3-3-8 Shortlist of marked objects

Key to Figure 3-3-8	
1	The number indicates a longer Shortlist. In this example, there are fifteen tiles in the Shortlist. Five tiles are partially shown and ten more tiles will show after the user clicks the arrow.
2	To expand the view to see the tiles, click the up arrow. Click the down arrow in the marked Shortlist to return to condensed view.

To scroll through a large set of tiles with the keyboard, use the arrow keys or the ASWD keys. Or, use the mouse to click on any tile.

Add a tag

Cases in a lab with a common attribute can be tagged, and then any reviewer in the lab can search for all of the cases that have been tagged with the same tag. A tag is a keyword set up by the lab manager or an administrator. The use of tags is optional. Follow your lab's policy for using tags.

Note: On the Review Station, a bookmark lets one reviewer have cases with that bookmark readily available to that *one reviewer.* Cases with the same tag are available to *all reviewers* at Review Stations connected to the same Image Management Server.

1. A tag must be set up by a manager or an administrator before the tag can be associated with a case. A manager or an administrator can set up a tag using the Settings menu. Refer to Part 1 of this manual for more information about the Settings options.

   Or, a manager or an administrator can set up a new tag from the **Tags** icon  in a Case Review screen:

   A. Click the **Tags** icon in the Case Control Panel.

   B. Click “New tag”

   C. Type in the name of the new tag.

   D. Click **Save** to save the new tag.

2. After the tag is set up, as a reviewer is reviewing a case, click the **Tags** icon  to open the tags area.

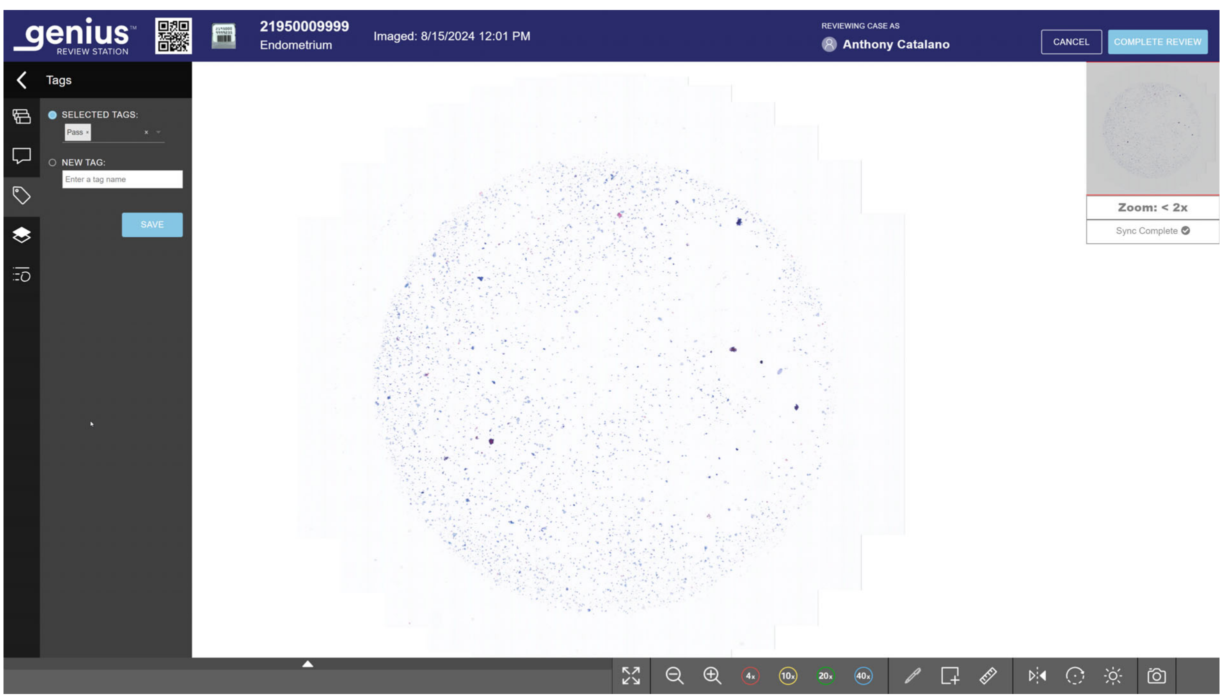


Figure 3-3-9 Tags during Case Review, manager role shown

3. In the "Selected Tags:" area, select the name of the tag from the available options in the drop-down list. The tags' names are listed in alphabetical order in the drop-down list. More than one tag can be selected.
4. Continue reviewing the case. The tag selection will be saved with the case when the review of the case is completed, or saved as "in-progress".

After a case is tagged the icon on the case list screen changes to the Tagged Case icon, and the name of the tag is on the case details section for that case.

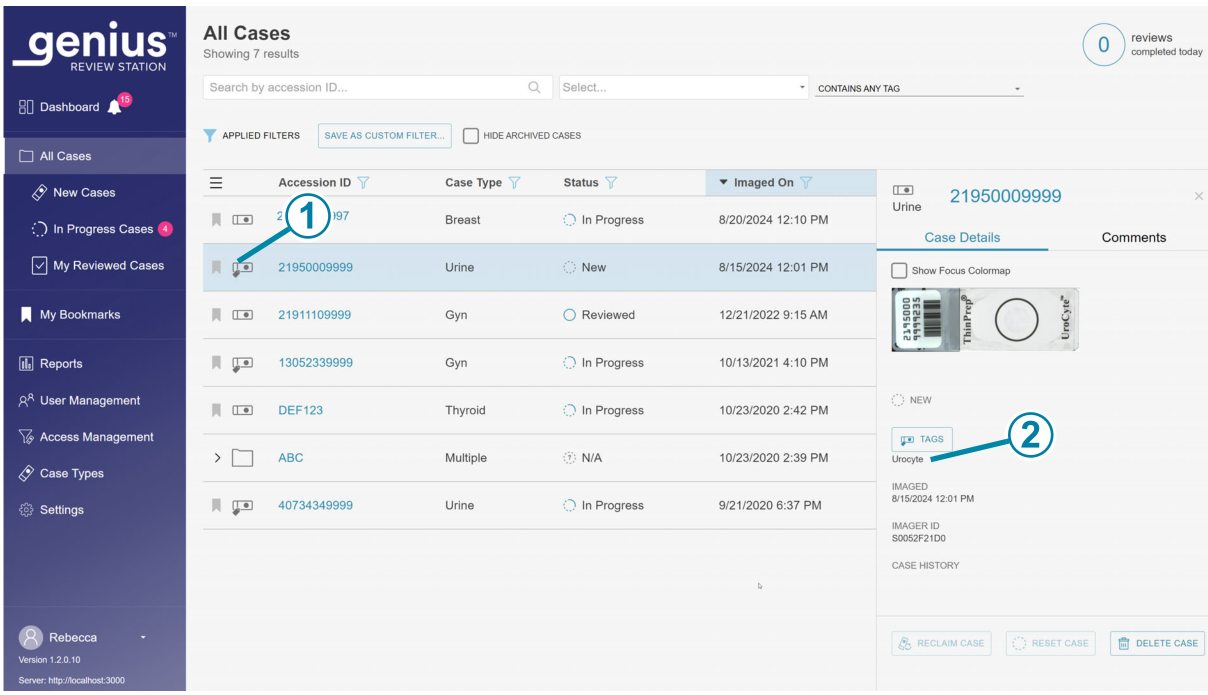


Figure 3-3-10 Case Details screen for a case with a tag

Key to Figure 3-3-10	
1	The tagged case icon shows in the Case List.

Key to Figure 3-3-10	
②	**Tags** button in the Case Details screen The name of the tag (or tags) associated with the case appear in the Case Details section. A reviewer can click the **Tags** button to add or remove a tag from the case. The steps are the same as using **Tags** button on the Case Review screen. If a manager or an administrator changes the name of a tag, the name of the tag updates in the case details screen. If a manager or an administrator deletes a tag from the Review Station network, that tag will no longer appear in the Case Details screen for a case.

More than one tag can be applied to the same case.

After a case is tagged, that case and all of the cases with the same tag can be found by using the **Search by tag...** feature on the Case List. Refer to Part 1 of this operator's manual for more information.

Note: For cases comprised of multiple slides grouped together with a primary ID, each slide in the group can use the same tag. Each slide in the group must be tagged individually to apply the same tag to each slide within the group.

Remove a tag

A tag can be removed from a case in the Case Review screen and in the Case Details screen.

1. As a reviewer is reviewing a case, click the **Tags** icon  . Or navigate to the Case Details screen and click the **Tags** button.
2. In the list of tags, scroll to the name of the tag to remove from the available options in the drop-down list, or type in the first few characters of the name of the tag.
3. Click the "x" to the right of the name of the tag to remove that tag from the case.
4. Save the selection.
   A. In the Case Review screen, click **Save** to remove the tag from the case and continue reviewing the case. Or, continue reviewing the case without removing the tag.

   Or,

   B. In the Case Details view, click **Continue** to remove the tag from this case, or click **Cancel** to return to the review screen without removing the tag.

Edit and Organize Annotations

While a reviewer has a case open, after a drawing session for annotations is complete, the reviewer can use the Image Review Panel to change the color and thickness of shapes, lines, and dots. The reviewer can also choose which annotation information displays on the whole slide image for subsequent reviewers.

Annotations are part of the review. If a reviewer makes annotations but cancels the review of the case, the annotations are not saved. After the reviewer completes the review of the case, any shapes added to the case previously, by you or another reviewer, are visible and unable to be changed.

Note: If a reviewer makes annotations and saves the review in progress, the annotations are retained. The reviewer can continue to make, change, or delete annotations. After the case review is completed, the annotations cannot be changed.

There are two ways to access the Image Review Panel:

- In the whole slide image, select an annotation with the cursor. Select the **Edit** button. The Image Review Panel opens and shows details for that annotation.
- Or, click on the Annotation details icon in the Case Control Panel. To show the annotations details for any annotation, click the down-arrow next to the annotation's name. To hide the annotations details for any annotation, click the up-arrow.

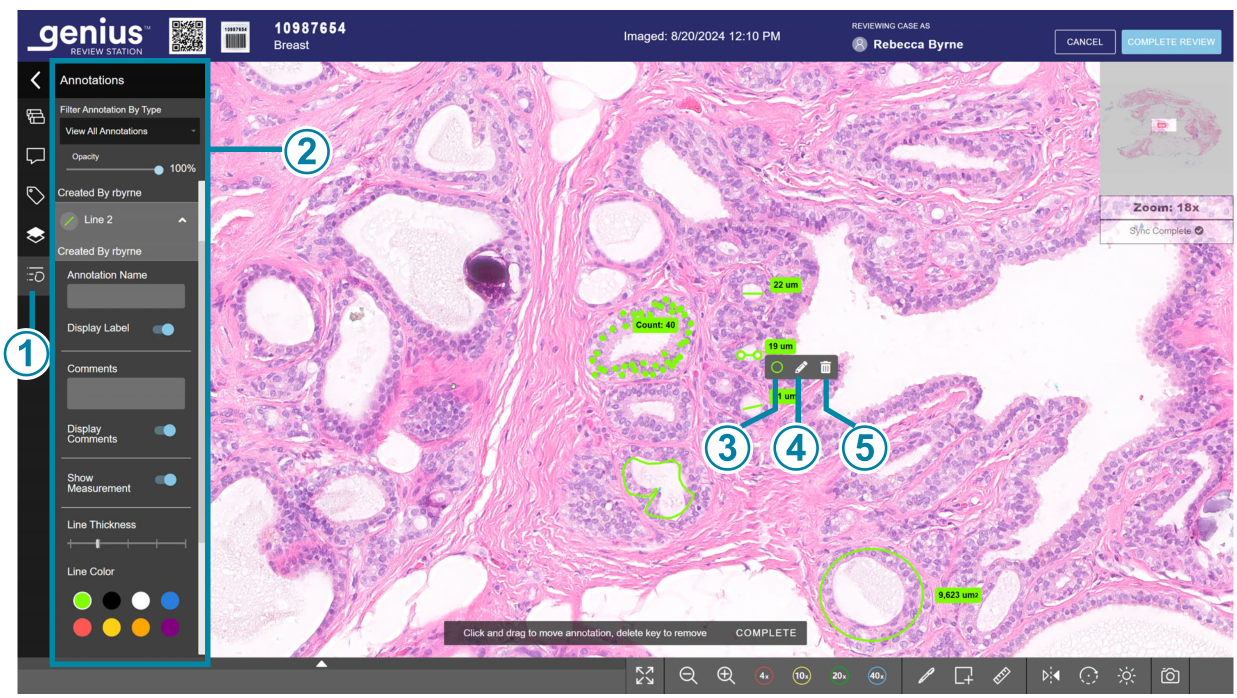


Figure 3-3-11 Image Review Panel, line annotation, example

Key to Figure 3-3-11	
1	 Annotation details Clicking on the Annotation details button opens the Image Review Panel. If an annotation is selected when the button is clicked, the view of that annotation is automatically expanded.
2	The Image Review Panel
3	 To open the Image Review Panel and change the color and line thickness for this annotation, click the colored circle.
4	 To open the Image Review Panel and change other attributes of this annotation, click the Edit button.
5	 To delete the selected annotation, click the delete button (trash can icon). ***Note:*** For a group of dots in a counter, selecting one dot and using the  button will delete the one, selected dot from the count. To delete the selected annotation with the keyboard, press the Delete key on the keyboard.

While the case review is still new or in progress, the reviewer can change or delete an annotation. After the case review is complete, the name in the Image Review Panel, and the line thickness and the color of an annotation will be visible to subsequent reviewers.

Note: If a case is saved in the “in progress” status and opened for review by another reviewer, annotations are visible to the reviewer who has read-only access to the case.

When the case review is still new or in progress, the reviewer makes the choice of whether to display the name, annotation comments and measurements on the whole slide image. The settings that this reviewer chooses determine what will be visible on the whole slide image to subsequent reviewers.

The settings in the Image Review Panel are described below.

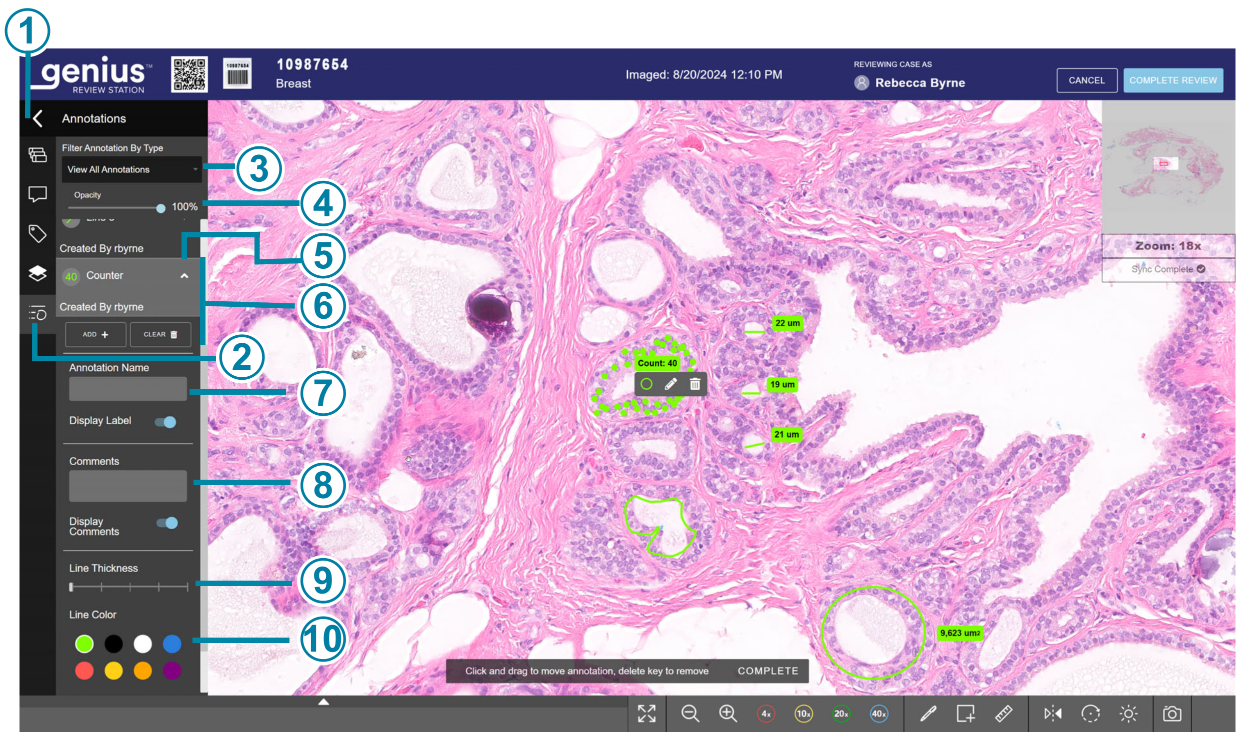


Figure 3-3-12 Image Review Panel, counter annotation, example

Key to Figure 3-3-12	
1	Click the arrow to show the Case Control Panel, if the panel is not already displayed.
2	Clicking on the Annotation details button opens the Image Review Panel.
3	Filter Annotation By Type Refer to “Filter which annotations are displayed” on page 3.34.

Key to Figure 3-3-12	
4	Adjust opacity of the annotations on the whole slide image. Refer to “Adjust the opacity of the annotations on the whole slide image” on page 3.34.
5	Use the arrow to show or hide the annotation details.
6	Options for the annotation type. In this example, the counter options are shown.
7	Annotation Name Refer to “Name an annotation” on page 3.35.
8	Annotation Comments Refer to “Add a comment to an annotation” on page 3.35.
9	Line Thickness Refer to “Change an annotation’s line thickness” on page 3.36.
10	Line Color Refer to “Change the color of an annotation” on page 3.36.

Filter which annotations are displayed

The reviewer can choose to display all of the annotations on a whole slide image or to filter the view so that only some of the annotations are displayed. The filtering is based on the type of annotation.

The filtering is temporary. When a reviewer closes the Image Review Panel or completes the review of the case, the filter resets to “View All Annotations”. To filter the annotations:

1. With the Image Review Panel displayed, click the down-arrow next to “View All Annotations”.
2. Click on the name of one type of annotation (for example, “Rectangle”). The display changes to show only that type of annotation on the whole slide image.

In long lists, a scroll bar is available.

Adjust the opacity of the annotations on the whole slide image

1. Set the desired opacity level for the annotations:
    - To make the lines and text in all of the annotations on this whole slide image more opaque, click on the **Opacity** slider and drag the slider to the left.
    - To make the lines and text in all of the annotations on this whole slide image more transparent, click on the **Opacity** slider and drag the slider to the right.

2. Chose any value from 0% opaque (transparent) to 100% opaque (solid). The annotations on the whole slide image immediately change appearance on screen.

This setting is temporary. The opacity level resets to 100% when the reviewer completes the review.

Name an annotation

By default, annotations are assigned a name which is their shape and a number (E.g., Rectangle 1, Rectangle 2, etc.).

1. To change the name, select the existing annotation either by clicking on it in the whole slide image or by clicking on the down-arrow next to the name of that annotation in the Image Review Panel.
2. Type the new name in the **Annotation Name** field.
   - To show the name of the annotation on the whole slide image, move the **Display Label** slider to the right.
   - To hide the name of the annotation on the whole slide image, move the **Display Label** slider to the left.

For the counter (dots) tool, the count is always displayed. For the measure (line) tool, the default setting displays the length of the line. To not show the length, turn the Display Label off (slide to the right) for the annotation.

After the review of the case is completed, a subsequent reviewer will have the ability to see the name of the annotation in the Image Review Panel. If the reviewer who creates the annotation opts to display the label, the name of the annotation will permanently display on the whole slide image in subsequent reviews.

Add a comment to an annotation

1. To add comments to an annotation, select an existing annotation either by clicking on the annotation in the whole slide image or by clicking on the down-arrow next to the name of that annotation in the Image Review Panel.
2. Type the comment in the **Comments** box.
   - To show the annotation comment on the whole slide image, move the **Display Comments** slider to the right.
   - To hide the annotation comment on the whole slide image, move the **Display Comments** slider to the left.

Note: A comment on an annotation is different from a comment on a case. An annotation comment on the whole slide image is only visible to reviewers when the case is open and the original reviewer opted to display comments. A comment on a case is visible from the case list and also when the case is open at the Genius Review Station.

After the review of the case is completed, the annotations are locked. A subsequent reviewer can see annotation comments if the reviewer who created the annotation comments opted to display comments. If the reviewer who creates the annotation opts to display the annotation comments, the annotation comments will permanently display on the whole slide image in subsequent reviews at the Genius Review Station. If the reviewer who creates the annotation does not display the comments, the annotation comments will permanently be hidden in subsequent reviews.

Change an annotation's line thickness

1. To change the thickness of the line or the size of the dot in an annotation, select an existing annotation either by clicking on the annotation in the whole slide image or by clicking on the down-arrow next to the name of that annotation in the Image Review Panel.
2. Set the desired thickness for the lines or dots.
   - To use a thicker line in the selected annotation, click and drag the bar on the line thickness scale to the right, or press the right-arrow key on the keyboard.
   - To use a thinner line in the selected annotation, click and drag the bar on the line thickness scale to the left, or press the left-arrow key on the keyboard.

The default setting for lines is a medium thickness. The default setting for dots in a counter is the smallest dot. The size of the lines or dots remains the same regardless of the magnification of the image.

After the review of the case is completed, the annotations are locked. A subsequent reviewer will see any annotations with the line thickness that the reviewer who created the annotation used.

Change the color of an annotation

1. To change the color of an annotation, select an existing annotation either by clicking on the annotation in the whole slide image or by clicking on the down-arrow next to the name of that annotation in the Image Review Panel.
2. Click on one of the eight available colors. The default color is green.

After the review of the case is completed, the annotations are locked. A subsequent reviewer will see any annotations in the color or colors that the reviewer who created the annotation used.

Keep a Case In Progress (optional)

A case can be reviewed and completed in one session. Once a reviewer opens a case from the Case List, that reviewer is the only one who can annotate, add marks, make comments, or complete the review. In the event that a reviewer cannot complete a review in one session before logging out, the Review Station also offers the option of keeping the review of a case in progress.

To change the status to In Progress, from the review screen click on the **Cancel** button in the upper right.

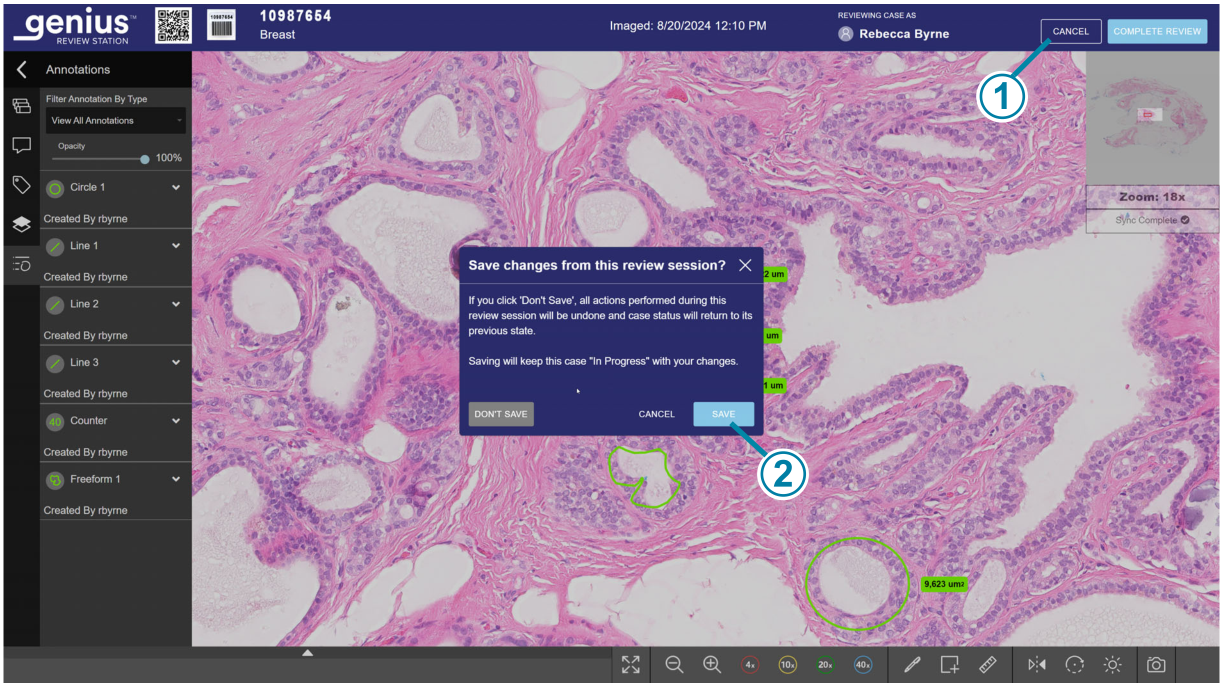


Figure 3-3-13 Save a case as In Progress, example

Key to Figure 3-3-13	
1	Click **Cancel**.
2	Click **Save**.

A dialog box appears with the option to save changes from the review session. To cancel the review, undo any new annotations, marks or comments, and keep the case in the "New Cases" status, select "Don't Save".

To save changes from this review session and change the status for the case to In Progress, select **Save**.

The dialog box also has a **Cancel** button which closes the dialog box.

While a case is in progress, a reviewer can add, edit, and remove new annotations. While a case is in progress, a reviewer can add, edit, and remove new comments. While a case is in progress, a reviewer can add and remove marks. Once the review is complete, the annotations, comments and marks are permanently associated with the case.

Complete a Review of a Case

1. When a reviewer is ready to complete the review of the case, click the **Complete Review** button in the upper right of the review screen.

Figure 3-3-14 Complete the review of a case

2. A confirmation message appears to confirm that you want to complete the review.
   - Click **Confirm Review** to confirm. The status for this Accession ID will change to "Complete". The case now appears with the status "Reviewed" in Case Lists, including the "My Reviewed" Case List for the reviewer. Any annotations, comments and marks made during the review are saved with the case. Annotations, comments and marks cannot be edited.
   - Click **Cancel** to keep the case at its current state.

Cases Grouped with a Primary ID

For cases that consist of multiple slides, the Digital Imager can be set up to group the individual slides together using the concept of a primary ID and a secondary ID. The primary ID is the portion of the accession ID that each of the slide IDs have in common, and the method for identifying a primary ID is configured on the Digital Imager.

On the Review Station, the primary ID “behaves” like a folder, grouping the individual slides together. Images from each individual slide in the grouped case are available within that folder. The folder is listed under the primary ID, and the individual slides that comprise the group are listed under the secondary ID.

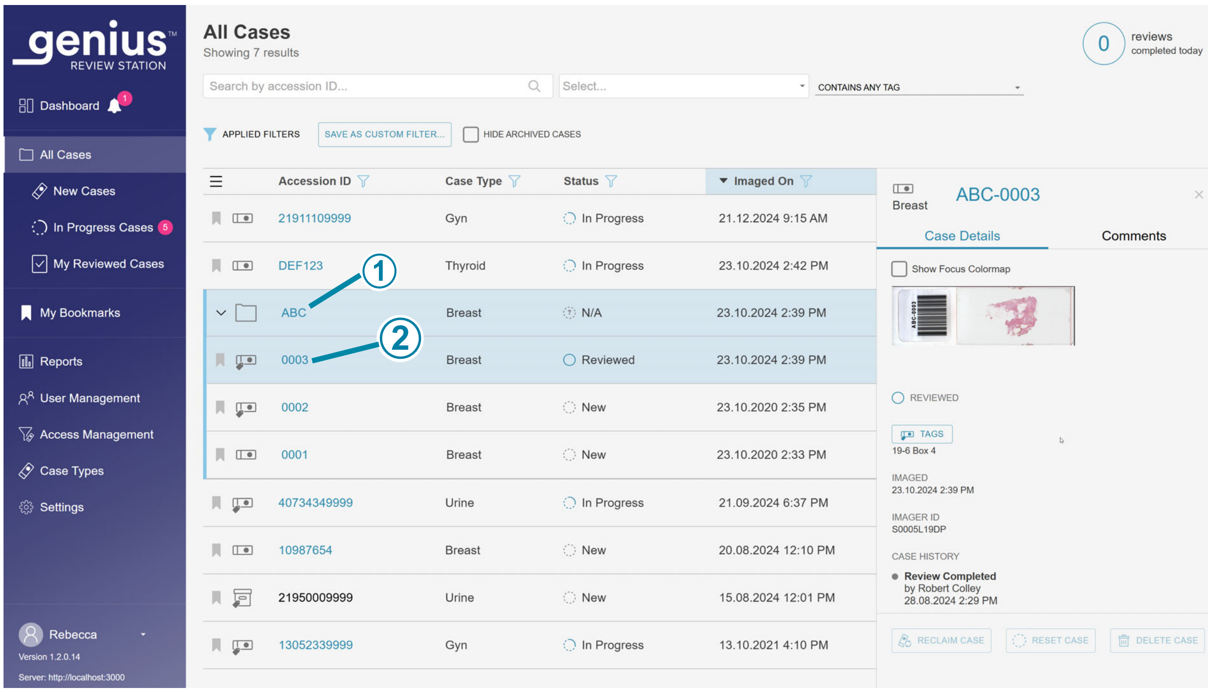


Figure 3-3-15 Case List with slides grouped under primary ID, example

Key to Figure 3-3-15	
1	Primary ID The ID for the group Click anywhere in the case listing to see each of the slides in a group. Or, click the arrow to the left of the primary ID to view or hide each of the slides in a group.
2	Secondary ID In case lists, the individual slide is listed by the secondary ID. The secondary ID is the unique slide ID.

The steps for reviewing each slide within a case grouped with a primary ID are similar to other case reviews. However, when any slide within the group is opened for review, all of the slides in the group open and must be viewed one at a time. Each slide within the group must be reviewed before the review of the case can be completed.

1. From the Case List, either open any slide in the group, or click on the primary ID for the group (the folder entry on the Case List). Refer to “Open a Case” on page 3.6.
2. To the left of the whole slide image, the **Case Slides** section of the Case Control Panel shows a thumbnail image of each slide in the group for this case. Review each slide in the case.
   - Navigate to each slide in the group by clicking on the thumbnail image in the **Case Slides** list.
   - As the reviewer views the whole slide image for a slide in the case, the blue dot next to the thumbnail image in the **Case Slides** list goes away.
   - The reviewer can review each slide in the group in any order.

Note: As with any case review, comments made to a slide in a grouped case are associated with the slide. When a case with multiple slides grouped with a primary ID is open for review, the comments shown in the Case Control Panel are all of the comments for all of the slides in the case. A reviewer can click on the **Go to Slide** message in Comments box and change the view in the whole slide image to the slide where the comment was made.

3. When all of the slides in the grouped case have been reviewed, use the **Complete Review** button to complete the review. The **Complete Review** button is not available until the last of the slides in the case is reviewed.

Note: If needed, a reviewer can save a review of any slide to the “in progress” status. Refer to “Keep a Case In Progress (optional)” on page 3.36. If some slides in a group case are at the “New” status and some are at the “in progress” status, the mix of statuses shows in the case list.

Note: If needed, additional slides can be added to a case after a review of the case has been completed at the Review Station. The reviewer will need to navigate to each of the slides in the case, regardless of whether the slide is at the “Reviewed” status or the “New” status, before the **Complete Review** button is available.

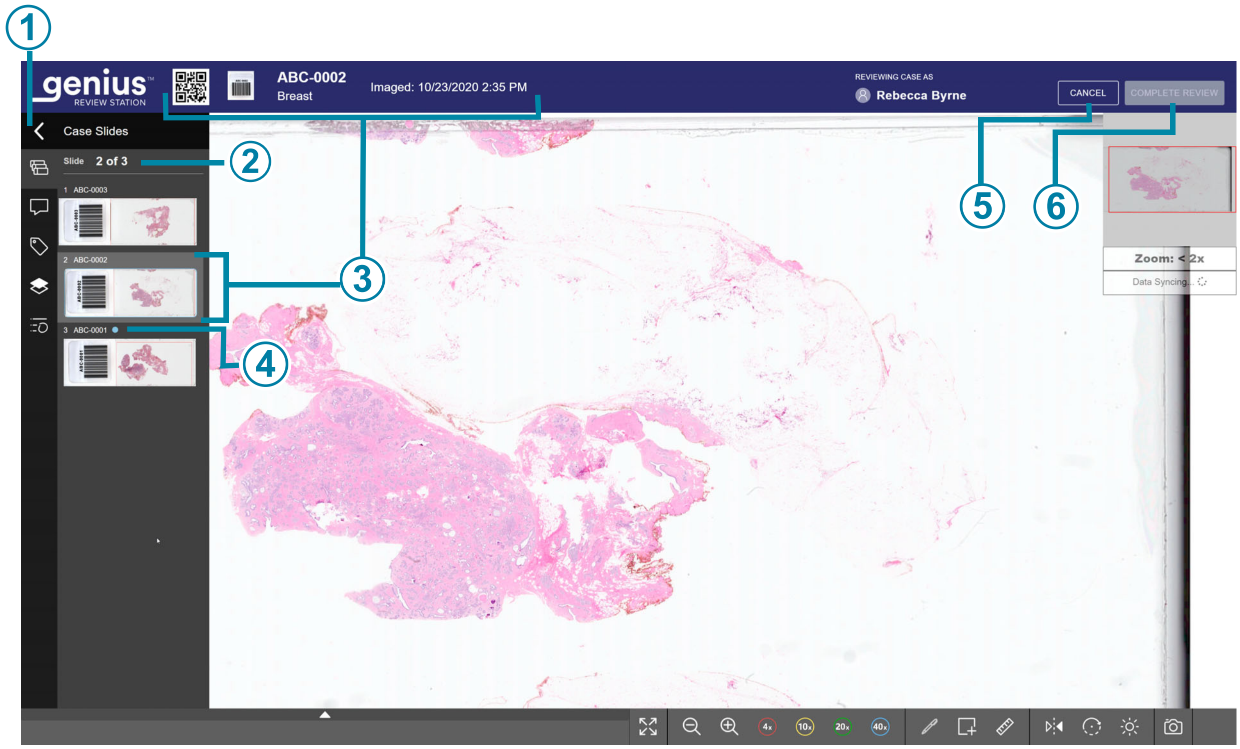
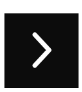


Figure 3-3-16 Case Control Panel for slides grouped under primary ID, example

Key to Figure 3-3-16	
1	 Use the arrow to show or hide the Case Control Panel. From the review screen, a reviewer can also show or hide the Case Control Panel menu by pressing the Enter key on the keyboard.
2	For cases composed of several slides, a count among the total number of slides is displayed. The order of appearance in the Case Slides list is the same order as shown on the Case List screen.
3	The accession ID for slide that is open for review, the slide whose whole slide image is shown.

Key to Figure 3-3-16	
④	The accession ID for each slide in the group is shown in the Case Slides list. A blue circle indicates a slide in this group has not been reviewed.
⑤	A review can be saved “In progress” for a slide in a case.
⑥	Each slide in the case must be reviewed before the review of the case can be completed.

In Reports, data for each individual slide is reported as a separate entry, rather than as a grouped case.

In the search results from searching by tag, data for each individual slide is reported as a separate entry, rather than as a grouped case.

In Bookmarks, if more than one individual slide from a group is part of the same Bookmark category, those slides are grouped in the Bookmark view.

The complete Accession ID is shown in several places for cases that are grouped by primary ID.

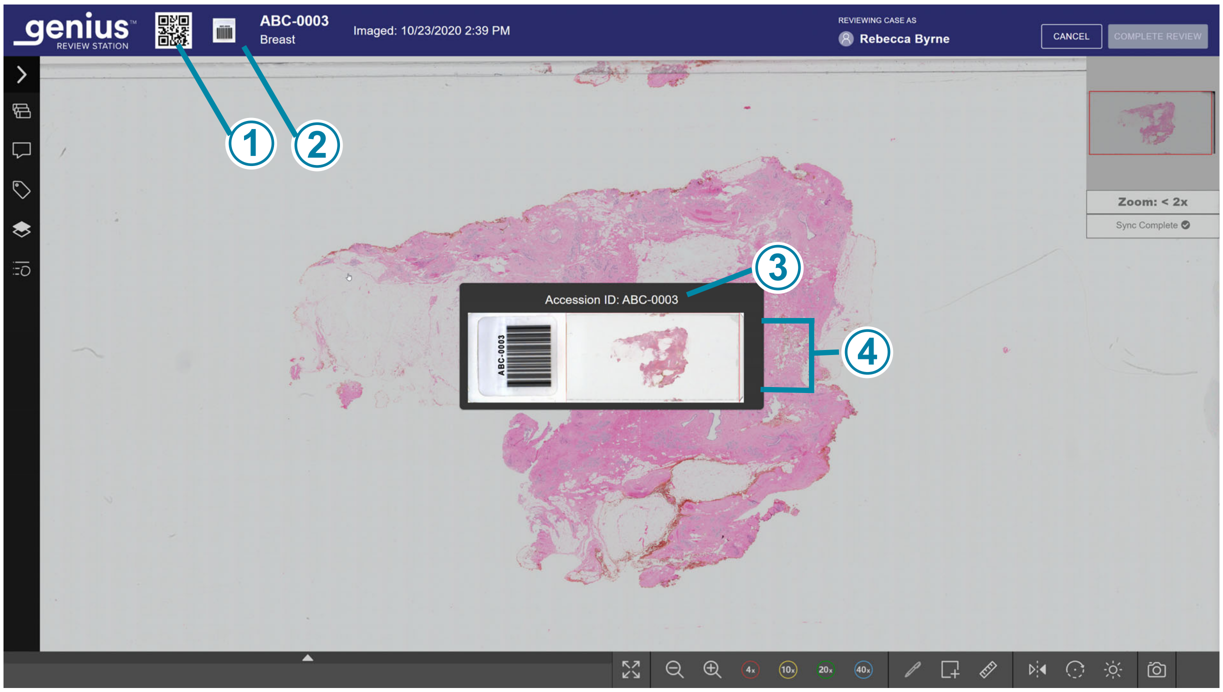


Figure 3-3-17 Macro image shows slide label area, example

Key to Figure 3-3-17	
1	The QR code represents the full Accession ID of the individual slide.
2	When an individual slide is open, to see the accession ID, click to the left of the Accession ID to view the macro image of the slide.
3	For slides that are part of a grouped case, the Accession ID takes the form of "primary ID-secondary ID" with a hyphen separating the primary ID from the secondary ID.
4	The macro image itself also shows what is printed on the slide label.

Note: Consider filtering options and the Review Station status when working with cases grouped with a primary ID.

For example:

A new case consists of three slides. Two are imaged on Monday, and one imaged on Tuesday. If a reviewer filters the new Case List with an "imaged on" date for Monday, the Case List will only yield two of the slides, grouped together by the primary ID. If the same Case List is filtered with an "imaged on" date of Tuesday, the Case List will only list one of the slides. It will appear under its complete accession ID, not as part of a group because the filtering of the Case List has separated it from the group. However, when any slide from that case is opened, all three of the slides in the case will open, and all three will need to be reviewed before the review of the case can be completed.

Table 3.2 Hotkeys, Mouse Clicks and Icons, Custom Case Types

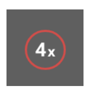
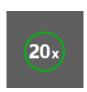
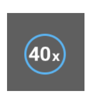
	With the mouse	On the keyboard
Zoom in, in small increments	Click zoom in button as many times as desired: 	+ (plus key) - zoom in
Zoom out, in small increments	Click the zoom out button as many times as desired: 	- (minus key) - zoom out
Zoom in, in a larger increment	Click and scroll the wheel on the mouse up (clockwise)	+ (plus key) - zoom in
Zoom out, in a larger increment	Click and scroll the wheel on the mouse down (counter-clockwise)	- (minus key) - zoom out
Zoom to 4x magnification	Click the 4x button: 	'- 4x magnification (ú on an AZERTY keyboard)
Zoom to 10x magnification	Click the 10x button: 	1 - 10x magnification
Zoom to 20x magnification	Click the 20x button: 	2 - 20x magnification
Zoom to 40x magnification	Click the 40x button: 	4 - 40x magnification
Pan to the left	Click and drag right	Left arrow - move left A - move left (Q on an AZERTY keyboard)

Table 3.2 Hotkeys, Mouse Clicks and Icons, Custom Case Types

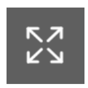
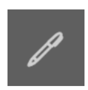
	With the mouse	On the keyboard
Pan to the right	Click and drag left	Right arrow - move right D - move right
Pan up	Click and drag down	Up arrow - move up W - move up (Z on an AZERTY keyboard)
Pan down	Click and drag up	Down arrow - move down S - move down
Toggle between full screen view and view with case control panel	Click the Expand to Full Screen button or the Contract from Full Screen button:  	Not available
Mark an object	Click the Mark tool: 	Not available
Snapshot	Click the Snapshot tool: 	Not available
Navigate to each slide grouped by a primary ID	Click the Case Slides icon: 	Not available
Add comments to the case	Click the Comments tool 	and type with a keyboard.
Layers (overlays)	Click on the Layers tool: 	Not available

Table 3.2 Hotkeys, Mouse Clicks and Icons, Custom Case Types

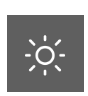
	With the mouse	**On the keyboard**
Annotations	Click the Annotations Details tool: 	Not available
Focus Colormap	Toggle with the slider.	Not available
Thumbnail Tracker	Toggle with the slider.	Not available
Opacity of Annotations	Adjust with the slider.	Not available
Annotation Name	Click in the field and type with a keyboard.	
Display Label for Annotation	Toggle with the slider.	Not available
Add Comments Related to an Annotation	Click in the field and type with a keyboard.	
Display Annotation Comments for Subsequent Reviewers to See	Toggle with the slider.	Not available
Display Annotation Measurements for Subsequent Reviewers to See	Toggle with the slider.	Not available
Flip	Click on the flip tool: 	Not available
Rotate View	Click on the flip tool. Then click the desired angle, or drag mouse to desired angle: 	Not available
Image Adjustments	Click the Image Adjustments tool, and use the slider to change the levels: 	With gamma, brightness or contrast selected with a mouse, up-arrow to increase or down-arrow do decrease.

Table 3.2 Hotkeys, Mouse Clicks and Icons, Custom Case Types

	With the mouse	On the keyboard
Tag from the review screen	Click the Tag tool: 	Not available
Shapes	Click the Shape that is visible to open the menu, then click to select a shape. The rectangle is the default shape. 	Not available
Rectangle	Click the Rectangle tool, and then click and drag in the image: 	Not available, but use the mouse and hold the Shift key to draw a square
Circle (oval)	Click the Circle tool, and then click and drag in the image:: 	Not available, but use the mouse and hold the Shift key to draw a circle (rather than an oval)
Polygon	Click the Polygon tool, and then click and drag in the image. Click to add points: 	Not available
Freeform (Scribble)	Click the Freeform tool, and then click and drag in the image: 	Not available

Table 3.2 Hotkeys, Mouse Clicks and Icons, Custom Case Types

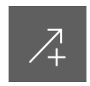
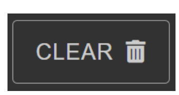
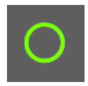
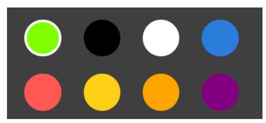
	With the mouse	On the keyboard
Arrow	Click the Arrow tool, and then click and drag in the image: 	Not available
Measure (draw a line)	Click the Measure tool, and then click and drag in the image: 	Not available
Counter (count a group of dots)	Counter (count a group of dots) 	Not available
Stop adding to a counter	Right-click the mouse	Not available
Delete one dot in a counter	Select the dot and click the trash can button: 	Use the mouse to select the dot, and then press the Delete key.
Delete an entire group of dots	Click the Clear button: 	Not available
Delete annotation	Click the trash can button: 	Select annotation with the cursor and use the Delete key on the keyboard

Table 3.2 Hotkeys, Mouse Clicks and Icons, Custom Case Types

	With the mouse	On the keyboard
Change the color or thickness of an annotation	Click the Color tool to open the palette: 	
Change the Thickness of Dots or Lines in an Annotation	Adjust with the slider: 	With the thickness option selected with the mouse, left-arrow key for thinner or right-arrow key for thicker.
Change the Color of an Annotation	Click the color in the palette: 	Not available
Change the name of an annotation	Click the Edit Annotation tool  and type with a keyboard.	

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HOLOGIC®

Genius™ Review Station

Operator's Manual

HOLOGIC®

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
+1-508-263-2900

EC REP Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium

www.hologic.com

Patent Information
www.hologic.com/patent-information

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