HOLOGIC®

Genius® Review Station

Operator's Manual



Software version 1.2.x
MAN-12121-001 Rev. 003

Genius®
Review Station
Operator's Manual



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For Use With Version 1.2.y Software

MAN-12121-001

Caution: Federal 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 Genius Digital Diagnostics System with the Genius Cervical AI algorithm.

The Genius Digital Diagnostics System with the Genius Cervical AI algorithm is a PC-based automated imaging and review system for use with ThinPrep cervical cytology sample slides. The Genius Digital Diagnostics System with the Genius Cervical AI algorithm 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.

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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. Use of the Genius Review Station not in accordance with these instructions may void the warranty.

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Instructions For Use

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HOLOGIC®

Genius® Digital Diagnostics System with the Genius Cervical AI Algorithm

Instructions for Use



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INTENDED USE

The Genius Digital Diagnostics System with the Genius Cervical AI algorithm includes the Genius Digital Imager, Genius Image Management Server (IMS), the Genius Review Station, and the Genius Cervical AI algorithm. The Genius Digital Diagnostics System with the Genius Cervical AI algorithm is intended for the creation and viewing of digital images of scanned ThinPrep® Pap Test glass slides. Objects of interest selected by the Genius Cervical AI algorithm from the scanned digital image are presented in a gallery format, next to the image of the whole cell spot on the Genius Review Station, for review and interpretation. The Genius Digital Diagnostics System with the Genius Cervical AI algorithm is intended to aid in cervical cancer screening 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 as defined by The Bethesda System for Reporting Cervical Cytology[1].

After digital review with the Genius Cervical AI algorithm, if there is uncertainty in the diagnosis, then direct examination of the glass slide by light microscopy should be performed. Digital images from the Genius Digital Diagnostics System with the Genius Cervical AI algorithm should be interpreted by qualified cytologists and pathologists in conjunction with the patient's screening history, other risk factors, and professional guidelines which guide patient management.

SUMMARY AND EXPLANATION OF THE SYSTEM

The Genius Digital Diagnostics System with the Genius Cervical AI algorithm uses Pap test slides prepared from gynecologic (cervical/vaginal) samples obtained from women for screening, diagnosis and management.

Slides that have been prepared for screening using the ThinPrep 2000 system, the ThinPrep 5000 processor, or the ThinPrep Genesis™ processor and stained with ThinPrep stain (Papanicolaou stain) 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 an in-focus, whole slide image.

For ThinPrep Pap test patient sample slides, the Genius Cervical AI algorithm identifies objects of interest found on a digital image of the slide. The objects classified as most clinically relevant are presented 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 Image Management Server acts as the central data manager for the Genius Digital Diagnostics System with the Genius Cervical AI algorithm. 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 CT or pathologist reviews cases at the Review Station. The Review Station is a dedicated 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

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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 and comments in the case review. The reviewer, in addition to reviewing the gallery images, has the option to move to any portion of the cell spot for examination.

LIMITATIONS

- Performance characteristics of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm are based on using Genius Cervical AI tools, including the entire gallery, to assist in diagnosing a case and should be used accordingly. The performance of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm using only a digital review of the entire cell spot has not been evaluated.
- There is no priority or ranking in the order with which the objects of interest are displayed in the gallery and therefore, the user must review all objects in the gallery.
- After review of the entire gallery of images provided by the Genius Cervical AI algorithm, if there is uncertainty in diagnosis, then direct examination of the glass slide by light microscopy should be performed.
- Only personnel who have been trained in the use of the Genius Digital Imager, Review Station and Genius Cervical AI algorithm should operate the system.
- ThinPrep Imaging System microscope slides with fiducial marks must be used.
- The Genius Digital Diagnostics System with the Genius Cervical AI algorithm is indicated for use only with the slides prepared using a ThinPrep 2000 system, ThinPrep 5000 processor or ThinPrep Genesis processor and stained with ThinPrep stain. The Genius Digital Diagnostics System with the Genius Cervical AI algorithm is not indicated for the ThinPrep Pap test slides prepared with any other cytology processor including the ThinPrep 3000 processor.
- The laboratory Technical Supervisor should establish individual workload limits for personnel using the Genius Digital Diagnostics System with the Genius Cervical AI algorithm. Please also see section on “Cytologist Workload Determination”.
- Gynecological slides must be stained using the ThinPrep stain (Papanicolaou stain) according to the applicable ThinPrep Imaging System slide staining protocol.
- Slides should be clean and free of debris before being placed on the system.
- The slide coverslip should be dry and located correctly.
- Slides that are broken or poorly coverslipped should not be used.
- Slides should be imaged by the Genius Digital Imager in a timely manner, according to normal laboratory practices.
- Slides used with the Genius Digital Imager must contain properly formatted accession number identification information as described in the operator’s manual.

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- The performance of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm using slides prepared from reprocessed sample vials has not been evaluated.
- The monitor and graphics card for the Review Station are those supplied by Hologic specifically for the Genius Digital Diagnostics System with the Genius Cervical AI algorithm. They are required for proper performance of the system and cannot be substituted.

WARNINGS

- For *In Vitro* Diagnostic Use
- The Genius Digital Imager generates, uses, and can radiate radio frequency energy and may cause interference to radio communications.
- The Genius Digital Imager uses glass microscope slides, which may have sharp edges. In addition, the slides may be broken in their storage packaging or on the instrument. Use caution when handling glass slides and when cleaning the instrument.
- Performance may vary from site to site as a result of differences in patient populations and reading practices. As a result, each laboratory using this device should employ quality assurance and control systems per CLIA regulation 42 CFR 493.1274 to ensure proper use and selection of appropriate workload limits.
- Users should employ appropriate cybersecurity measures when the device is used for remote review.
- Service Installation Only. The system must be installed by trained Hologic personnel only.
- For professional use only.

PRECAUTIONS

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Digital Imager, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Care should be taken to assure that slides are correctly oriented in the Digital Imager slide carrier to prevent rejection by the system.
- The Digital Imager should be placed on a flat, sturdy surface away from any vibrating machinery to assure proper operation.

TRAINING AND QUALITY CONTROL

- Evaluation of cases should be performed only by cytologists and pathologists who have been trained, by Hologic or organizations designated by Hologic, to evaluate digital images of scanned ThinPrep Pap Test glass slides using Genius Cervical AI.
- For Cytologists who begin clinical use of the device, labs should consider additional training policies and procedures, as needed, such as re-review of a lab-determined number of cases.

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- If a product malfunction occurs, which caused, or could lead to an adverse event, the device user should consider filing a Medical Device Report (MDR) to US FDA using MedWatch Form 3500 (https://www.fda.gov/media/76299/download) for voluntary reporting.

PERFORMANCE CHARACTERISTICS

GENIUS DIGITAL DIAGNOSTICS SYSTEM WITH THE GENIUS CERVICAL AI ALGORITHM COMPARED TO GLASS SLIDE MANUAL REVIEW

A multi-center Genius Cervical AI Clinical Study was performed within the United States. The objective of the study was to show that routine screening of ThinPrep Pap test slides using the Genius Digital Diagnostics System with the Genius Cervical AI algorithm was comparable to the approved method of screening using glass slides with a light microscope.

The study included 1994 slides and four (4) clinical sites (laboratories). Slides were prepared from residual material after the clinical sites signed out the case, from women who were screened for cervical cancer using the ThinPrep Pap test. Samples that were enrolled were processed on the ThinPrep 2000 system, the ThinPrep 5000 processor, or the ThinPrep Genesis processor. At each of four (4) clinical sites, three (3) independent teams consisting of one (1) cytologist (CT) and one (1) pathologist at each site (CT/Pathologist teams) reviewed all cases at their site. All cases at the corresponding site were reviewed independently by the three teams at that particular site and, therefore, the number of reviews at the site were 3 x the number of slides at the site. Site CT/Pathologist teams screened cases in 3 review phases as follows: manual review of glass slides with a light microscope without the assistance of the ThinPrep Imaging System (TIS) (Manual review), review of glass slides with the ThinPrep Imaging System (TIS review), and review of digital images with the Genius Digital Diagnostics System with the Genius Cervical AI algorithm (Genius Cervical AI review), in that order. Cases with an ASCUS, AGC, LSIL, ASC-H, HSIL, Cancer or unsatisfactory for evaluation (UNSAT) result by the CT were also reviewed by the pathologist. A minimum 14-day washout period occurred between each review phase. The cases were randomized prior to each review phase. Cytological diagnoses and specimen adequacy were determined in accordance with the Bethesda System criteria.

An adjudicated diagnosis was used as a “gold standard” (“reference” or “ground truth”). Cases were screened by an adjudication panel, composed of three (3) adjudication CT/Pathologist teams, consisting of one (1) CT and one (1) pathologist each (adjudication CT/Pathologist teams). Slides were reviewed independently by the three teams. All cases, regardless of result, were reviewed by CTs and pathologists. For each case, results from each adjudication CT/Pathologist team were used to obtain a consensus result, defined as the result for which there was majority agreement (by at least two of the three adjudication CT/Pathologist teams). If a consensus result was not obtained initially, these cases underwent review by the three adjudication pathologists simultaneously using a multi-headed microscope (multi-head review). The reference result was based on either the consensus result (if met initially) or the multi-head review result (if consensus was not obtained initially). Cytological diagnoses and specimen adequacy were determined in accordance with the Bethesda System criteria: NILM, ASCUS, AGC, LSIL, ASC-H, HSIL, Cancer and UNSAT.

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Laboratory and Patient Characteristics

The cytology laboratories participating in the study were comprised of four (4) sites. All sites selected had extensive experience in the processing and evaluation of gynecologic ThinPrep Pap test slides and were trained in the use of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm.

There were 1995 slides that were eligible for the study. Of these, 1994 slides were included in the study and one (1) was excluded from the study because the slide failed the quality audit due to a scratched coverslip, an exclusion criterion. The total number of reviews was 5,982 (3 x 1994 slides). Thirty-four (34) cases (102 reviews) had adjudication results of UNSAT and the remaining 1960 cases (5,880 reviews) were Satisfactory (SAT) for evaluation and had reference adjudication diagnoses. Table 1 provides characteristics of the participating clinical sites. Table 2 describes the patient populations with SAT slides, at each of the study sites.

Table 1. Site Characteristics

Site	1	2	3	4
ThinPrep Pap Tests Per Year	48,000	239,750	329,500	4,500
Number of Cytologists in Study	3	3	3	3
Number of Pathologists in Study	3	3	3	3

Table 2. Site Demographics

Site Number	Total number	Median Age (yrs)	# Hysterectomy (% of enrolled)	# Postmenopausal (% of enrolled)
1	488	33.0	18 (3.7)	37 (7.6)
2	494	36.0	6 (1.2)	24 (4.9)
3	490	35.0	22 (4.5)	43 (8.8)
4	488	37.0	6 (1.2)	41 (8.4)
Overall	1960	35.0	52 (2.6)	141 (7.4)

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Eligibility Criteria

Cases were eligible to be included in the study if they met the following criteria: ThinPrep slides of known diagnoses generated from residual cytological specimens (within 6 weeks from date of collection) in the approximate number from the following enrollment diagnostic categories:

- NILM: 1060 cases
- ASCUS: 225 cases
- AGC: 20 cases
- LSIL: 225 cases
- ASC–H: 225 cases
- HSIL: 225 cases
- Cancers: 20 cases (squamous and/or adenocarcinoma)
- UNSAT 20 cases

Cases were excluded from the study if any of the following criteria applies:

- Any slides deemed not adequate, (if slide is broken, dilute, or is otherwise unreadable).

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Objective of the Clinical Study

The primary objectives of this study included comparing the sensitivity and specificity when diagnosing cases imaged and reviewed on the Genius Digital Diagnostics System with the Genius Cervical AI algorithm with the sensitivity and specificity of Manual review and also with TIS review. An adjudicated diagnosis was used as a "gold standard" ("reference" or "ground truth"). The comparison of sensitivities and specificities was performed at the following thresholds (described in Table 3 below): ASCUS+, LSIL+, ASC-H+, HSIL+, Cancer.

Table 3. Category Partitions

Threshold	Negative	Positive
ASCUS+	NILM	ASCUS, AGC, LSIL, ASC-H, HSIL, Cancer
LSIL+	NILM, ASCUS, AGC	LSIL, ASC-H, HSIL, Cancer
ASC-H+	NILM, ASCUS, AGC, LSIL	ASC-H, HSIL, Cancer
HSIL+	NILM, ASCUS, AGC, LSIL, ASC-H	HSIL, Cancer
Cancer	NILM, ASCUS, AGC, LSIL, ASC-H, HSIL	Cancer
Abbreviations for Diagnostic Thresholds: NILM: negative for intraepithelial lesion or malignancy; ASCUS: atypical squamous cells of undetermined significance; AGC: atypical glandular cells; LSIL: low grade squamous intraepithelial lesion; ASC-H: atypical squamous cells – cannot exclude HSIL; HSIL: High grade squamous intraepithelial lesion		

Sensitivity and specificity of each review type (Genius Cervical AI review, Manual review and TIS review) were calculated on all cases with a satisfactory reference result at the ASCUS+, LSIL+, ASC-H+, HSIL+ and Cancer diagnostic thresholds. Of these cases, UNSAT Genius Cervical AI, Manual, or TIS review results were considered positive at each diagnostic threshold.

Sensitivity was separately calculated on all cases with an UNSAT reference result, where sensitivity was defined as the proportion of Genius Cervical AI, Manual, or TIS review results of UNSAT or ASCUS+. Specificity was also calculated, where specificity was defined as the proportion of satisfactory Genius Cervical AI, Manual, or TIS review results on all cases with a satisfactory reference result.

Differences in sensitivities and differences in specificities were calculated along with two-sided 95% confidence intervals (95% CI).

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A) GENIUS CERVICAL AI REVIEW COMPARED WITH MANUAL REVIEW

A.1 Performance of Genius Cervical AI Review and Manual Review

Table 4.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Compared to Adjudicated Diagnosis

	Sensitivity %			Specificity %		
Diagnostic Threshold	**Genius Cervical AI (95% CI)**	**Manual (95% CI)**	**Difference (Genius Cervical AI – Manual) (95% CI)**	**Genius Cervical AI (95% CI)**	**Manual (95% CI)**	**Difference (Genius Cervical AI – Manual) (95% CI)**
ASCUS+	91.7 [1950/2127] (90.1, 93.3)	90.1 [1917/2127] (88.7, 91.8)	1.6 [33/2127] (-0.1, 3.2)	91.0 [3414/3753] (89.7, 92.1)	92.2 [3461/3753] (91.1, 93.2)	-1.3 [-47/3753] (-2.3, -0.2)
LSIL+	89.1 [1467/1647] (87.2, 91.0)	84.7 [1395/1647] (82.3, 86.8)	4.4 [72/1647] (2.1, 6.7)	91.7 [3883/4233] (90.5, 92.9)	94.1 [3984/4233] (93.1, 95.0)	-2.4 [-101/4233] (-3.5, -1.4)
ASC-H+	87.8 [938/1068] (84.8, 90.2)	79.6 [850/1068] (76.3, 82.5)	8.2 [88/1068] (4.8, 11.6)	94.2 [4531/4812] (93.2, 95.1)	97.0 [4669/4812] (96.4, 97.7)	-2.9 [-138/4812] (-3.8, -1.9)
HSIL+	81.5 [699/858] (78.5, 84.4)	74.0 [635/858] (70.1, 77.5)	7.5 [64/858] (4.0, 11.4)	94.8 [4763/5022] (94.0, 95.6)	97.2 [4882/5022] (96.6, 97.8)	-2.4 [-119/5022] (-3.0, -1.7)

The sensitivity of the Genius Cervical AI was statistically significantly higher for LSIL+, ASC-H+ and HSIL+. Increase in sensitivity was 4.4%, 8.2% and 7.5% for LSIL+, ASC-H+ and HSIL+, respectively. There were statistically significant decreases in specificity for ASCUS+, LSIL+, ASC-H+, and HSIL+ diagnostic thresholds. The decrease in specificity was 1.3%, 2.4%, 2.9% and 2.4% for ASCUS+, LSIL+, ASC-H+, and HSIL+, respectively.

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A.2 Genius Cervical AI Review vs. Manual Review Stratified by Site

ASCUS+

Sensitivity is a percent of "reference" ASCUS+ cases classified in Genius Cervical AI reviews or in Manual reviews as ASCUS+ or UNSAT, and specificity is a percent of "reference" NILM cases classified in either review as NILM.

Table 5.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Stratified by Site at ASCUS+

Sites	Number of Cases	Sensitivity (95%CI)			Specificity (95%CI)		
		Genius Cervical AI	Manual	Difference	Genius Cervical AI	Manual	Difference
Site 1	488	93.4 [538/576] (90.0, 96.1)	87.8 [506/576] (83.9, 91.3)	5.6 [32/576] (1.7, 8.7)	91.7 [814/888] (88.6, 94.1)	95.6 [849/888] (93.6, 97.3)	-3.9 [-35/888] (-6.3, -1.7)
Site 2	494	87.7 [479/546] (83.6, 90.9)	93.2 [509/546] (90.0, 95.8)	-5.5 [-30/546] (-9.0, -2.0)	93.3 [873/936] (91.2, 95.2)	90.9 [851/936] (88.4, 93.5)	2.4 [22/936] (0.3, 4.7)
Site 3	490	92.2 [506/549] (88.9, 95.0)	88.7 [487/549] (85.4, 92.0)	3.5 [19/549] (0.4, 6.1)	92.6 [853/921] (90.1, 94.9)	92.0 [847/921] (89.9, 93.8)	0.7 [6/921] (-1.9, 2.8)
Site 4	488	93.6 [427/456] (90.8, 96.1)	91.0 [415/456] (87.3, 94.7)	2.6 [12/546] (-0.6, 5.8)	86.7 [874/1008] (83.9, 89.4)	90.7 [914/1008] (88.1, 93.0)	-4.0 [-40/1008] (-6.2, -1.6)
Total	1960	91.7 [1950/2127] (90.1, 93.3)	90.1 [1917/2127] (88.7, 91.8)	1.6 [33/2127] (-0.1, 3.2)	91.0 [3414/3753] (89.7, 92.1)	92.2 [3461/3753] (91.1, 93.2)	-1.3 [-47/3753] (-2.3, -0.2)

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LSIL+

Sensitivity is a percent of "reference" LSIL+ cases classified in Genius Cervical AI reviews or in Manual reviews as LSIL+ or UNSAT, and specificity is a percent of "reference" (NILM or ASCUS or AGC) cases classified in either review as NILM or ASCUS or AGC.

Table 6.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Stratified by Site at LSIL+

Sites	Number of Cases	Sensitivity (95%CI)			Specificity (95%CI)		
		Genius Cervical AI	Manual	Difference	Genius Cervical AI	Manual	Difference
Site 1	488	88.5 [401/453] (84.2, 92.2)	83.7 [379/453] (78.9, 87.8)	4.9 [22/453] (0.5, 9.5)	91.0 [920/1011] (88.2, 93.8)	94.3 [953/1011] (92.3, 96.4)	-3.3 [-33/1011] (-5.6, -1.1)
Site 2	494	85.9 [348/405] (81.0, 89.8)	93.1 [377/405] (89.7, 96.2)	-7.2 [-29/405] (-11.1, -3.3)	92.9 [1000/1077] (90.8, 94.8)	92.3 [994/1077] (89.8, 94.5)	0.6 [6/1077] (-1.5, 2.7)
Site 3	490	89.7 [390/435] (86.2, 93.0)	72.6 [316/435] (66.9, 77.6)	17.0 [74/435] (12.2, 22.3)	92.4 [956/1035] (89.9, 94.5)	97.1 [1005/1035] (95.9, 98.3)	-4.7 [-49/1035] (-7.1, -2.9)
Site 4	488	92.7 [328/354] (89.5, 95.1)	91.2 [323/354] (87.2, 94.6)	1.4 [5/354] (-2.7, 5.9)	90.7 [1007/1110] (88.4, 92.9)	93.0 [1032/1110] (90.8, 94.9)	-2.3 [-25/1110] (-4.1, 0.1)
Total	1960	89.1 [1467/1647] (87.2, 91.0)	84.7 [1395/1647] (82.3, 86.8)	4.4 [72/1647] (2.1, 6.7)	91.7 [3883/4233] (90.5, 92.9)	94.1 [3984/4233] (93.1, 95.0)	-2.4 [-101/4233] (-3.5, -1.4)

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ASC-H+

Sensitivity is a percent of "reference" ASC-H+ cases classified in Genius Cervical AI reviews or in Manual reviews as ASC-H+ or UNSAT, and specificity is a percent of "reference" (NILM or ASCUS or AGC or LSIL) cases classified in either review as NILM or ASCUS or AGC or LSIL.

Table 7.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Stratified by Site at ASC-H+

Sites	Number of Cases	Sensitivity (95%CI)			Specificity (95%CI)		
		Genius Cervical AI	Manual	Difference	Genius Cervical AI	Manual	Difference
Site 1	488	85.7 [257/300] (80.0, 90.4)	80.0 [240/300] (74.1, 85.3)	5.7 [17/300] (0.0, 11.8)	92.4 [1075/1164] (89.7, 94.6)	96.1 [1119/1164] (94.5, 97.7)	-3.8 [-44/1164] (-5.6, -2.0)
Site 2	494	83.3 [230/276] (77.3, 88.7)	90.9 [251/276] (86.1, 95.4)	-7.6 [-21/276] (-13.4, -2.7)	96.5 [1164/1206] (94.9, 97.9)	96.0 [1158/1206] (94.5, 97.5)	0.5 [6/1206] (-1.0, 2.1)
Site 3	490	92.3 [241/261] (87.8, 95.9)	69.7 [182/261] (62.6, 77.2)	22.6 [59/261] (15.6, 28.9)	94.5 [1143/1209] (92.5, 96.4)	98.5 [1191/1209] (97.7, 99.2)	-4.0 [-48/1209] (-5.7, -2.3)
Site 4	488	90.9 [210/231] (87.0, 94.4)	76.6 [177/231] (68.8, 84.0)	14.3 [33/231] (6.3, 22.8)	93.2 [1149/1233] (91.2, 95.1)	97.4 [1201/1233] (96.3, 98.5)	-4.2 [-52/1233] (-6.2, -2.4)
Total	1960	87.8 [938/1068] (84.8, 90.2)	79.6 [850/1068] (76.3, 82.5)	8.2 [88/1068] (4.8, 11.6)	94.2 [4531/4812] (93.2, 95.1)	97.0 [4669/4812] (96.4, 97.7)	-2.9 [-138/4812] (-3.8, -1.9)

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HSIL+

Sensitivity is a percent of "reference" HSIL+ cases classified in Genius Cervical AI reviews or in Manual reviews as HSIL+ or UNSAT, and specificity is a percent of "reference" (NILM or ASCUS or AGC or LSIL or ASC-H) cases classified in either review as NILM or ASCUS or AGC or LSIL or ASC-H.

Table 8.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Stratified by Site at HSIL+

Sites	Number of Cases	Sensitivity (95%CI)			Specificity (95%CI)		
		Genius Cervical AI	Manual	Difference	Genius Cervical AI	Manual	Difference
Site 1	488	79.4 [193/243] (72.4, 86.3)	74.5 [181/243] (68.4, 81.0)	4.9 [12/243] (-2.4, 12.3)	93.5 [1142/1221] (91.1, 95.4)	95.7 [1169/1221] (94.0, 97.2)	-2.2 [-27/1221] (-3.9, -0.9)
Site 2	494	77.5 [179/231] (70.3, 84.6)	87.4 [202/231] (80.3, 93.3)	-10.0 [-23/231] (-17.0, -4.1)	96.8 [1211/1251] (95.5, 97.9)	96.8 [1211/1251] (95.4, 98.0)	0.0 [0/1251] (-1.1, 1.0)
Site 3	490	83.8 [171/204] (77.8, 89.5)	54.4 [111/204] (45.7, 62.9)	29.4 [60/204] (22.4, 37.5)	95.6 [1210/1266] (94.0, 97.0)	99.4 [1259/1266] (98.9, 99.8)	-3.9 [-49/1266] (-5.3, -2.5)
Site 4	488	86.7 [156/180] (82.1, 91.3)	78.3 [141/180] (70.7, 86.8)	8.3 [15/180] (0.0, 15.7)	93.5 [1200/1284] (91.8, 95.1)	96.8 [1243/1284] (95.5, 98.0)	-3.3 [-43/1284] (-4.9, -1.7)
Total	1960	81.5 [699/858] (78.5, 84.4)	74.0 [635/858] (70.1, 77.5)	7.5 [64/858] (4.0, 11.4)	94.8 [4763/5022] (94.0, 95.6)	97.2 [4882/5022] (96.6, 97.8)	-2.4 [-119/5022] (-3.0, -1.7)

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Cancer

Sensitivity is a percent of "reference" Cancer cases classified in Genius Cervical AI reviews or in Manual reviews as Cancer or UNSAT, and specificity is a percent of "reference" (NILM or ASCUS or AGC or LSIL or ASC-H or HSIL) cases classified in either review as NILM or ASCUS or AGC or LSIL or ASC-H or HSIL.

Table 9.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Stratified by Site at Cancer

Sites	Number of Cases	Sensitivity (95%CI)			Specificity (95%CI)		
		Genius Cervical AI	Manual	Difference	Genius Cervical AI	Manual	Difference
Site 1	488	66.7 [14/21] (25.0, 100.0)	76.2 [16/21] (50.0, 100.0)	-9.5 [-2/21] (-33.3, 11.1)	98.3 [1418/1443] (97.0, 99.2)	98.6 [1423/1443] (97.7, 99.3)	-0.3 [-5/1443] (-1.1, 0.3)
Site 2	494	66.7 [14/21] (20.8, 100.0)	85.7 [18/21] (63.0, 100.0)	-19.0 [-4/21] (-44.4, 0.0)	98.6 [1440/1461] (97.8, 99.3)	97.7 [1428/1461] (96.5, 98.8)	0.8 [12/1461] (0.1, 1.6)
Site 3	490	60.6 [20/33] (33.3, 84.6)	39.4 [13/33] (16.7, 66.7)	21.2 [7/33] (3.7, 40.0)	98.9 [1421/1437] (98.2, 99.5)	99.4 [1429/1437] (98.8, 99.9)	-0.6 [-8/1437] (-1.3, 0.1)
Site 4	488	76.2 [16/21] (44.4, 100.0)	81.0 [17/21] (55.6, 100.0)	-4.8 [-1/21] (-22.2, 13.3)	98.4 [1420/1443] (97.6, 99.1)	98.4 [1420/1443] (97.6, 99.2)	0.0 [0/1443] (-0.8, 0.8)
Total	1960	66.7 [64/96] (51.7, 80.6)	66.7 [64/96] (54.3, 79.0)	0.0 [0/96] (-9.8, 11.1)	98.5 [5699/5784] (98.0, 98.9)	98.5 [5700/5784] (98.1, 98.9)	-0.0 [-1/5784] (-0.4, 0.4)

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UNSAT

Sensitivity is a percent of "reference" UNSAT cases classified in Genius Cervical AI reviews or in Manual reviews as UNSAT or ASCUS+, and specificity is a percent of "reference" Satisfactory (SAT) slides classified in either review as SAT.

Table 10.
Sensitivity and Specificity of Genius Cervical AI Review and Manual Review Stratified by Site at UNSAT

Sites	Number of Cases	Sensitivity (95%CI)			Specificity (95%CI)		
		Genius Cervical AI	Manual	Difference	Genius Cervical AI	Manual	Difference
Site 1	503	86.7 [39/45] (71.1, 100)	51.1 [23/45] (26.7, 73.3)	35.6 [16/45] (11.1, 57.8)	99.6 [1458/1464] (98.9, 100)	99.9 [1463/1464] (99.8, 100)	-0.3 [-5/1464] (-1.0, 0.1)
Site 2	500	77.8 [14/18] (55.6, 94.4)	77.8 [14/18] (55.6, 100)	0.0 [0/18] (-16.7, 16.7)	99.6 [1476/1482] (99.1, 100)	99.7 [1478/1482] (99.3, 100)	-0.1 [-2/1482] (-0.5, 0.1)
Site 3	495	80.0 [12/15] (40.0, 100)	53.3 [8/15] (26.7, 66.7)	26.7 [-4/15] (13.3, 33.3)	99.7 [1465/1470] (99.2, 100)	99.9 [1468/1470] (99.7, 100)	-0.2 [-3/1470] (-0.6, 0.1)
Site 4	496	70.8 [17/24] (37.5, 95.8)	75.0 [18/24] (50.0, 95.8)	-4.2 [-1/24] (-29.2, 25.0)	100 [1464/1464] (100, 100)	99.3 [1454/1464] (98.8, 99.8)	0.7 [10/1464] (0.2, 1.2)
Total	1994	80.4 [82/102] (67.6, 91.2)	61.8 [63/102] (50.0, 72.5)	18.6 [19/102] (5.9, 31.4)	99.7 [5863/5880] (99.5, 99.9)	99.7 [5863/5880] (99.5, 99.9)	0.0 [0/5880] (-0.2, 0.2)

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A.3: Tables of performance of each Bethesda Category

Table 11 through Table 18 summarize results from Genius Cervical AI review and Manual review for each of the major descriptive diagnosis classifications of the Bethesda System as determined by the adjudication diagnosis: NILM, ASCUS, AGC, LSIL, ASC-H, HSIL, Cancer, and the diagnostic category UNSAT.

Table 11. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of NILM

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius Cervical AI	**UNSAT**	3	10	1	0	0	0	0	0	14
	NILM	10	3250	113	12	8	19	2	0	3414
	ASCUS	0	122	43	0	7	4	1	0	177
	AGC	1	19	1	0	0	2	2	0	25
	LSIL	0	16	22	0	4	0	0	0	42
	ASC-H	1	30	10	0	1	5	1	1	49
	HSIL	1	10	6	0	3	2	5	0	27
	Cancer	0	4	0	1	0	0	0	0	5
	Total	16	3461	196	13	23	32	11	1	3753

Among the 3753 reviews determined by the adjudication panel to be NILM, 3414 (91.0%) reviews in the Genius Cervical AI Review and 3461 (92.2%) reviews in the Manual Review were diagnosed as NILM, and 81 (2.2%) reviews in the Genius Cervical AI Review and 44 (1.2%) reviews in the Manual Review were diagnosed as ASC-H+, including 5 (0.13%) reviews in Genius Cervical AI Review and 1 (0.03%) review in the Manual Review that were diagnosed as Cancer.

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Table 12. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of ASCUS

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius Cervical AI	**UNSAT**	0	2	1	0	0	0	0	0	3
	NILM	0	49	40	0	16	6	2	0	113
	ASCUS	0	35	70	1	32	1	3	0	142
	AGC	0	0	0	0	0	0	0	0	0
	LSIL	0	20	51	0	48	2	0	0	121
	ASC-H	0	11	15	0	10	8	3	0	47
	HSIL	0	1	8	0	11	3	6	0	29
	Cancer	0	0	2	0	0	1	0	1	4
	Total	0	118	187	1	117	21	14	1	459

Among the 459 reviews determined by the adjudication panel to be ASCUS, 142 (30.9%) reviews in the Genius Cervical AI Review and 187 (40.7%) reviews in the Manual Review were diagnosed as ASCUS, and 113 (24.6%) reviews in the Genius Cervical AI Review and 118 (25.7%) reviews in the Manual Review were diagnosed as NILM.

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Table 13. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of AGC

		Manual								
		UNSAT	NILM	ASCUS	AGC	LSIL	ASC-H	HSIL	Cancer	Total
Genius Cervical AI	UNSAT	0	0	0	0	0	0	0	0	0
	NILM	0	5	0	0	0	1	0	1	7
	ASCUS	0	0	0	0	0	0	0	0	0
	AGC	0	1	0	1	0	0	0	3	5
	LSIL	0	0	0	0	0	0	0	0	0
	ASC-H	0	1	0	0	0	0	0	0	1
	HSIL	0	0	0	0	0	0	0	0	0
	Cancer	0	0	0	0	0	0	1	7	8
	Total	0	7	0	1	0	1	1	11	21

Among the 21 reviews determined by the adjudication panel to be AGC, 5 (23.8%) reviews in the Genius Cervical AI Review and 1 (4.8%) review in the Manual Review were diagnosed as AGC, and 7 (33.3%) reviews in the Genius Cervical AI Review and 7 (33.3%) reviews in the Manual Review were diagnosed as NILM.

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Table 14. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of LSIL

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius Cervical AI	**UNSAT**	0	0	0	0	0	0	0	0	0
	NILM	0	2	6	0	2	0	1	0	11
	ASCUS	0	10	17	0	35	1	1	0	64
	AGC	0	0	0	0	0	0	0	0	0
	LSIL	0	18	35	0	351	2	4	0	410
	ASC-H	0	0	8	0	16	1	1	0	26
	HSIL	0	1	3	0	39	7	15	1	66
	Cancer	0	0	1	0	1	0	0	0	2
	Total	0	31	70	0	444	11	22	1	579

Among the 579 reviews determined by the adjudication panel to be LSIL, 410 (70.8%) reviews in the Genius Cervical AI Review and 444 (76.7%) reviews in the Manual Review were diagnosed as LSIL, and 11 (1.9%) reviews in the Genius Cervical AI Review and 31 (5.4%) reviews in the Manual Review were diagnosed as NILM.

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Table 15. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of ASC-H

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius Cervical AI	**UNSAT**	0	0	0	0	0	0	0	0	0
	NILM	0	9	0	0	0	5	5	0	19
	ASCUS	0	4	4	1	2	4	5	0	20
	AGC	0	1	1	0	0	1	0	0	3
	LSIL	0	0	0	0	3	1	2	0	6
	ASC-H	0	6	14	0	8	23	10	0	61
	HSIL	0	10	20	0	10	21	33	1	95
	Cancer	0	0	0	0	0	0	1	5	6
	Total	0	30	39	1	23	55	56	6	210

Among the 210 reviews determined by the adjudication panel to be ASC-H, 61 (29.0%) reviews in the Genius Cervical AI Review and 55 (26.2%) reviews in the Manual Review were diagnosed as ASC-H, and 19 (9.0%) reviews in the Genius Cervical AI Review and 30 (14.3%) reviews in the Manual Review were diagnosed as NILM.

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Table 16. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of HSIL

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius Cervical AI	**UNSAT**	0	0	0	0	0	0	0	0	0
	NILM	0	1	1	1	0	5	11	4	23
	ASCUS	0	0	3	0	0	7	9	0	19
	AGC	0	1	1	0	0	2	6	1	11
	LSIL	0	0	0	0	12	0	7	0	19
	ASC-H	0	3	9	1	8	18	34	2	75
	HSIL	1	18	21	8	23	62	418	21	572
	Cancer	0	0	1	1	1	1	20	19	43
	Total	1	23	36	11	44	95	505	47	762

Among the 762 reviews determined by the adjudication panel to be HSIL, 572 (75.1%) reviews in the Genius Cervical AI Review and 505 (66.3%) reviews in the Manual Review were diagnosed as HSIL, and 23 (3.0%) reviews in the Genius Cervical AI Review and 23 (3.0%) reviews in the Manual Review were diagnosed as NILM.

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Table 17. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Diagnoses of Cancer

		Manual								
		UNSAT	NILM	ASCUS	AGC	LSIL	ASC-H	HSIL	Cancer	Total
Genius Cervical AI	UNSAT	0	0	0	0	0	0	0	0	0
	NILM	0	1	0	0	0	0	1	2	4
	ASCUS	0	0	0	0	0	0	1	0	1
	AGC	0	0	1	1	0	0	0	3	5
	LSIL	0	0	0	0	0	0	0	0	0
	ASC-H	0	0	0	0	0	1	0	1	2
	HSIL	0	0	1	1	0	1	13	4	20
	Cancer	0	0	1	5	0	1	3	54	64
	Total	0	1	3	7	0	3	18	64	96

Among the 96 reviews determined by the adjudication panel to be Cancer, 64 (66.7%) reviews in the Genius Cervical AI Review and 64 (66.7%) reviews in the Manual Review were diagnosed as Cancer, and 4 (4.2%) reviews in the Genius Cervical AI Review and 1 (1.0%) review in the Manual Review were diagnosed as NILM.

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Table 18. Genius Cervical AI Review and Manual Review Results for All Diagnostic Categories in Slides with Adjudicated Results of UNSAT

		Manual								
		UNSAT	**NILM**	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius Cervical AI	**UNSAT**	50	22	0	0	0	0	0	0	72
	NILM	6	14	0	0	0	0	0	0	20
	ASCUS	2	1	0	0	0	0	0	0	3
	AGC	0	1	1	0	0	0	0	0	2
	LSIL	0	0	0	0	0	0	0	0	0
	ASC-H	1	0	1	1	0	1	0	0	4
	HSIL	0	0	0	0	0	0	0	0	0
	Cancer	0	1	0	0	0	0	0	0	1
	Total	59	39	2	1	0	1	0	0	102

Among the 102 reviews determined by the adjudication panel to be UNSAT, 72 (70.6%) reviews in the Genius Cervical AI Review and 59 (57.8%) reviews in the Manual Review were diagnosed as UNSAT, and 20 (19.6%) reviews in the Genius Cervical AI Review and 39 (38.2%) reviews in the Manual Review were diagnosed as NILM.

For slides diagnosed as UNSAT by adjudication, the Genius Digital Diagnostics System with the Genius Cervical AI algorithm correctly identified 18.6% more slides than Manual as UNSAT or ASCUS+.

In summary, comparison of the performances of Genius Digital Diagnostic System with the Genius Cervical AI algorithm and Manual reviews with regard to false NILM results is presented in Table 19 below.

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Table 19. Summary of False NILM results for Genius Cervical AI Review and Manual Review

Review Type	Reference results by Adjudication						
% False NILM	**ASCUS**	**AGC**	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Overall**
Genius Cervical AI	24.6% (113/459)	33.3% (7/21)	1.9% (11/579)	9.0% (19/210)	3.0% (23/762)	4.2% (4/96)	8.3% (177/2127)
Manual	25.7% (118/459)	33.3% (7/21)	5.4% (31/579)	14.3% (30/210)	3.0% (23/762)	1.0% (1/96)	9.9% (210/2127)
Genius Cervical AI – Manual	-1.1% (-5/459)	0.0% (0/21)	-3.5% (-20/579)	-5.2% (-11/210)	0.0% (0/762)	3.1% (3/96)	-1.6% (-33/2127)

Comparison of the performances of Genius Digital Diagnostic System with the Genius Cervical AI algorithm and Manual reviews with regard to false LSIL+ for the cases with NILM reference results by adjudication is presented in Table 20 below.

Table 20. Summary of False positive results for Genius Cervical AI Review and Manual Review

Percent of LSIL, ASC-H, HSIL and Cancer for cases with NILM reference results by Adjudication					
Review Type	**LSIL**	**ASC-H**	**HSIL**	**Cancer**	**Total**
Genius Cervical AI	1.12% (42/3753)	1.31% (49/3753)	0.72% (27/3753)	0.13% (5/3753)	3.28% (123/3753)
Manual	0.61% (23/3753)	0.85% (32/3753)	0.29% (11/3753)	0.03% (1/3753)	1.79% (67/3753)
Genius Cervical AI – Manual	0.51% (19/3753)	0.45% (17/3753)	0.43% (16/3753)	0.11% (4/3753)	1.49% (56/3753)

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B. GENIUS CERVICAL AI REVIEW COMPARED WITH TIS REVIEW

Performance of Genius Cervical AI Review and TIS Review

The study also compared the performance of ThinPrep slides reviewed on the Genius Digital Diagnostic System with the Genius Cervical AI algorithm with ThinPrep slides reviewed on the ThinPrep Imaging System (TIS). The results for the Genius Cervical AI review versus TIS review are presented in Table 21.

Table 21. Sensitivity and Specificity of Genius Cervical AI Review and TIS Review Compared to Adjudicated Diagnosis

	Sensitivity %			Specificity %		
Diagnostic Threshold	**Genius Cervical AI (95% CI)**	**TIS (95% CI)**	**Difference (Genius Cervical AI – TIS) (95% CI)**	**Genius Cervical AI (95% CI)**	**TIS (95% CI)**	**Difference (Genius Cervical AI – TIS) (95% CI)**
ASCUS+	91.7 [1950/2127] (90.1, 93.3)	91.6 [1948/2127] (90.0, 93.0)	0.1 [2/2127] (-1.6, 1.5)	91.0 [3414/3753] (89.7, 92.1)	92.6 [3474/3753] (91.5, 93.6)	-1.6 [-60/3753] (-2.8, -0.6)
LSIL+	89.1 [1467/1647] (87.2, 91.0)	87.7 [1444/1647] (85.6, 89.8)	1.4 [23/1647] (-0.6, 3.6)	91.7 [3883/4233] (90.5, 92.9)	93.3 [3950/4233] (92.2, 94.4)	-1.6 [-67/4233] (-2.6, -0.5)
ASC-H+	87.8 [938/1068] (84.8, 90.2)	84.3 [900/1068] (80.9, 87.0)	3.6 [38/1068] (0.6, 6.6)	94.2 [4531/4812] (93.2, 95.1)	96.4 [4639/4812] (95.6, 97.2)	-2.2 [-108/4812] (-3.1, -1.3)
HSIL+	81.5 [699/858] (78.5, 84.4)	77.9 [668/858] (74.0, 81.5)	3.6 [31/858] (0.0, 7.4)	94.8 [4763/5022] (94.0, 95.6)	96.6 [4850/5022] (95.9, 97.3)	-1.7 [-87/5022] (-2.4, -1.0)

The observed sensitivity of the Genius Cervical AI review was greater than TIS review at the ASCUS+, LSIL+, ASC-H+, and HSIL+ thresholds. The increase in sensitivity was 3.6% for both ASC-H+ and HSIL+ and statistically significant. There were statistically significant decreases in specificity for the ASCUS+, LSIL+, ASC-H+, and HSIL+ diagnostic thresholds. The decrease in specificity was 1.6%, 1.6%, 2.2% and 1.7% for ASCUS+, LSIL+, ASC-H+, and HSIL+, respectively.

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C. DESCRIPTIVE DIAGNOSIS FOR BENIGN CELLULAR CHANGES

Table 22 shows the descriptive diagnosis marginal frequencies for benign cellular changes and other non-neoplastic findings for all sites combined. Each case was read by each of 3 site CT/Pathologist teams. Each case was read first by a cytologist; non-NILM slides (as determined by the cytologist) were read by a pathologist from the same site CT/Pathologist team.

Table 22. Unadjudicated Marginal Frequencies – Summary of Descriptive Diagnosis for Benign Cellular Changes

	Manual Review		TIS Review		Genius Cervical AI Review	
Number of Reviews	5880		5880		5880	
Descriptive Diagnosis	**N**	**%**	**N**	**%**	**N**	**%**
Benign Cellular Changes	**721**	**12.3**	**686**	**11.7**	**1035**	**17.6**
Organisms:						
Trichomonas vaginalis	71	1.2	70	1.2	103	1.8
Fungal organisms consistent with Candida spp.	261	4.4	222	3.8	312	5.3
Shift in flora s/o bacterial vaginosis	371	6.3	373	6.3	562	9.6
Bacteria consistent with *Actinomyces* spp.	16	0.3	19	0.3	54	0.9
Cellular changes consistent with Herpes virus	2	0	2	0	3	0.1
Other infection	0	0	0	0	1	0
Other Non-Neoplastic Findings	**440**	**7.5**	**346**	**5.9**	**513**	**8.7**
Reactive cellular changes associated with inflammation	227	3.9	160	2.7	279	4.7
Atrophy	191	3.2	168	2.9	198	3.4
Reactive cellular changes associated with radiation	1	0	0	0	0	0
Reactive cellular changes associated with IUD	0	0	1	0	0	0
Glandular cells status post hysterectomy	0	0	0	0	2	0
Endometrial cells in a woman ≥45 yrs of age	21	0.4	17	0.3	34	0.6

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Presence of Endocervical Component	**4387**	**74.6**	**4239**	**72.1**	**4602**	**78.3**

A higher percentage of infectious organisms/vaginal infections (17.6% [1035/5880] vs 12.3% [721/5880]) and non-neoplastic findings (8.7% [513/5880] vs 7.5% [440/5880]) was observed using Genius Cervical AI review compared to Manual review, respectively. A higher percentage of infectious organisms/vaginal infections (17.6% [1035/5880] vs 11.7% [686/5880]) and non-neoplastic findings (8.7% [513/5880] vs 5.9% [346/5880]) was also observed using Genius Cervical AI review compared to TIS review, respectively.

ANALYTICAL PERFORMANCE OF THE GENIUS DIGITAL DIAGNOSTICS SYSTEM WITH THE GENIUS CERVICAL AI ALGORITHM

CELL COUNT STUDY

A study was conducted to evaluate the performance of the cell count metric produced by the Genius Cervical AI algorithm compared to a manual cell count.

ThinPrep Pap test patient sample slides were prepared on a ThinPrep 5000 processor, stained and coverslipped. The same slides were imaged on three Genius Digital Imagers three separate times. To obtain the manual cell count for the slides in the study, a CT viewed the whole slide image presented on the Genius Review Station, counted the cells presented in a portion of the cell spot image, and estimated the total number of cells based on the portion, similar to the normal process for counting cells on slides viewed on a microscope. The cell counts derived on each Digital Imager by the algorithm in the Genius Digital Diagnostics System were compared to the manual cell count estimate.

A total of 50 specimens, including at least 8 slides with counts near the clinically important threshold of 5000 cells, were enrolled in the study. The slides covered a range of cellularity typical of a clinical environment.

Using this study data, the within-imager precision %CV was 0.6% and between-imager %CV was 2.7%.

Figure 1 compares the cell counts between the Genius Cervical AI algorithm and a manual cell count method for each specimen.

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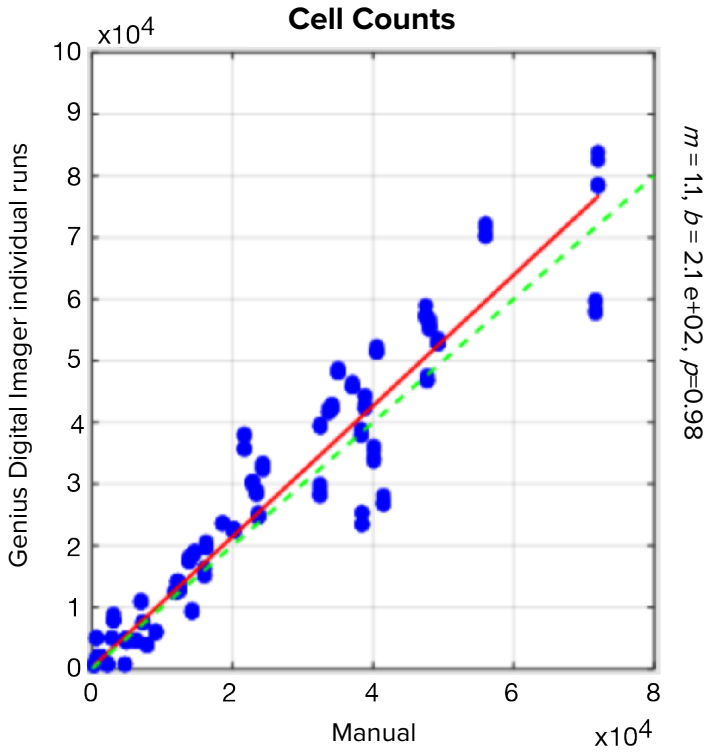
Figure 1. Scatter Plot of Digital Result versus Manual Result



The appropriate linear regression analysis was performed, and slope was 1.06 with 95% CI: (1.01; 1.11) and the intercept of 213 with 95% CI: (28; 398). The relative systematic difference between digital review and manual review counts at 5,000 cells was 10% with 95% CI: (4%; 17%).

The results of the Cell Count Study were acceptable.

OBJECTS OF INTEREST (OOI) REPRODUCIBILITY STUDY

A study was conducted to demonstrate that the Genius Cervical AI algorithm accurately and reproducibly selects Objects of Interest (OOI), at one site. An OOI is a cell or cluster of cells on a glass slide scanned by the Genius Diagnostics System with the Genius Cervical AI algorithm that most likely contains clinically relevant information for diagnostic purposes. The study compared OOIs selected by the Genius Cervical AI algorithm to the reference diagnosis by adjudication for the slide. The study evaluated the performance of the Genius Cervical AI algorithm to present images suitable for diagnosing abnormal cervical cases. The study also measured reproducibility of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm.

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In the study, 37 ThinPrep Pap test slides were enrolled, selected from slides used in the clinical study for the Genius Digital Diagnostics System with the Genius Cervical AI algorithm, covering the full range of abnormal diagnostic categories as defined in *The Bethesda System for Reporting Cervical Cytology*. These slides were made on the ThinPrep 2000 system, ThinPrep 5000 processor, and ThinPrep Genesis processor. The slides were imaged three times on three different Genius Digital Imagers.

Three CTs independently reviewed the nine runs of each case on the Genius Digital Diagnostics System with the Genius Cervical AI algorithm, blinded as to the reference diagnosis for the case. In each review on the Genius Digital Diagnostics System with the Genius Cervical AI algorithm, the CT recorded what the CT observed in every tile in the gallery for the case on the Review Station.

The accuracy and reproducibility of the algorithm were measured by comparison to the adjudicated reference diagnoses determined during the clinical study.

OOI Study Results

Table 23. OOI Summary by Reference Category (all CTs)

Reference Dx	# Slides	# of Evaluations	Proportion Abnormal OOIs	Median # Abnormal OOIs	Range of Number Abnormal OOIs (Min; Max)	Proportion Category+ OOIs	Median # Category+ OOIs	Range of Number Cat+ OOIs (Min; Max)
UNSAT	2	54	31%	0	0 ; 5			
NILM	5	135	16%	0	0 ; 4			
ASCUS	5	135	100%	6	2 ; 17	100%	6	2 ; 17
LSIL	5	135	100%	10	3 ; 23	96%	5	0 ; 23
ASC-H	5	135	100%	13	4 ; 22	100%	11	3 ; 19
AGC	5	135	100%	12	3 ; 24	100%	12	3 ; 24
HSIL	5	135	100%	18	12 ; 25	100%	9	2 ; 21
CANCER	5	135	100%	14	5 ; 20	92%	6	0 ; 14
All Abnormal	30	810	100%	13	3 ; 25	98%	8	0 ; 24

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OOI Summary by Reference Category Table Key:

- # of evaluations = (total valid runs) * (# of CTs for the given diagnosis subset of slides)
- Proportion abnormal = the fraction of evaluations for which at least one abnormal OOI was observed
- Median # abnormal = the median number of abnormal OOIs in the evaluations
- Proportion category+ = the fraction of evaluations for which at least one OOI that is equal or greater than the reference diagnosis observed.

Reference Dx	"Category+" OOI labels
ASCUS	ASCUS, LSIL, ASC-H, AGC, HSIL, Cancer
LSIL	LSIL, ASC-H, HSIL, Cancer
ASC-H	ASC-H, HSIL, Cancer
HSIL	HSIL, Cancer
Cancer	Cancer

- Median # category+ = the median number of OOIs that are category+ in the evaluations

Note that, for the reference cancer slide reviews, while 100% had OOIs marked by the CTs as ASCUS+, 92% had OOIs marked as cancer.

Agreement Rates by Threshold

Table 24 below shows the positive agreement rate of the OOIs at various abnormal thresholds.
For example, there were 20 LSIL+ slides (combined LSIL, ASC-H, HSIL, and CANCER), evaluated by 3 CTs over 9 imaging runs for a total of 540 evaluations. Of those, 530 had LSIL OOIs or higher for an agreement rate of 530/540 = 98%.

Table 24. Agreement rates by Reference Threshold

Threshold	# of Evaluations	Agreement Rate
ASCUS+	810	100%
LSIL+	540	98%
ASC-H+	405	99%
HSIL+	270	99%
CANCER	135	92%

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OOI Reproducibility

Table 25 below shows the between-instrument and within-instrument agreement rates for the presence of Category+ OOIs.

Table 25. OOI Reproducibility

	# of Pairs	% Agreement
Between-instrument	999	96%
Within-instrument	999	99%

TECHNICAL PERFORMANCE CHARACTERISTICS

Multiple studies were conducted to evaluate the performance of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm.

Study Name	Study Description	Results
Slide Feeder	Evaluate the configuration of the slide feeder mechanism, user interaction with the slide feeder, including hardware, software, feedback mechanisms, and Failure Mode and Effects Analysis (FMEA).	Performance met the defined criteria
Light Source	Verify the intensity and spectral variation of the LED light source at various time intervals.	Performance met the defined criteria
Imaging Optics	Test magnification, relative irradiance, optical distortions, and chromatics aberrations.	Performance met the defined criteria
Mechanical Scanner Movement	Test positioning accuracy and repeatability for the X-Y and Z stages.	Performance met the defined criteria
Digital Imaging Sensor	Measure and evaluate linearity, spatial uniformity, dark current, noise, opto-electronic conversion function, and electron conversion factor of the sensor.	Performance met the defined criteria
Image Processing Software	Test image processing for the Genius Digital Diagnostics System with the Genius Cervical AI algorithm.	Performance met the defined criteria
Image Composition	Test specifications on the scanning method.	Performance met the defined criteria
Image File Format	Test compression method, compression ratio, file format, and file organization.	Performance met the defined criteria
Image Review Manipulation Software	Test continuous panning, continuous zooming, and digital bookmarks.	Performance met the defined criteria
Computer Environment	Test computer hardware, operating system, memory, hard disk, graphics card, graphics card driver, color management settings, color profile, display interface and network specification.	Performance met the defined criteria

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Study Name	Study Description	Results
Display	Test to verify the performance of the display including color-calibration tools and quality-control.	Performance met the defined criteria
Structural Similarity Index Measurement (SSIM)	Assessment of the SSIM that combines measurements of luminance, contrast, and structure at the pixel level across multiple runs, instruments, and calibration cycles.	Performance met the defined criteria
Color Reproducibility	Test to quantify the accuracy and precision of the color transformation from the slide to the display monitor.	Performance met the defined criteria
Spatial Resolution	Test to evaluate the spatial resolution, including the composite optical performance of all components in the image acquisition phase.	Performance met the defined criteria
Focus Test	Test to demonstrate the focus quality of the whole slide images produced by the Genius Digital Imager.	Performance met the defined criteria
Whole Slide Tissue Coverage	Test to demonstrate that the entire specimen on the clinical slide is detected by the device.	Performance met the defined criteria
Stitching Error	Test to assess the quality and accuracy of stitching image swaths in the Genius Digital Imager.	Performance met the defined criteria
Turnaround Time	Test to evaluate the average time required to execute zooming and panning operations, and to refresh the display in response to user input.	Performance met the defined criteria
User Interface	Human Factors Engineering or Usability Engineering testing regarding user interactions with the Genius Digital Imager and Genius Review Station.	Performance met the defined criteria

CYTOLOGIST SCREENING TIME STUDY

As part of the Genius Cervical AI Clinical Study, Hologic collected cytologist screening time data and calculated accuracy.

The study data includes the case review times for a total of 12 cytologists, screening a total of 1994 digital cytology cases in a clinical setting, although the review periods varied as cytologists were not fully dedicated to the clinical study. The study measured the diagnostic performance results of each CT compared to adjudicated diagnoses.

The results are summarized below in Table 26 which shows the median case review time for the 12 CTs compared to the sensitivity and specificity results at the ASCUS + threshold, as compared to adjudicated results.

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Table 26. CT Review Times and ASCUS+ Sensitivity / Specificity

Site ID	Number of Cases	% ASCUS+	CT	Median Case Review Time (sec)	Range of Case Review Time (sec) (5th ; 95th percentile)	ASCUS+ Sensitivity	ASCUS+ Specificity
1	488	39.3 (192/488)	1	104	41 ; 644	90.7%	90.4%
			2	116	48 ; 479	81.3%	96.8%
			3	103	48 ; 416	91.2%	92.6%
2	494	36.8 (182/494)	1	94	49 ; 348	85.5%	95.5%
			2	148	82 ; 363	98.0%	72.6%
			3	105	66 ; 249	97.4%	92.0%
3	490	37.3 (183/490)	1	46	25 ; 120	92.3%	93.8%
			2	93	44 ; 263	96.2%	87.9%
			3	99	46 ; 284	88.0%	96.1%
4	488	31.1 (152/488)	1	136	72 ; 290	92.7%	91.6%
			2	73	42 ; 259	93.8%	91.9%
			3	57	31 ; 232	93.8%	91.6%

Figures 2 and 3 show scatterplots for the sensitivity and specificity results, respectively, as well as the resulting regression coefficients.

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Figure 2. Sensitivity vs. Median Review Time

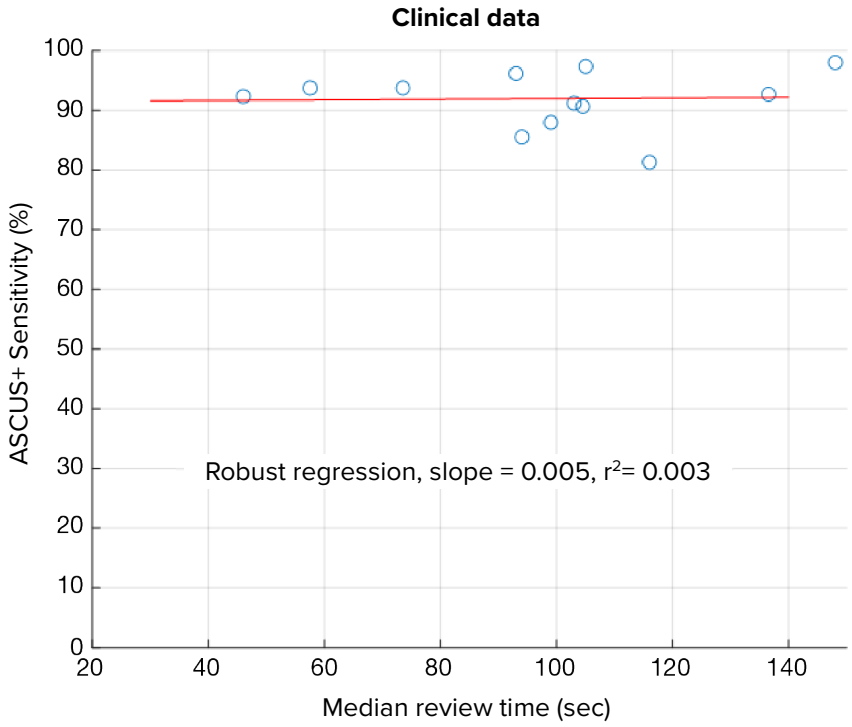

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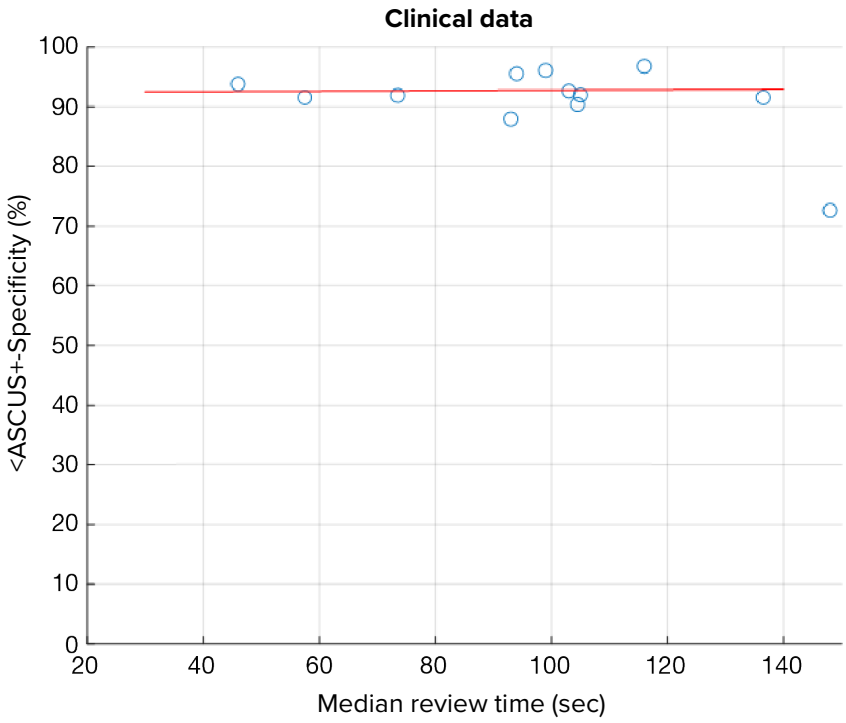
Figure 3. Specificity vs. Median Review Time



Regression analysis based on performance of 12 CTs showed that correlation coefficients for both the sensitivity and specificity analyses are low (0.003 and 0.180, respectively), indicating minimal dependence between performance and review time.

The data based on performance of 12 CTs in this study did not find that the CT case review time impacted the diagnostic performance at the ASCUS+ threshold.

CYTOLOGIST WORKLOAD DETERMINATION

Workload is defined by CLIA as a maximum of 100 slides in no less than an 8-hour workday. This refers to a full manual review (FMR) of 100 slides on a microscope. All cases diagnosed from the Genius Digital Diagnostics System with the Genius Cervical AI algorithm count as 0.5 or ½ CLIA slide equivalent. In the Genius Cervical AI clinical study, CTs accurately diagnosed cases using digital images presented by the system more efficiently than with a full manual review of a case.

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Use the below method to calculate workload, which cannot exceed the CLIA maximum limit of 100 slides (or 100 CLIA slide equivalents) in no less than an 8-hour workday:

- All Genius Cervical AI (GCAI) case reviews count as 0.5 slide (½ CLIA slide equivalent)
- All full manual reviews of the glass slide count as 1 slide (1 CLIA slide equivalent)
- A full manual review of the glass slide in addition to a GCAI review counts as 1.5 slides (1.5 CLIA slide equivalents)

$$0.5*GCAI + 1.5*(GCAI + FMR)+ 1*FMR \leq 100 \text{ CLIA slide equivalents}$$

Example 1 - workload for reviewing ThinPrep Pap tests with the Genius Digital Diagnostic System with the Genius Cervical AI algorithm:

200 Genius Cervical AI Case Reviews = 100 CLIA slide equivalents
(200 * 0.5 = 100)

Total number of CLIA slide equivalents screened: 100

Example 2 - workload for reviewing ThinPrep Pap tests with the Genius Digital Diagnostics System with the Genius Cervical AI algorithm, when some cases were reviewed both digitally and on glass:

180 Genius Cervical AI Case Reviews = 90 CLIA slide equivalents [180 * 0.5 = 90]

6 Genius Cervical AI Case Reviews + FMR = 9 CLIA slide equivalents [(6 * 0.5)+(6 * 1) = 9]

Total number of CLIA slide equivalents screened: 99 (90 + 9)

Notes:

- ALL laboratories should have a clear standard operating procedure for documentation of workload counting and for establishing workload limits.
- It is the responsibility of the Technical Supervisor to evaluate and set workload limits for individual cytologists based on laboratory clinical performance.
- According to CLIA '88, these workload limits should be reassessed every six months.

CYBERSECURITY

Medical device security is a shared responsibility between stakeholders, including healthcare facilities, patients, providers, and manufacturers of medical devices.

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The Genius Digital Diagnostics System with the Genius Cervical AI algorithm is designed for security using a layered architecture approach to cybersecurity. Risks have been reduced as far as possible, and Hologic continually evaluates security patches, software updates including off-the-shelf (OTS), and the effectiveness of controls in the layered security architecture. Hologic applies critical security updates immediately after validation and applies non-critical security patches during regular scheduled maintenance periods.

Refer to and follow the Security instructions in the Genius Digital Imager Operator's Manual, the Genius Review Station Operator's Manual and the Genius IMS User's Manual.

CONCLUSIONS

The data from the studies conducted on the Genius Digital Diagnostics System with the Genius Cervical AI algorithm demonstrate that the Genius Digital Diagnostics System with the Genius Cervical AI algorithm, is safe and effective 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 criteria as defined *by The Bethesda System for Reporting Cervical Cytology*[1].

- In the Genius Cervical AI Clinical Study, for all sites combined for ASCUS+, there was an observed improvement in sensitivity of the Genius Digital Diagnostics System with Genius Cervical AI review method over the Manual Review method. This increase of 1.6% was not statistically significant, with a 95% confidence interval of -0.1% to 3.2%.
- For LSIL+, ASC-H+ and HSIL+, the improvement in sensitivity of the Genius Digital Diagnostics System with Genius Cervical AI method over the Manual Review method was statistically significant and was as follows:
    - For LSIL+: 4.4% with a confidence interval of 2.1% to 6.7%
    - For ASC-H+: 8.2% with a confidence interval of 4.8% to 11.6%
    - For HSIL+: 7.5% with a confidence interval of 4.0% to 11.4%. With regard to false negative (less than HSIL) rate for HSIL+, the 7.5% increase in HSIL + sensitivity means a decrease in Manual false negative rate of 26.0% to 18.5% false negative rate by the Genius Digital Diagnostics System with the Genius Cervical AI algorithm resulted in 28.8% reduction in the number false negative reviews (28.8% = (26.0%-18.5%)/26.0%).
- For Cancer, the observed sensitivities of the Genius Digital Diagnostics System with Genius Cervical AI method and Manual Review method were the same, with a confidence interval of -9.8% to 11.1%.

The data from the studies conducted on the Genius Digital Diagnostics System with the Genius Cervical AI algorithm showed that screening time is reduced without affecting diagnostic performance when compared to the manual review. The workload limit for the Genius Digital Diagnostic System with the Genius Cervical AI algorithm was established at 200 case reviews in no less than an 8-hour workday, if there were no cases reviewed with FMR and is not to exceed 100 CLIA equivalent slides in no less than an 8-hour workday.

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Specimen adequacy as described in Bethesda 2014 can be determined using Genius Digital Diagnostics System with the Genius Cervical AI algorithm. Unsatisfactory rates between manual and Genius Cervical AI-assisted review were similar in the clinical study. Estimated cell count was found to be comparable between manual and Genius Cervical AI-assisted review as well. Additionally, endocervical component was similar using Genius Cervical AI-assisted review compared to manual review.

For the clinical sites and the study populations tested, the data from the clinical study demonstrates that the use of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm to assist during primary screening of ThinPrep Pap test slides for all cytologic interpretations, as defined by the Bethesda System, is safe and effective for the detection of cervical abnormalities.

MATERIALS REQUIRED

MATERIALS PROVIDED

- Genius Digital Imager
    - Digital Imager (PRD-05815, RM-ASY-18588, or RM-ASY-18589)
    - Digital Imager computer (CMP-01687, ASY-18113, or RM-ASY-18113)
    - Slide carriers (ASY-14299)
- Genius Review Station
    - Monitor (CMP-01669 or RM-CMP-01669)
    - Review Station computer*
- Genius Image Management Server
    - Server*
    - Network switch*
    - Monitor, keyboard, mouse for the Image Management Server (for customers using a Hologic-supplied Image Management Server)

*In some configurations of the system, the laboratory may supply the Review Station computer into which Hologic installs a Hologic-supplied graphics card. Refer to Genius Review Station Operator's Manual for the minimum specifications for the computer. In some configurations of the system, a laboratory may supply the server hardware and network switch. Refer to Genius IMS user's manual for the minimum specifications for the server and network switch.

- Complete instructions for operating the components in the system are also required and provided by Hologic. Depending on the software version installed, the operating instructions are:
    - Genius Digital Imager Operator's Manual:
      MAN-08469-001 (software version 1.1.x) or MAN-12119-001 (software version 1.2.x)
    - Genius Review Station Operator's Manual:
      MAN-08467-001 (software version 1.1.x) or MAN-12121-001 (software version 1.2.x)
    - Genius Image Management Server Dashboard User's Manual:
      MAN-08468-001 (software version 1.1.x) or MAN-12120-001 (software version 1.2.x)

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MATERIALS REQUIRED BUT NOT PROVIDED

- Slide staining racks
- Keyboard and mouse for each Review Station (for customers not using a Hologic-supplied Review Station computer)

STORAGE

- Refer to the Technical Specifications included in the Digital Imager operator's manual.
- Additional storage requirements may apply. Refer to the documentation provided with the server, monitors and computers.

BIBLIOGRAPHY

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

TECHNICAL SERVICE AND PRODUCT INFORMATION

For technical service and assistance related to use of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm, contact Hologic:

Telephone: 1-844-465-6442

Fax: 1-508-229-2795

For international or toll-free blocked calls, please contact 1-508-263-2900.

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1. Introduction

Chapter One

Introduction

SECTION A

OVERVIEW

The Genius Review Station is one component of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm. The Review Station is a computer with a specific monitor for diagnostic review of images. The computer runs a captive (kiosk mode) software application hosted by a Genius Image Management Server (IMS). A Review Station communicates with an Image Management Server, which provides slide data sets 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 ThinPrep® microscope slides that have been imaged on a Genius Digital Imager. Digital images of a slide's cell spot area are available for a CT or pathologist to review on the Review Station monitor, rather than using a microscope to review a glass slide.

- For cervical cancer screening of gynecological samples prepared on ThinPrep Imaging System slides, an artificial intelligence image analysis algorithm within the product identifies clinically relevant 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.

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.

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1 INTRODUCTION



Figure 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.

Note: In this operator's manual, a shortened form of the system name is sometimes used for clarity. "Genius Digital Diagnostics System" and "Genius Digital Diagnostics System with the Genius Cervical AI algorithm" refer to the same thing.

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Indication for Use

The Review Station is one component of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm.

The Genius Digital Diagnostics System with the Genius Cervical AI algorithm includes the Genius Digital Imager, Genius Image Management Server (IMS), the Genius Review Station, and the Genius Cervical AI algorithm. The Genius Digital Diagnostics System with the Genius Cervical AI algorithm is intended for the creation and viewing of digital images of scanned ThinPrep Pap Test glass slides. Objects of interest selected by the Genius Cervical AI algorithm from the scanned digital image are presented in a gallery format, next to the image of the whole cell spot on the Genius Review Station, for review and interpretation. The Genius Digital Diagnostics System with the Genius Cervical AI algorithm is intended to aid in cervical cancer screening 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 as defined by *The Bethesda System for Reporting Cervical Cytology*[1].

After digital review with the Genius Cervical AI algorithm, if there is uncertainty in the diagnosis, then direct examination of the glass slide by light microscopy should be performed. Digital images from the Genius Digital Diagnostics System with the Genius Cervical AI algorithm should be interpreted by qualified cytologists and pathologists in conjunction with the patient's screening history, other risk factors, and professional guidelines which guide patient management.

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

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1 INTRODUCTION

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

The Genius Digital Diagnostics System with the Genius Cervical AI algorithm uses Pap test slides prepared from gynecologic (cervical/vaginal) samples obtained from women for screening, diagnosis and management.

Slides that have been prepared for screening using the ThinPrep 2000 system, the ThinPrep 5000 processor, or the ThinPrep Genesis™ processor and stained with ThinPrep stain (Papanicolaou stain) 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 a designated area of the microscope slide, creating an in-focus, whole slide image.

For ThinPrep Pap test patient sample slides, the Genius Cervical AI algorithm identifies objects of interest found on a digital image of the slide. The objects classified as most clinically relevant are presented 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 with the Genius Cervical AI algorithm. 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 CT or pathologist reviews cases at the Review Station. The Review Station is a dedicated 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 and comments in the case review. The reviewer, in addition to reviewing the gallery images, has the option to move to any portion of the cell spot for examination.

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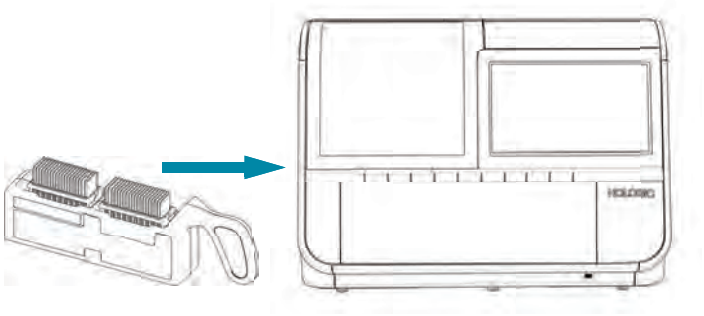
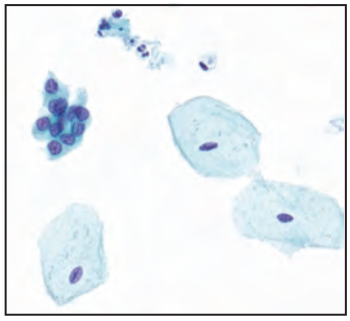
System Process: Genius Digital Diagnostics System with the Genius Cervical AI Algorithm



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

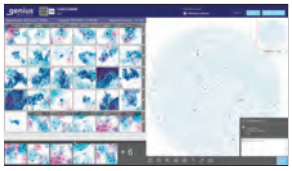
The cell spot is imaged.



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.

Case review by the cytologist or pathologist



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

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 1-2 System Process:
Genius Digital Diagnostics System with the Genius Cervical AI Algorithm

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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.

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SECTION D

REVIEW STATION TECHNICAL SPECIFICATIONS

Overview of Components

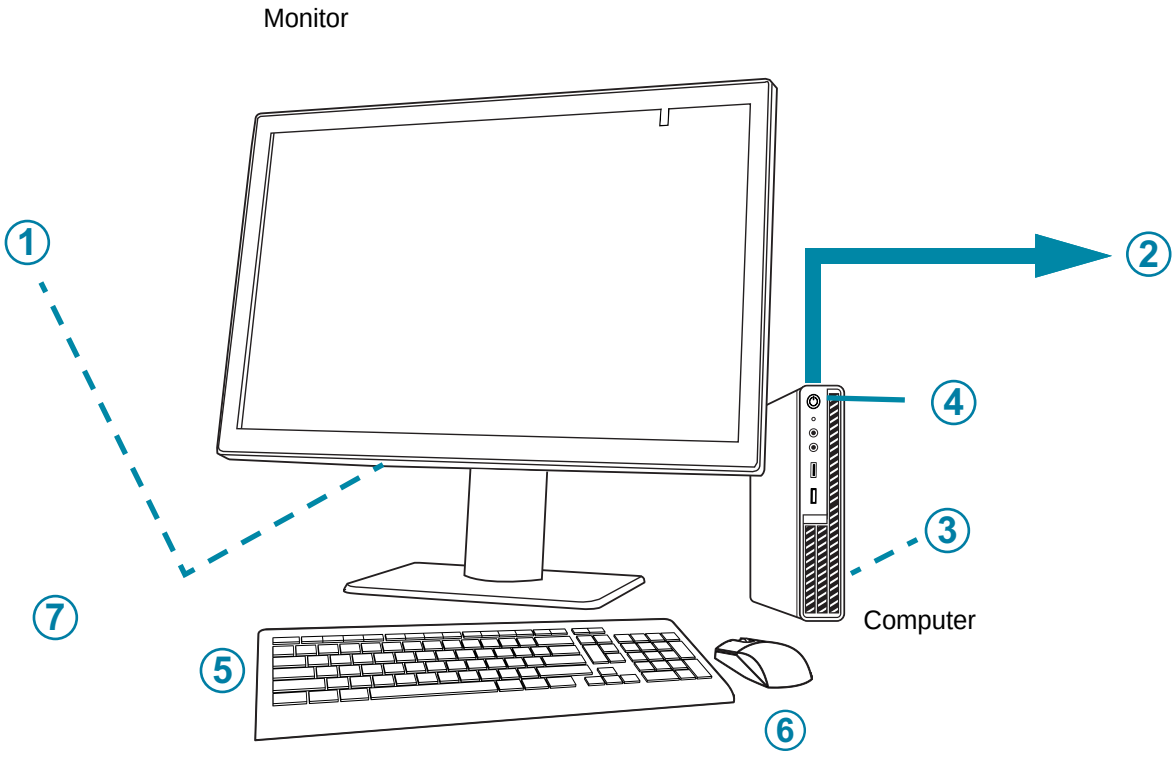

Figure 1-3 Review Station Components

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

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Key to Figure 1-3	
④	Computer power button, location varies by computer model
⑤	Computer keyboard
⑥	Computer mouse
⑦	Barcode scanner (optional, not shown in Figure 1-3)

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Review Station Monitor Dimensions

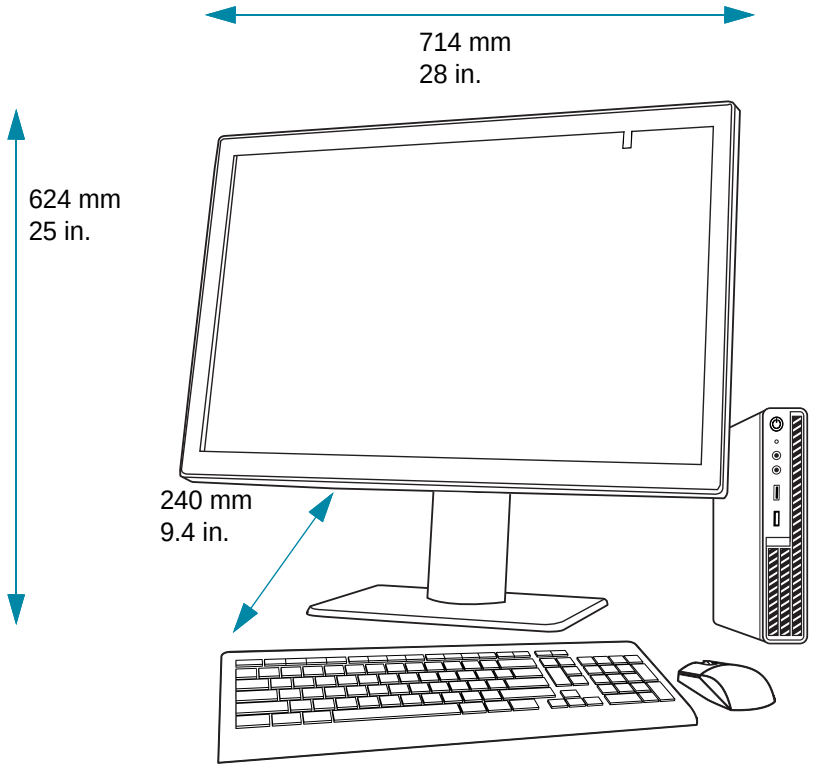

Figure 1-4 Review Station Monitor Dimensions

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
- An available PCIe Gen3 x16 slot in the PC for the Barco GPU card

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- 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.

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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.

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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.

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.

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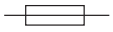
Symbols Used on the Instrument

The following symbols may appear on this instrument.

Symbol	Title	Description	Standard information
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.4
 hologic.com/ifu	Consult the instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.4.3
	*In vitro* diagnostic medical device	Indicates a medical device that is intended to used as an in vitro diagnostic medical device	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.5.1
	Fuse (Not user-accessible)	To identify fuse boxes or their location	IEC 60417 Graphical symbols for use on equipment, symbol 5016
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.7
	Authorized Representative in the European Community	Indicates the Authorized Representative in the European Community	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.2
	Manufacturer	Indicates the medical device manufacturer, as defined in the EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.1

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Symbol	Title	Description	Standard information
	Date of manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.3
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.6
	On (Power switch)	Indicates that the control places the equipment in a fully powered state.	IEC 60417-1 Graphical symbols for use on equipment, symbol 5007
	Off (Power switch)	Indicates that using the control will disconnect power to the device.	IEC 60417-1 Graphical symbols for use on equipment, symbol 5008
	On/Off, Standby mode	To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption.	IEC 60417—Graphical symbols for use on equipment -- Reference number 5009
	USB 3 port (computer)	To identify a port or plug meeting the generic requirements of the Universal Serial Bus (USB). To indicate that the device is plugged into a USB port or is compatible with a USB port.	IEC 60417 —Graphical symbols for use on equipment -- Reference number 3650
	Ethernet port (computer)	To identify the computer network itself or to indicate the connecting terminals of the computer network	IEC 60417 —Graphical symbols for use on equipment -- Reference number 5988

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Symbol	Title	Description	Standard information
	Country of manufacture	To identify the country of manufacture of products	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.1
	Importer	Indicates the entity importing the *medical device* into the locale	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.1.8

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

Figure 1-5 Symbols Used on the Monitor and Computer

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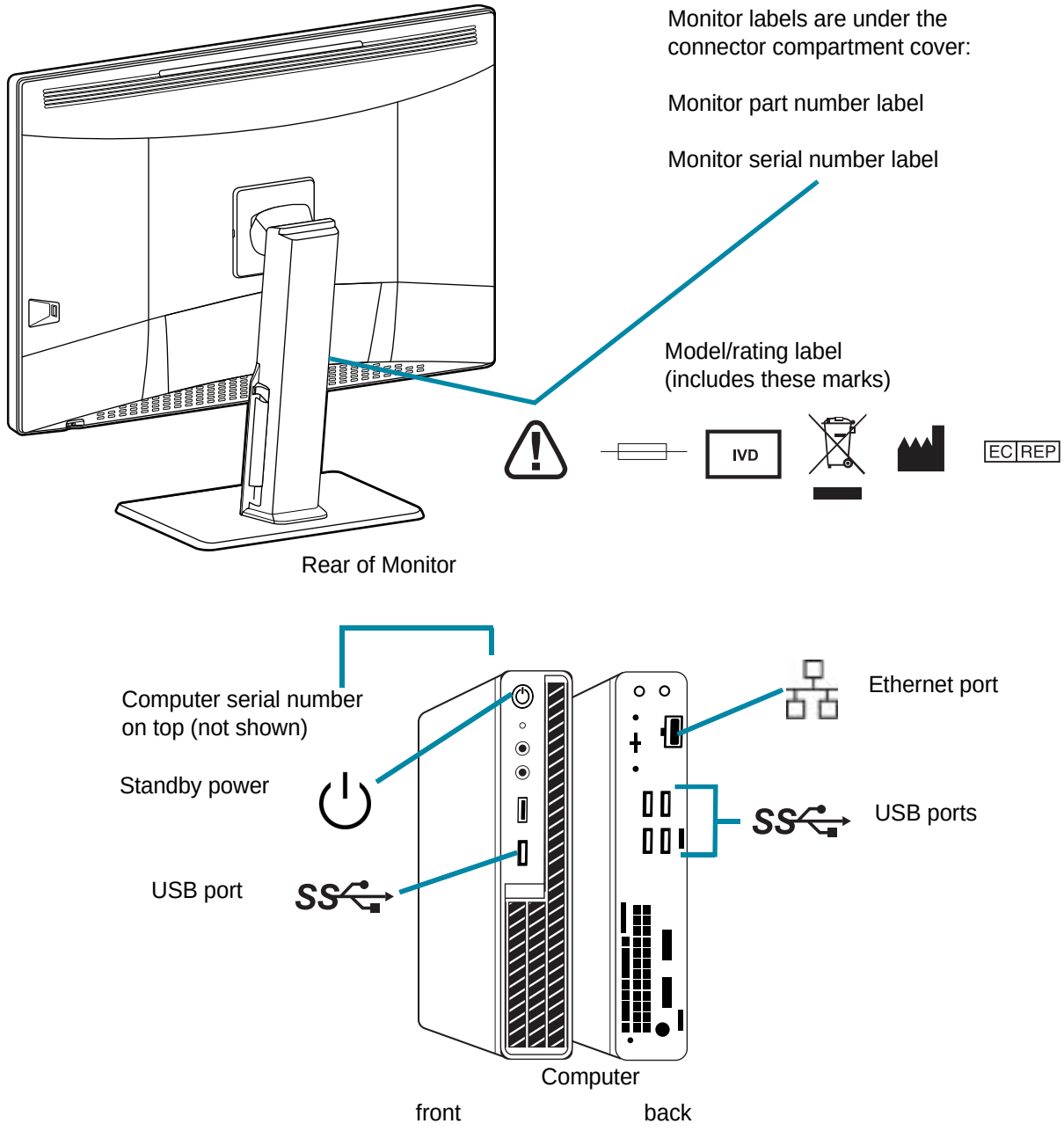
Location of Labels



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 1-6 Location of Labels on the Instrument

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Warnings

WARNING: For professional use only.

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

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

WARNING: Users should employ appropriate cybersecurity measures when the device is used for remote review.

Limitations

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

Digital images from the Genius Digital Diagnostics System with the Genius Cervical AI algorithm should be interpreted by qualified cytologists and pathologists in conjunction with the patient's screening history and other risk factors, and professional guidelines which guide patient management.

Performance characteristics of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm are based on using Genius Cervical AI tools, including the entire gallery, to assist in diagnosing a case and should be used accordingly. The performance of the Genius Digital Diagnostics System with the Genius Cervical AI algorithm using only a digital review of the entire cell spot has not been evaluated.

When Genius Review Stations are located remotely from the imaging site, the Genius Digital Diagnostics System can be connected to the laboratory’s network to enable the remote Review Stations to access the Genius Image Management Server. Hologic supplies minimum network specifications which should be met for optimal speed in loading images and case data. Customers who choose to remotely connect the Genius Review Station to the Genius Image Management Server are responsible for the maintenance of their network’s cybersecurity.

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SECTION G

DISPOSAL

Disposal of the device

Please contact Hologic Service. (Refer to Chapter 7, Service Information.)

Do not dispose in municipal waste.



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

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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 7, Service Information.)

Leave the instrument in the packing cartons for installation by 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

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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 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).

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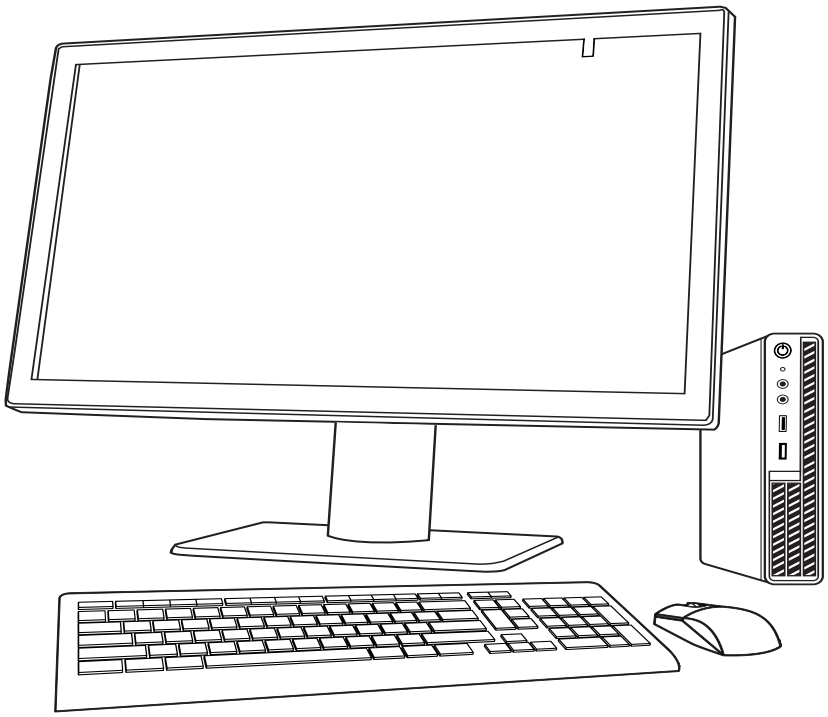

Figure 2-1 A Typical Review Station Configuration

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. Customers may have corporate security, safeguarding, and/or management software that is required for systems to join their networks. While not specifically validated, these products, by design, do not typically adversely affect system performance and may be installed at the customer's discretion.

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

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Operating system patching

The Review Station software runs on Microsoft Windows (various editions). Hologic tests the Genius Digital Diagnostics System to ensure compatibility with Microsoft Windows updates. Hologic customers are informed via customer technical bulletin of the versions validated. 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.

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Figure 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 customized, 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 browser for the system application.

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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 1.9).

A network connection connects the Review Station to a networking device. (See Figure 1-6.) The networking device enables communication to the Genius Image Management Server. For the cabling requirements for the connection, consider the cable length. A minimum of cat 5e cabling is required, with distances not exceeding these maximum distances:

- Cat 5e Up to 1 Gbps speed, maximum distance of 100 meters
- Cat 6 Up to 10 Gbps speed, maximum distance of 55 meters
- Cat 6a Up to 10 Gbps speed, maximum distance of 100 meters

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.

The recommended network speed between the Genius Review Station and Genius Image Management Server is 200 Mbps or faster. However, if this speed is not attainable, a minimum network speed of at least 100 Mbps is recommended for optimal speed in loading images and case data. Contact your network administrator if the speed test value is below this threshold. Refer to "Network Speed" on page 2.10.

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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.

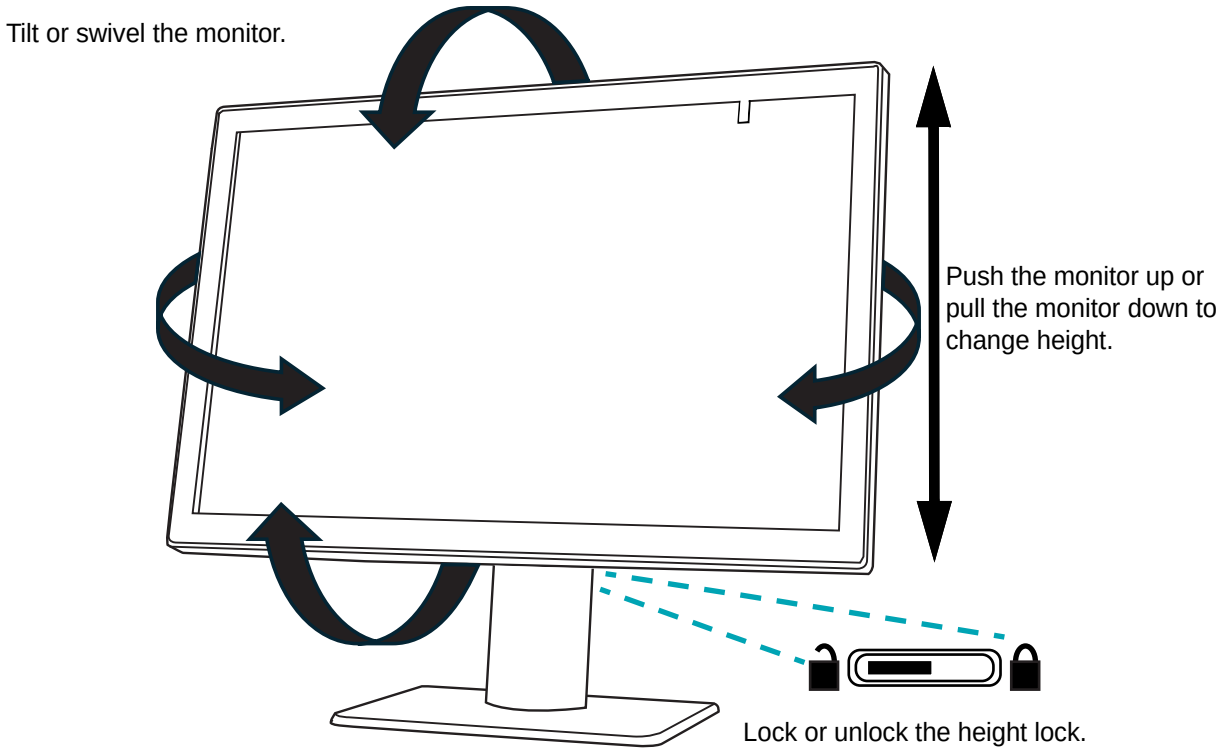

Figure 2-3 Adjust Height or Tilt

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.

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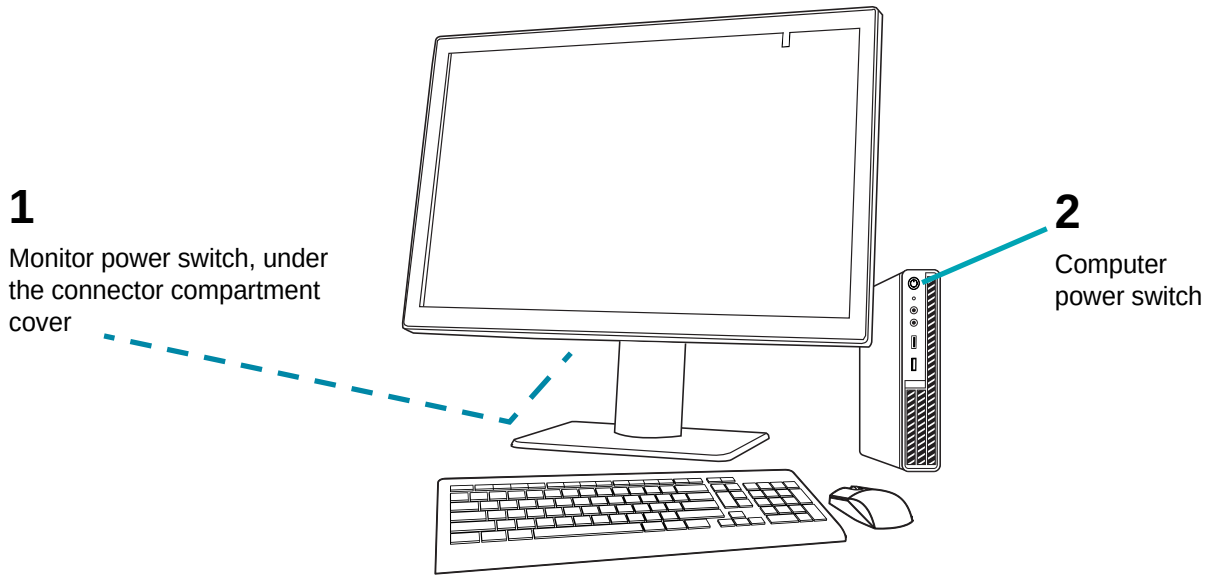

Figure 2-4 Power Switches

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

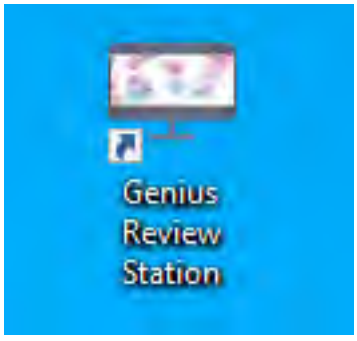

Figure 2-5 Launch the Application

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3. The application launches.

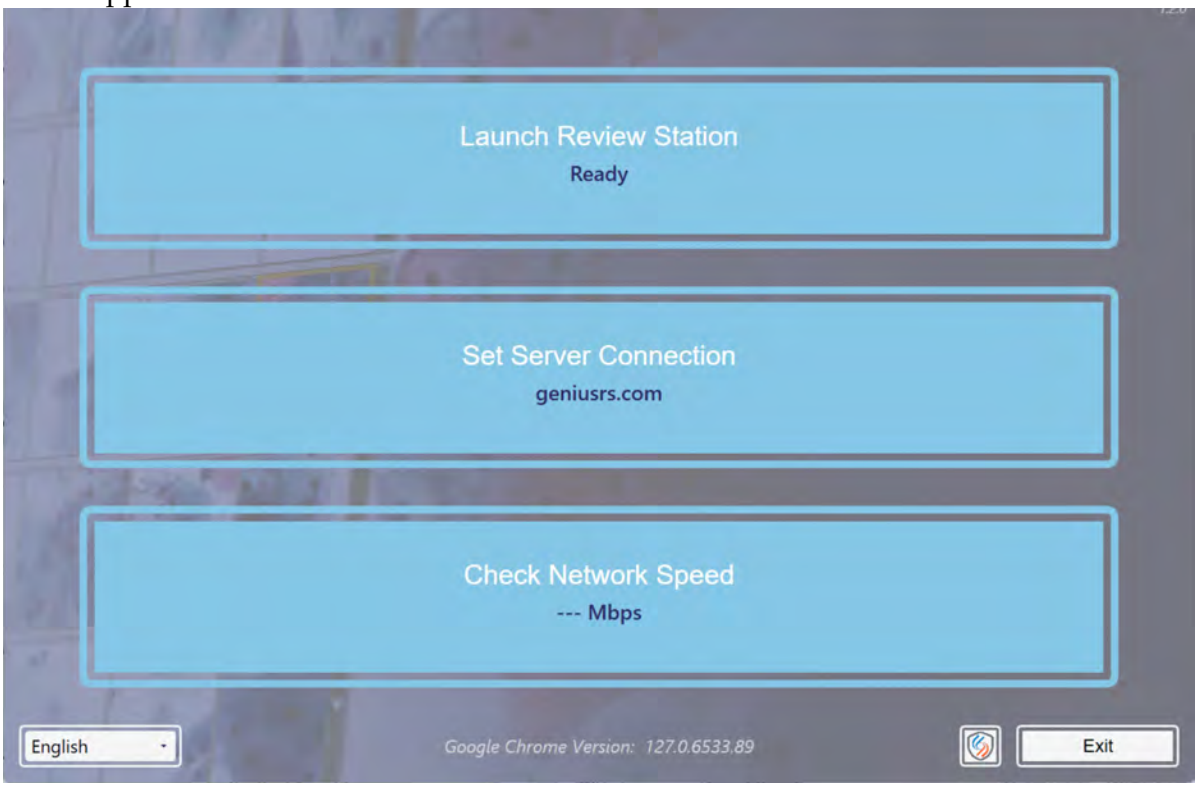

Figure 2-6 Launch the Review Station Software

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**.

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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.

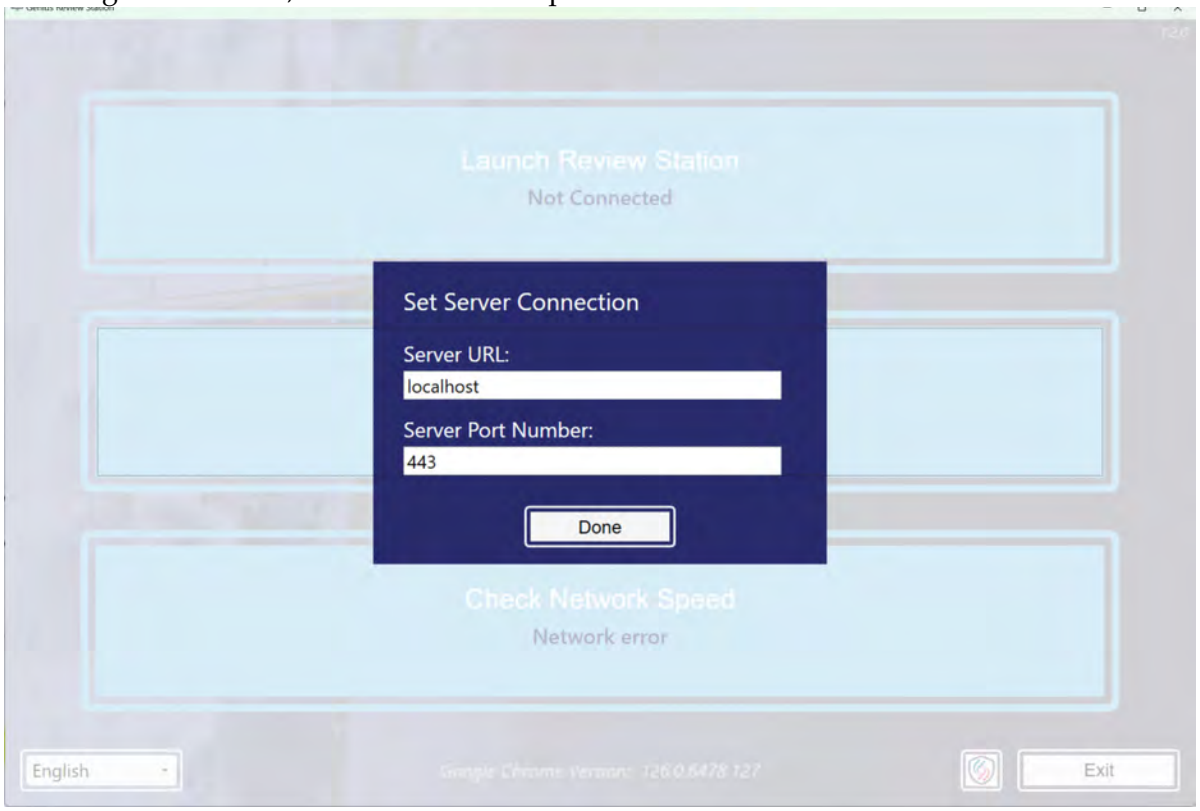

Figure 2-7 Enter Server IP Address

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.

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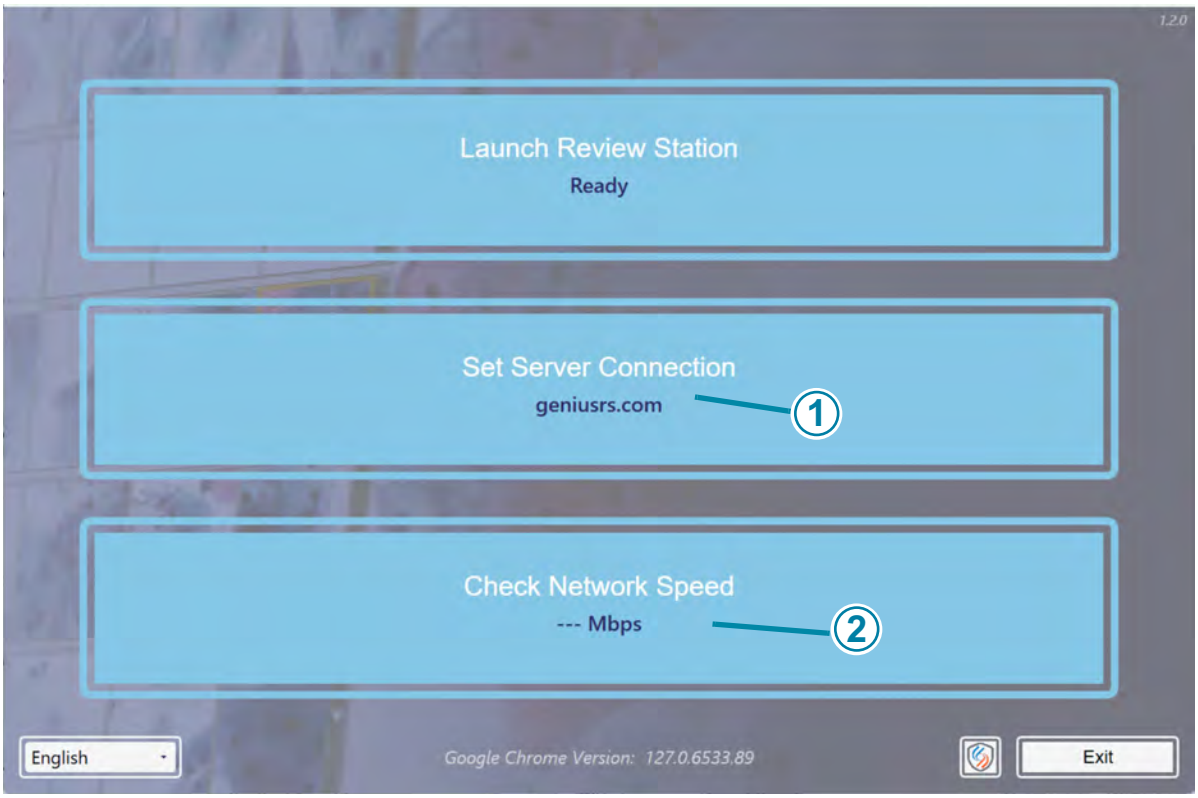

Figure 2-8 Review Station Startup Screen, Example

Key to Figure 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 3.9.)

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Figure 2-9 Login Screen

The Review Station is ready for use when the dashboard is displayed (Figure 2-10).

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Figure 2-10 Review Station Dashboard

SECTION G STORAGE AND HANDLING - POST INSTALLATION

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.

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SECTION H

SYSTEM SHUTDOWN

Normal Shutdown



Figure 2-11 Exit the Application

Key to Figure 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 left 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.

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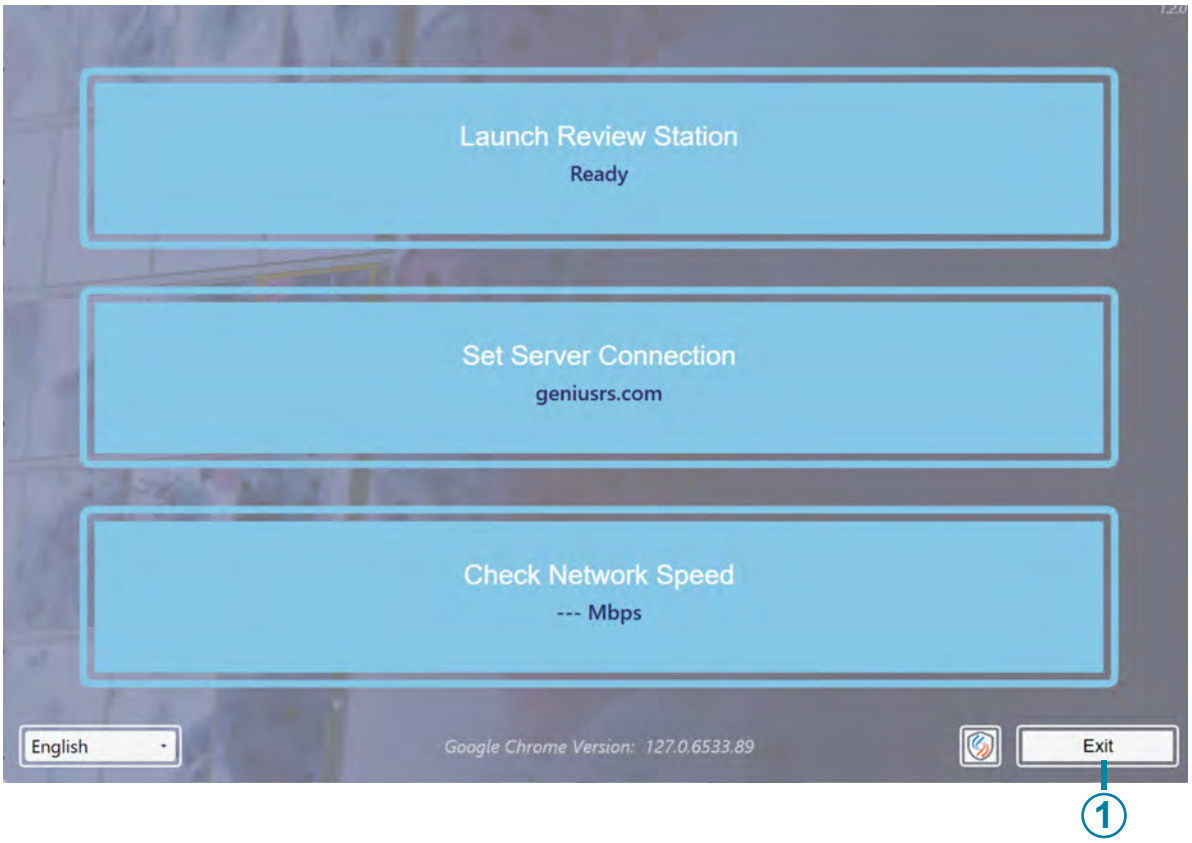

Figure 2-12 Exit the Launch Application

Key to Figure 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.

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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 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. The different user roles have different permissions for different functions. These instructions describe all of the Review Station features.

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

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3 User Interface

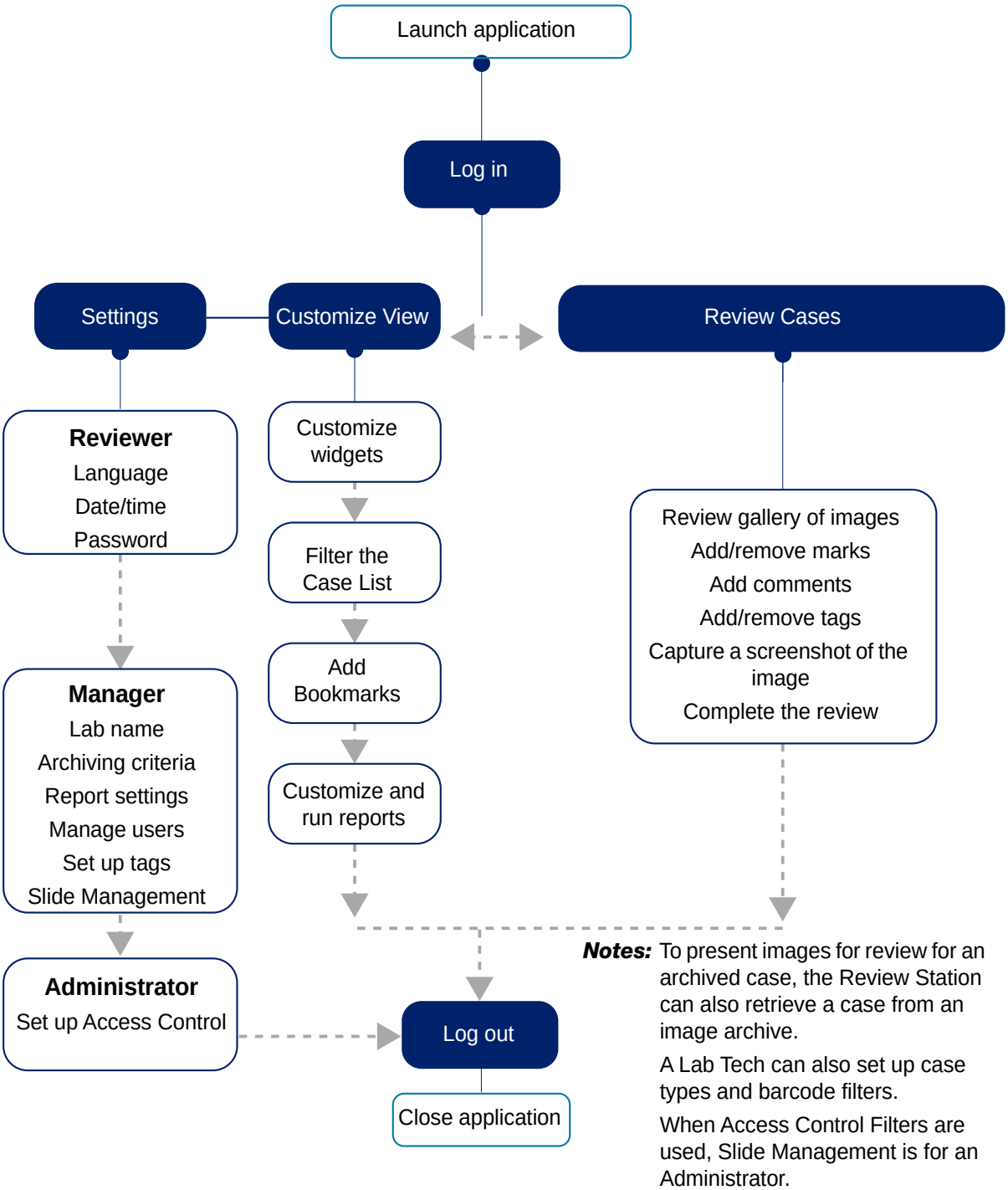

Figure 3-1 Overview of Review Station Functions

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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:

Log In 3.7
- Normal Login 3.7
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3 User Interface

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 3.39.

Table 3.1 Permissions by User Role

	Reviewer	Manager	Administrator	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	✔	✔	✔	✔

✔	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.

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Table 3.1 Permissions by User Role

	Reviewer	Manager	Adminis-trator	Lab Tech
Run slide event reports	✓	✓	✓	✓
Run slide data reports	✓	✓	✓	✓
Set up and run custom reports	✓	✓	✓	✓
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)	✓	✓	✓	⊘
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	⊘	✓*	✓	✓

✓	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.

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Table 3.1 Permissions by User Role

	Reviewer	Manager	Administrator	Lab Tech
Reset an in-progress case to the new status	⊘	▼✎	✓	⊘
Reset other user's password	⊘	▼✎	✓	⊘
Run CT workload reports for several CTs	⊘	▼✎	✓	⊘
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.	⊘	▼✎ 🧍	✓	⊘
Set up access control filters	⊘	⊘	🏛	⊘
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.

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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.

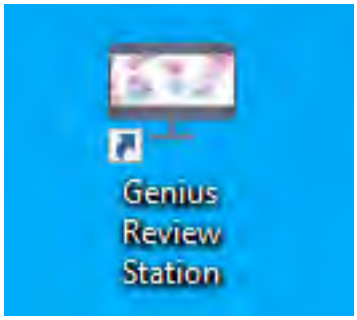

Figure 3-2 Launch the Application from the Computer Desktop

2. The application launches.

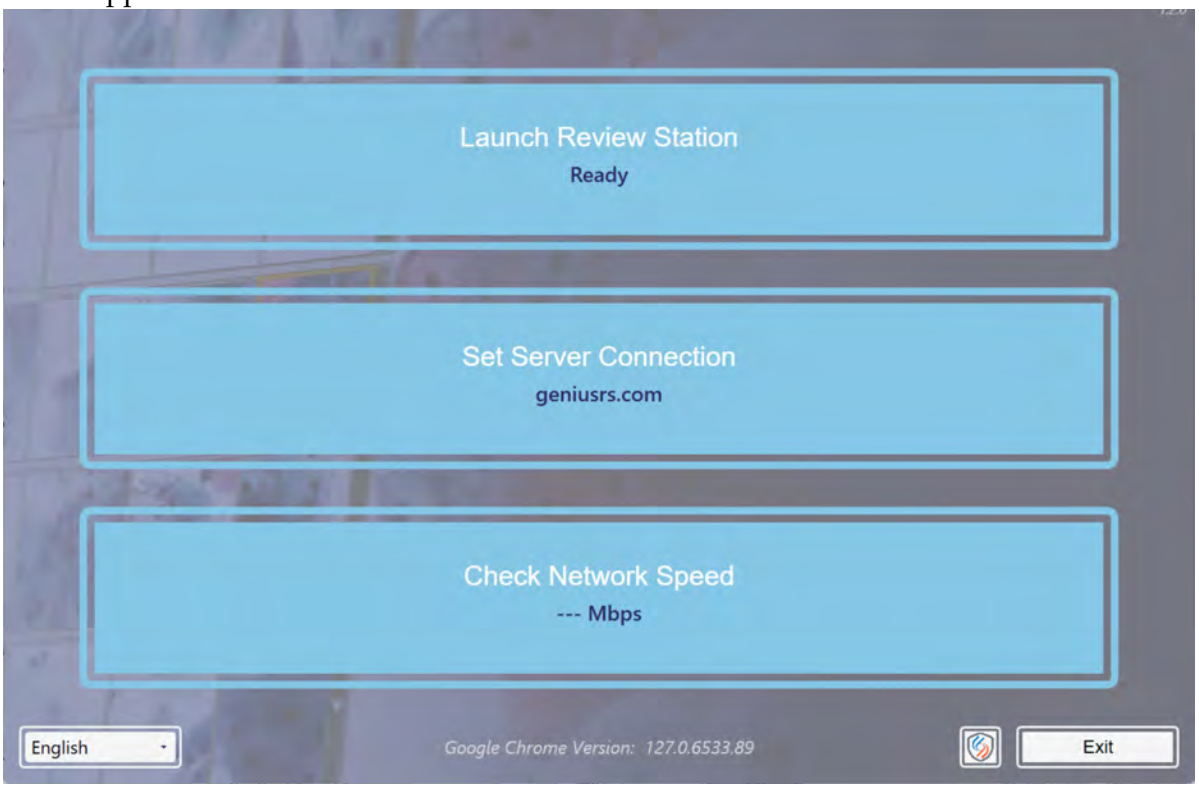

Figure 3-3 Launch the Review Station Software

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- 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.

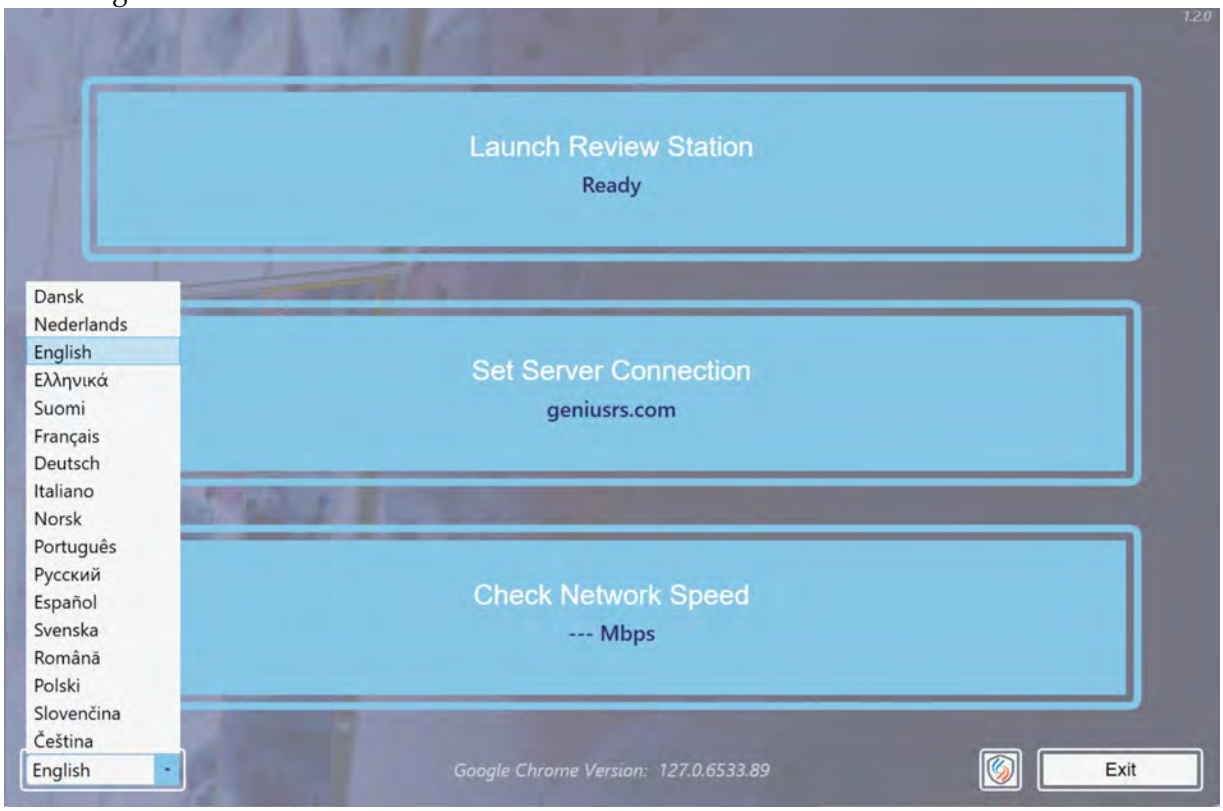

Figure 3-4 Select Language When Launch Application (Optional)

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

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Figure 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 3.19 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 scanned image 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 6.5 for more information.

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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. If the e-mail address is not in the user account, a user must use their Review Station username to log in.

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 3.37.

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 3.19 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 3.45.

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

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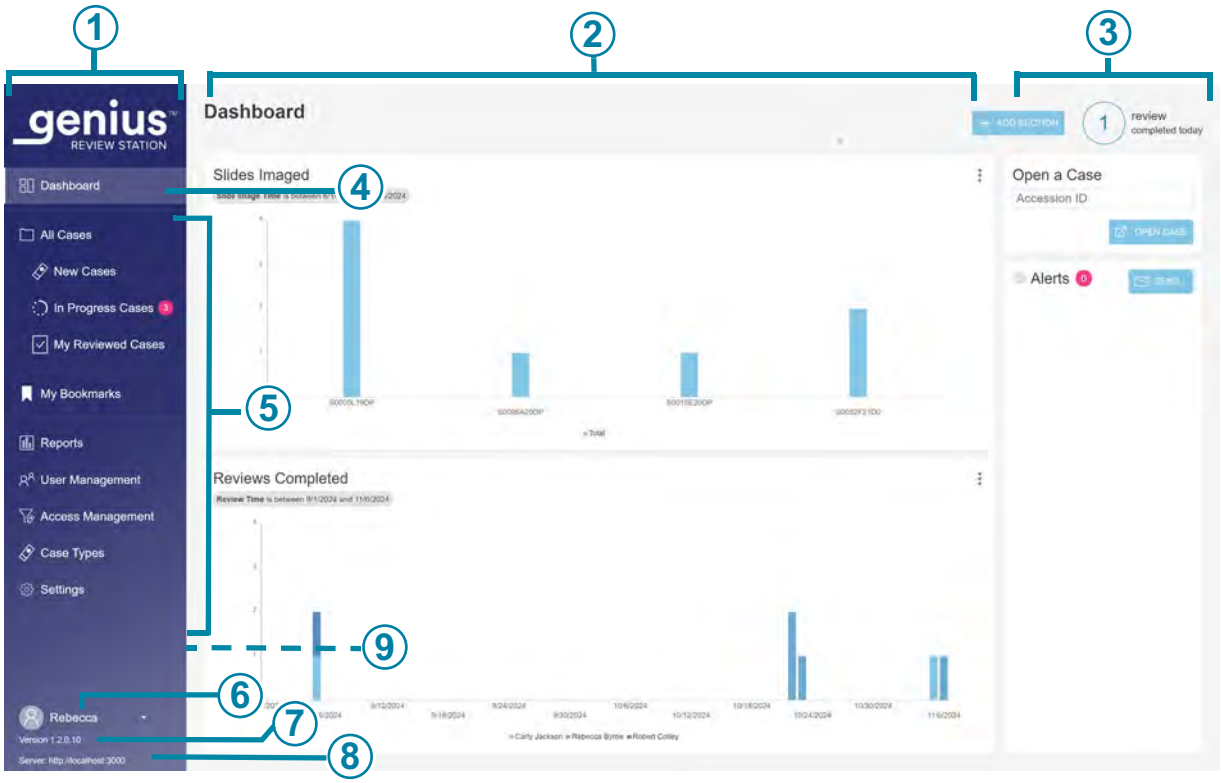

Figure 3-6 Review Station Dashboard

Key to Figure 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.

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Key to Figure 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 3.52. • My Bookmarks, which can be customized for each user. Refer to page 3.64. • Reports. Refer to page 3.65. • User Management settings (available to users with a manager role or an administrator role). Refer to page 3.32. • Access Management settings (available only to users with an administrator role). Refer to page 3.32. • Case Types. The Case Type is always “Gyn”. • Settings, which can be customized for each user. Refer to page 3.18.
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 3-7 shows a typical Case List view:

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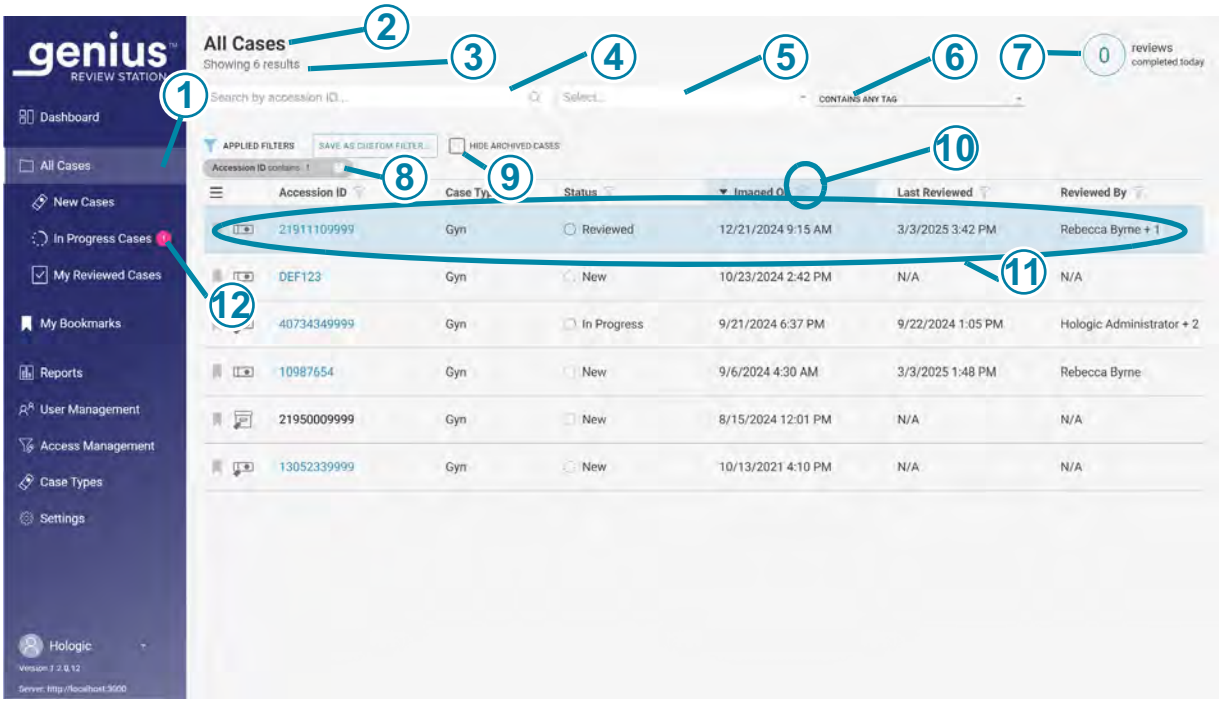

Figure 3-7 Typical Case List (All Cases Selected in this Example)

Key to Figure 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.

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Key to Figure 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 3.52. 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 3.59)
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.

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

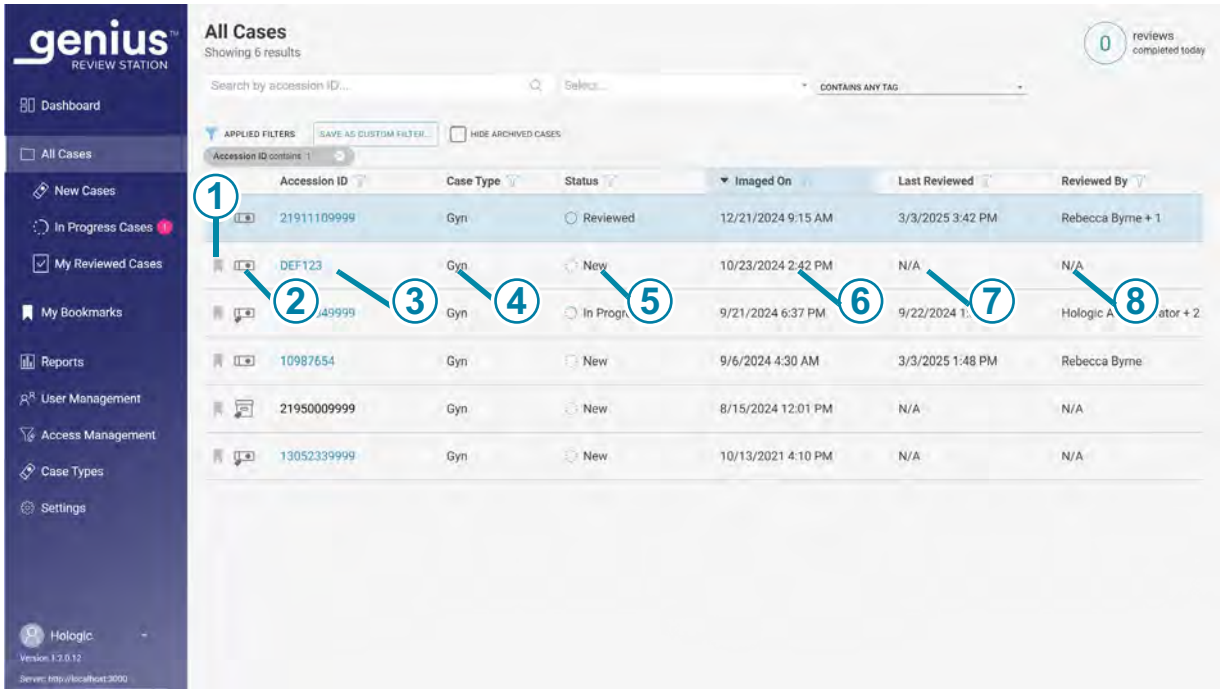

Figure 3-8 Typical Case List (All Cases Selected in this Example)

Key to Figure 3-8	
1	Bookmark icon (Refer to “Bookmarks” on page 3.64) 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 is available at the Review Station (has not been archived). Tag icon - A reviewer has applied a tag to this case. Archived icon - A case with the archived icon has been archived. (Refer to “Archive” on page 3.22.) When retrieval of an archived case is in progress, blue arrows display on the archived icon.

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Key to Figure 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 for the case: Gyn
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 on 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

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- 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 Event 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.

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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.

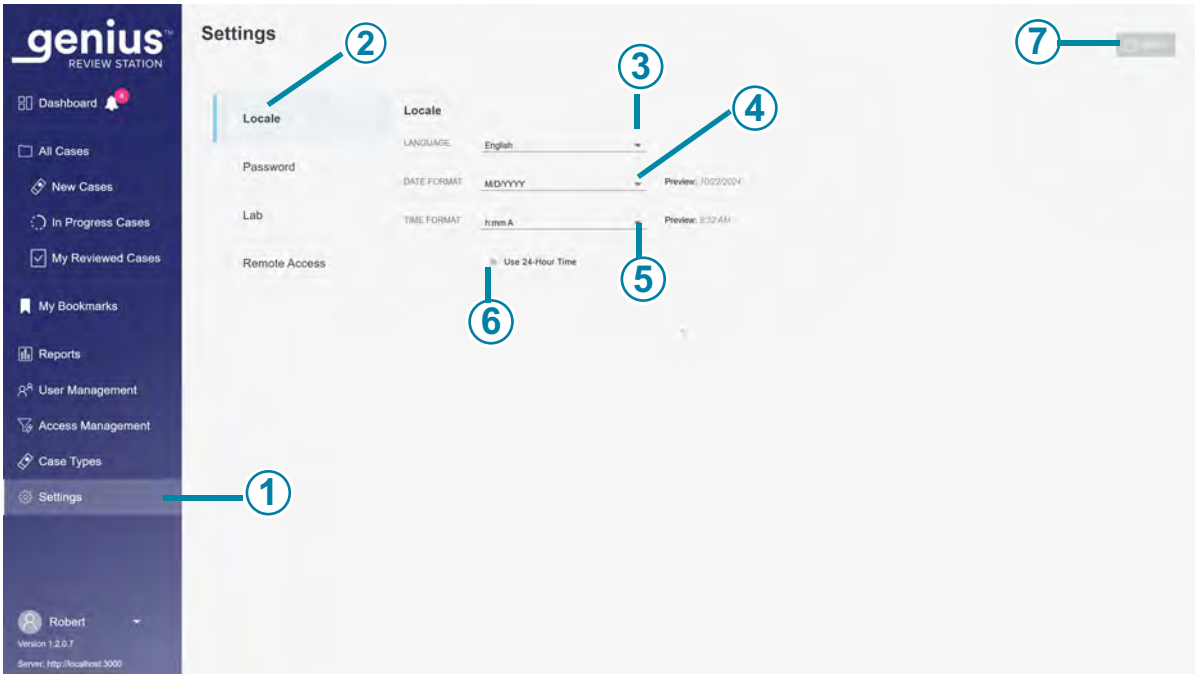

Figure 3-9 Set the Language, Date Format, Time Format

Key to Figure 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.

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Key to Figure 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.

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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.

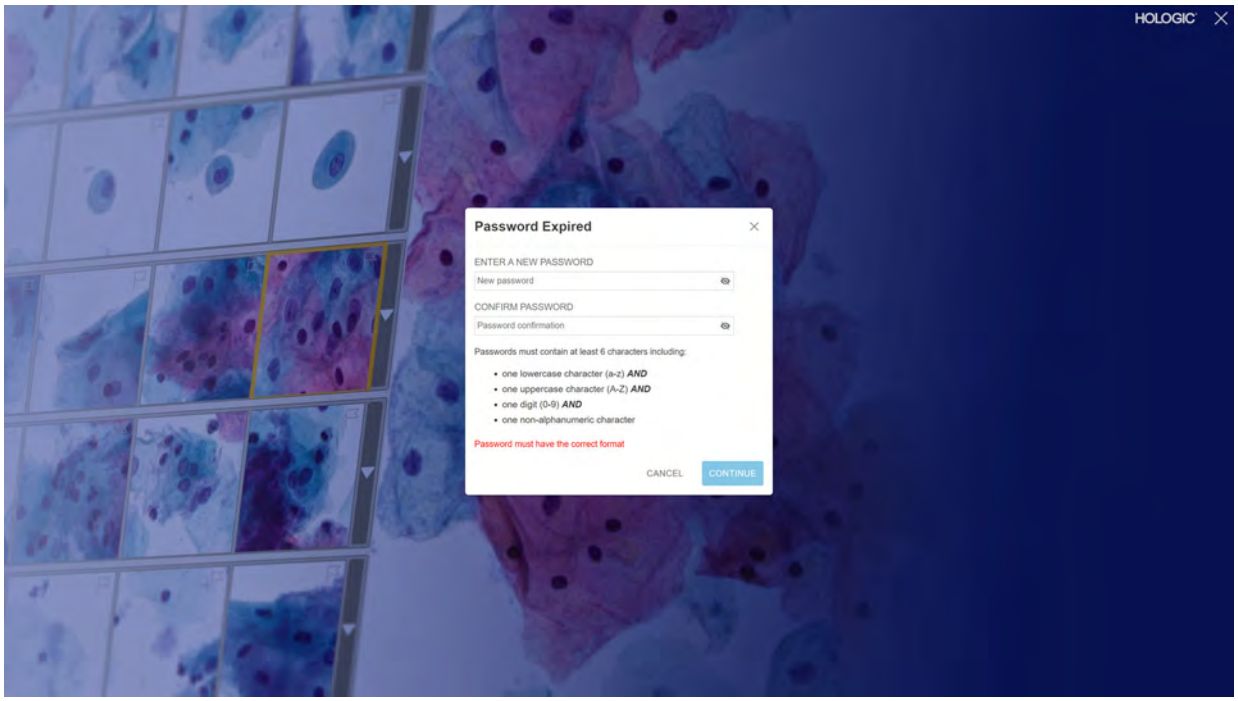

Figure 3-10 Reset an Expired Password

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

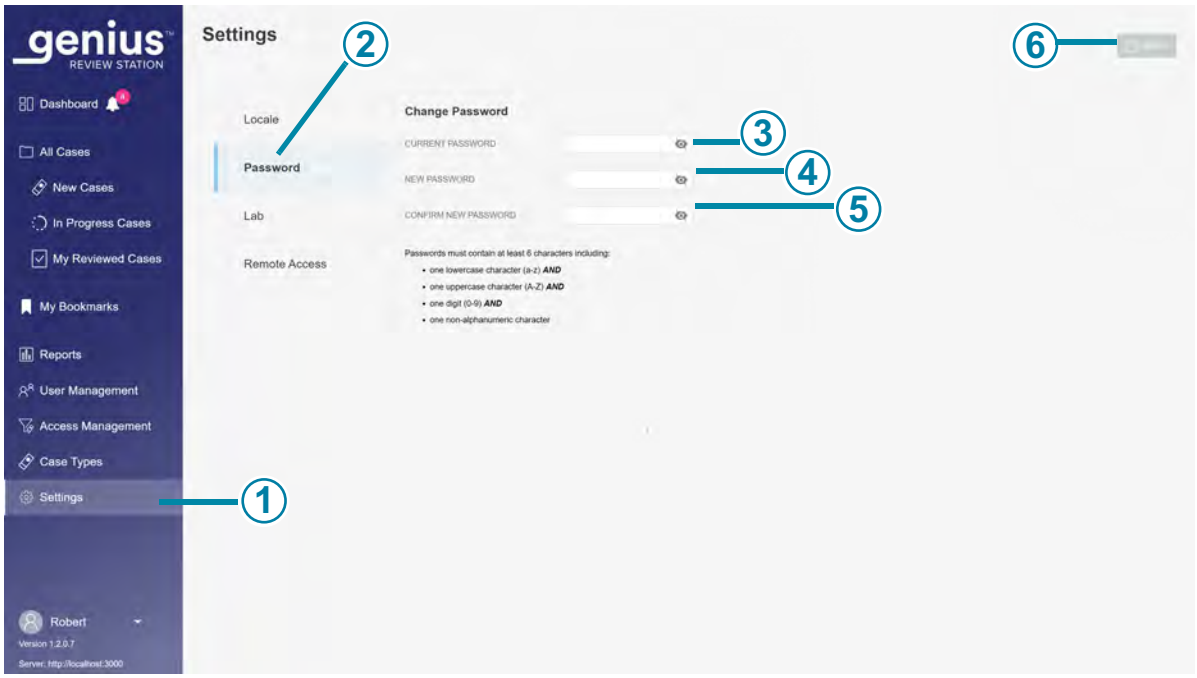

Figure 3-11 Change Password

Key to Figure 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.

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Key to Figure 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 3-12 and Figure 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

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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 suits the needs 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 reviewer 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 tag case is tagged, any reviewer can search for cases using 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.

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Note: If a manager 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 3.62.

Refer to "Add a tag" on page 4.21 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 customer 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 3.61.

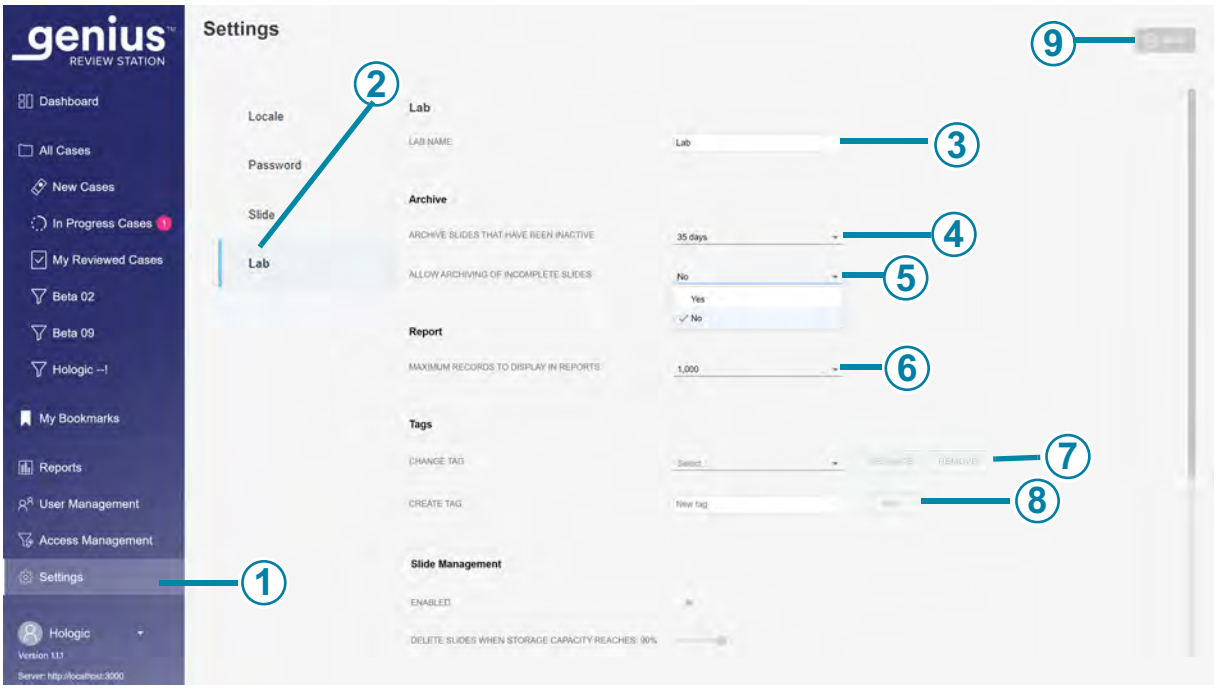

Figure 3-12 Lab Settings

Key to Figure 3-12	
1	The lighter color in the menu bar indicates that **Settings** is selected.

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Key to Figure 3-12	
②	The blue color in the list of settings indicates that the **Lab** settings are selected.
③	**Lab name** To have a lab name appear on Reports, type in the name of your lab.
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.

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Key to Figure 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 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.

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

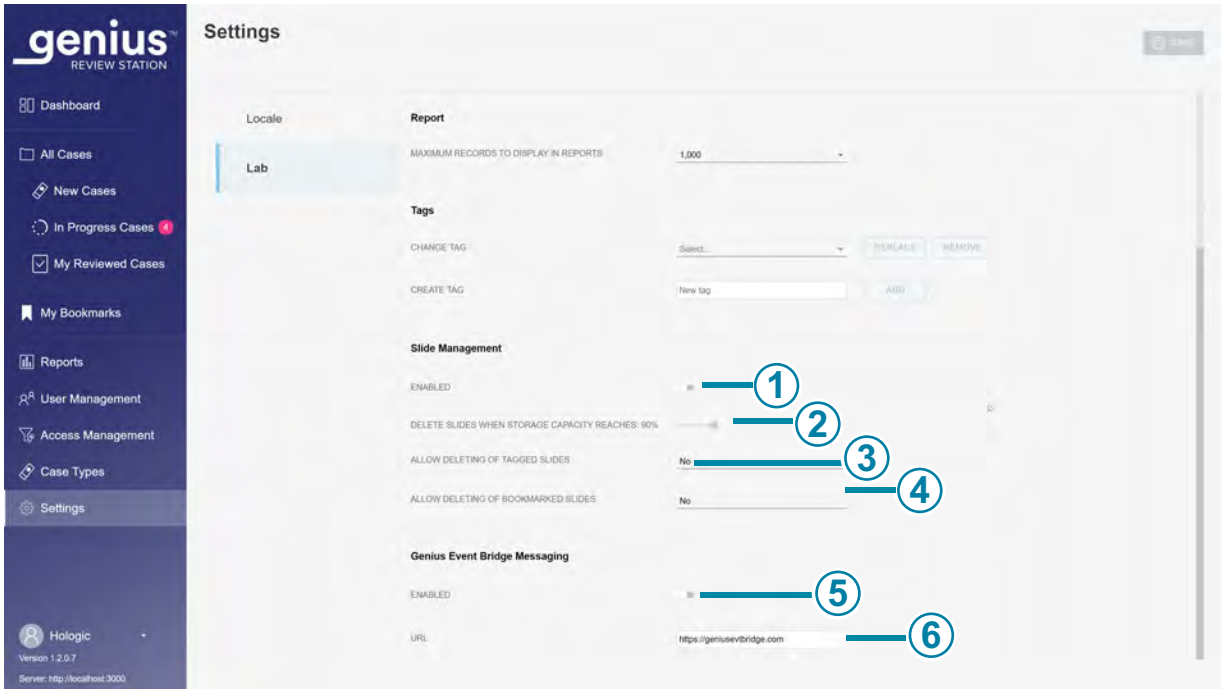

Figure 3-13 Settings for Slide Management

Key to Figure 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 3.29 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.

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Key to Figure 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.**

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Key to Figure 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 Messaging, 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.

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

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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 CT 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.

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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 6.3.

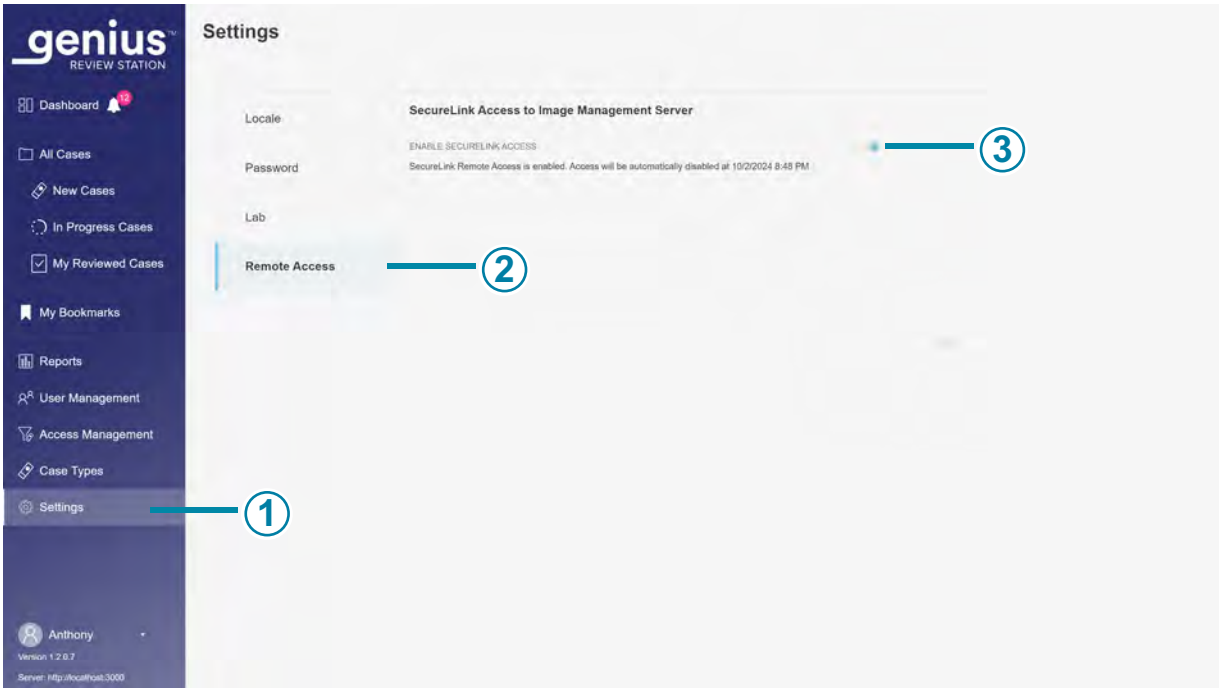

Figure 3-14 Review Station Settings for Remote Access to the Image Management Server

Key to Figure 3-14	
1	The lighter color in the menu bar indicates that **Settings** is selected.

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Key to Figure 3-14	
②	The blue color in the list of settings indicates that the **Remote Access** settings are selected.
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 6.4 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 only)

From the User Management screen, a manager or an administrator can view and export lists of current users, add, deactivate or unlock 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 into any Review Station connected to the same Image Management Server.

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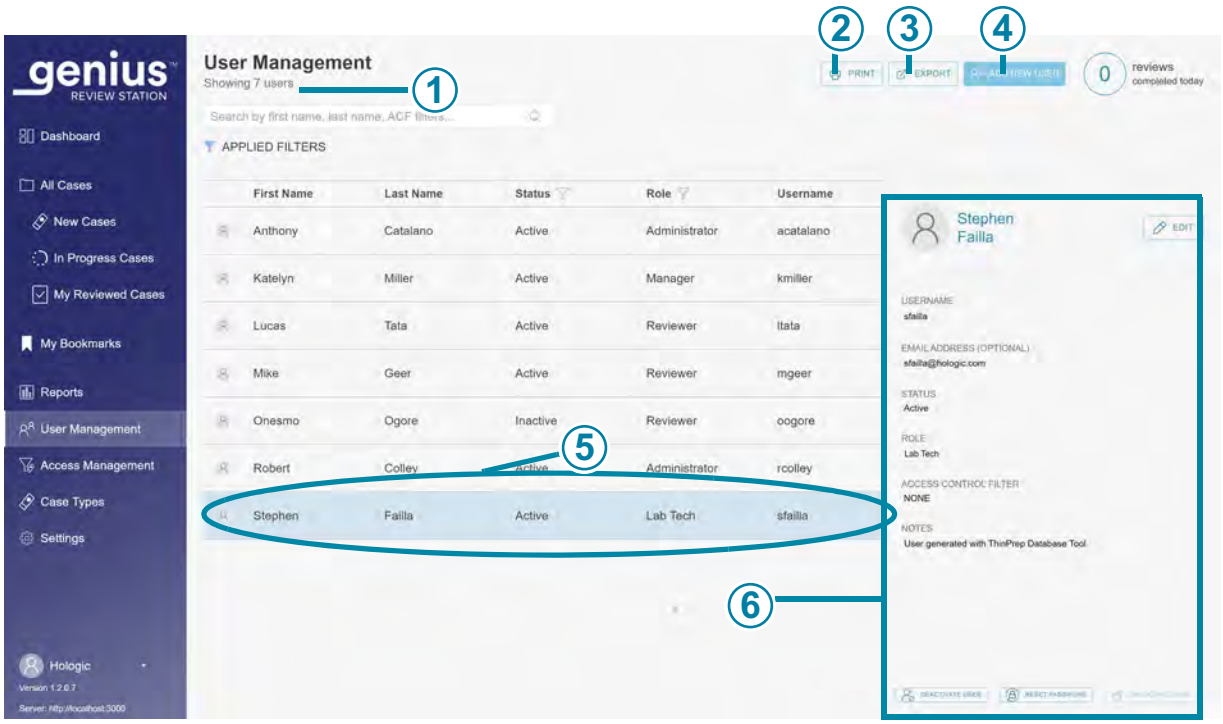

Figure 3-15 User Management: List of Users

Key to Figure 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 3.34.
5	The list of users shows the first name, last name, status, role and username for users in the Review Station network.

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Key to Figure 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, all users with locked accounts, 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 into 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.
- 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 3.37 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.

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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 access the Case Types screen. The Case Type is always "Gyn".
   - 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 "Add a tag" on page 4.21.
   - A user with the lab tech role can run reports.
   - A user with the lab tech role can delete new cases on the Review Station.

   In addition to reviewing cases, a user with the reviewer role can search for and review cases. A reviewer can run reports, but a reviewer's view is typically limited to the workload for that reviewer.

   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 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 3.58.
   - A manager can "reclaim" an in-progress case from a reviewer. Refer to "Reclaim a case" on page 3.56.
   - A manager can "reset" an in-progress case from a reviewer to the "New" status. Refer to "Reset a case" on page 3.57.

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- A manager can send Alerts to other users in the Review Station network. Refer to “Send an alert” on page 3.62.
- 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 3.58.
- An administrator can “reclaim” an in-progress case from a reviewer. Refer to “Reclaim a case” on page 3.56.
- An administrator can “reset” an in-progress case from a reviewer to the “New” status. Refer to “Reset a case” on page 3.57.
- An administrator can send Alerts to all other users in the Review Station network. Refer to “Send an alert” on page 3.62.
- 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 3.39.
- 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 access the Case Types screen. The Case Type is always “Gyn”.

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.

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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 easy to find. Furthermore, an administrator can type the name of an access control filter into the in 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.

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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.

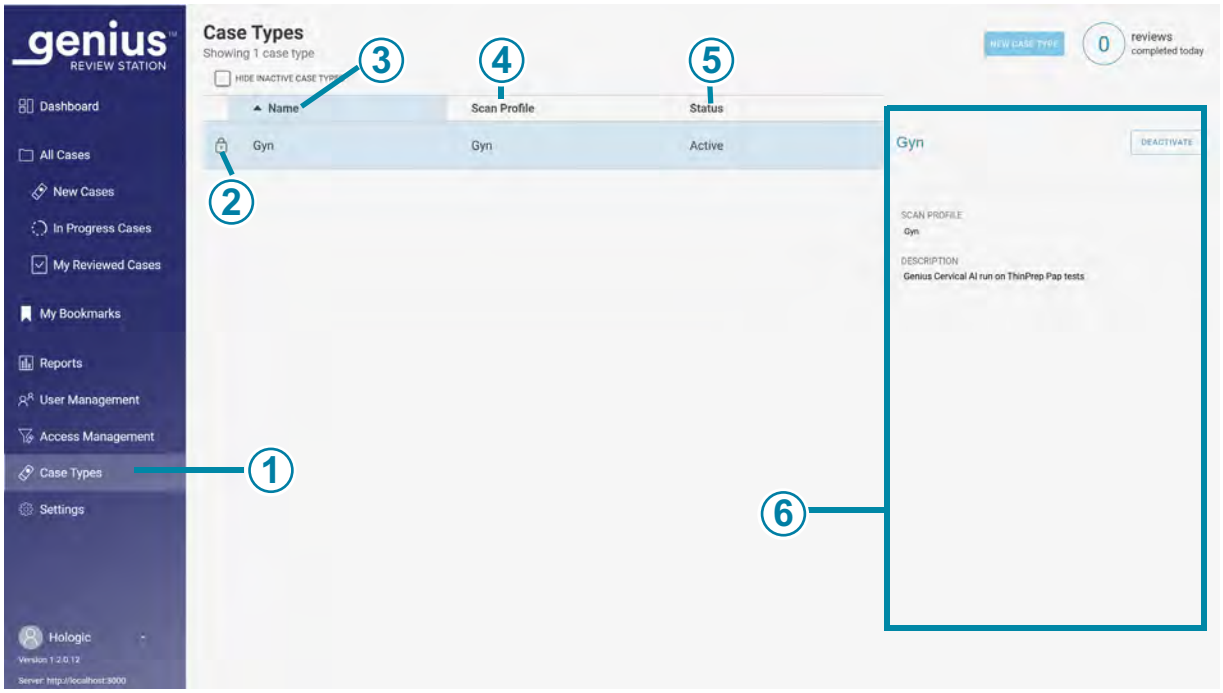

Figure 3-16 Case Types

Key to Figure 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.
3	**Name** The Gyn case type at the Genius Review Station also appears in the carrier selection options at the Genius Digital Imager. The name of the case type also appears in several reports.

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Key to Figure 3-16	
④	**Scan Profile** The scan profile for the Gyn case type is “Gyn”.
⑤	**Status** A case type must be in the active status in order to image slides. Do not deactivate the Gyn case type.
⑥	This panel shows information about the Gyn case type.

Access Control Filters

(Administrator only)

From the Access Control Filters screen, an administrator can create new 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.

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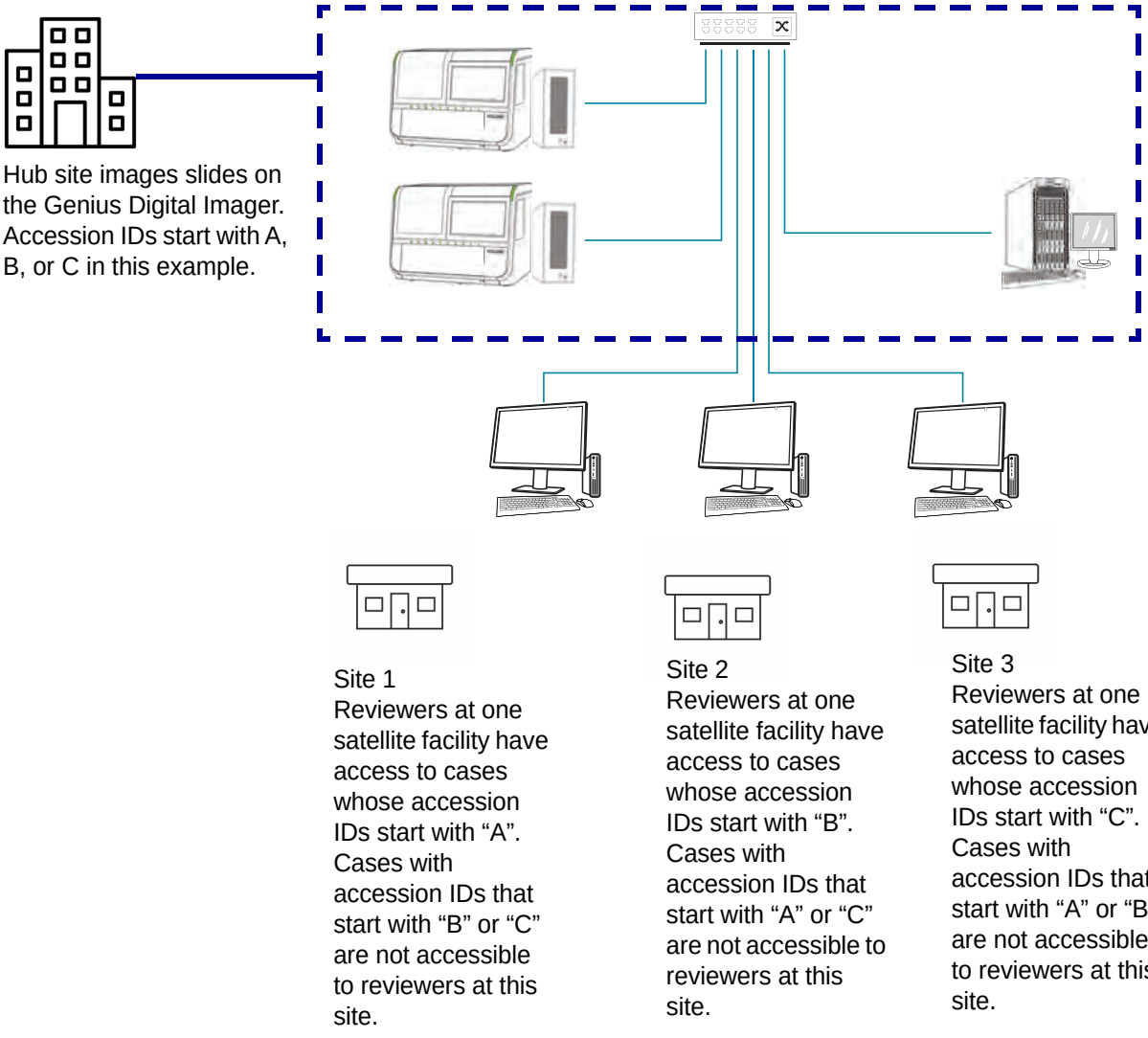

Figure 3-17 Controlling Access by Accession ID, Example

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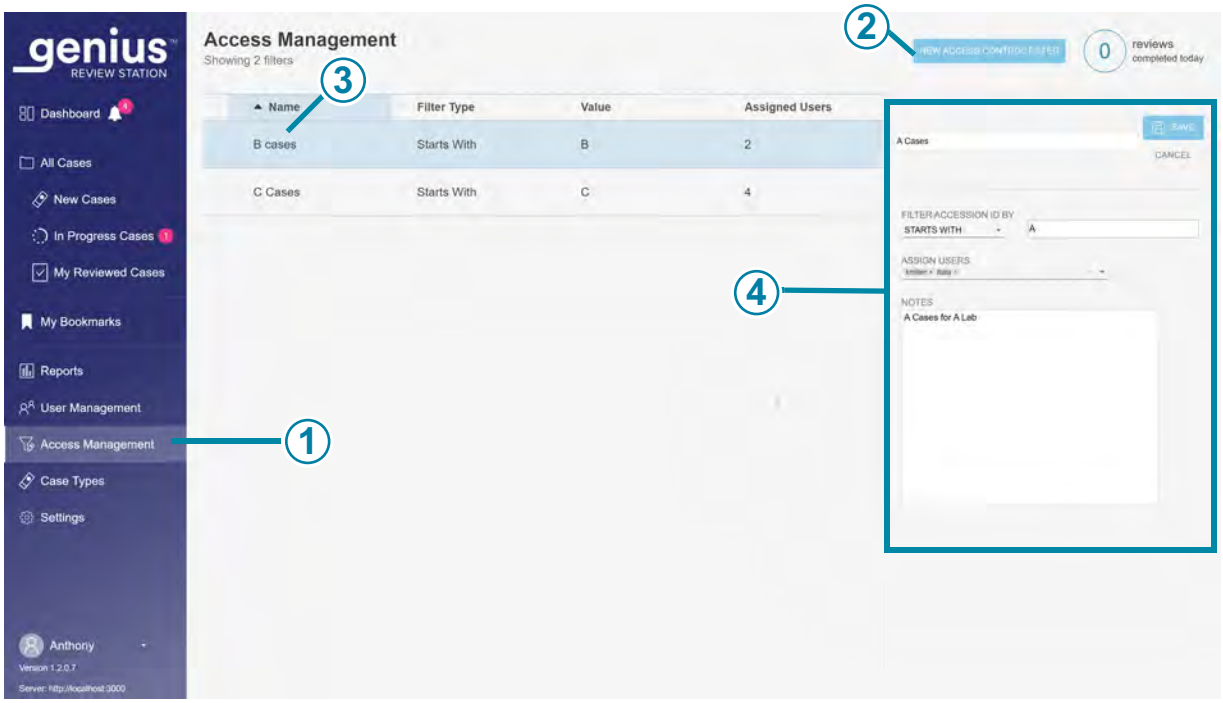

Figure 3-18 Access Management (Administrator Only)

Key to Figure 3-18	
1	Access Management appears in the menu bar for Review Station administrators.
2	Use the **New Access Control Filter** button creates a new filter. Refer to “Create an access control filter” on page 3.42.
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.

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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 Accession 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 into 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 3.44 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 Managment 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.

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- 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.

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Edit an access control filter

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

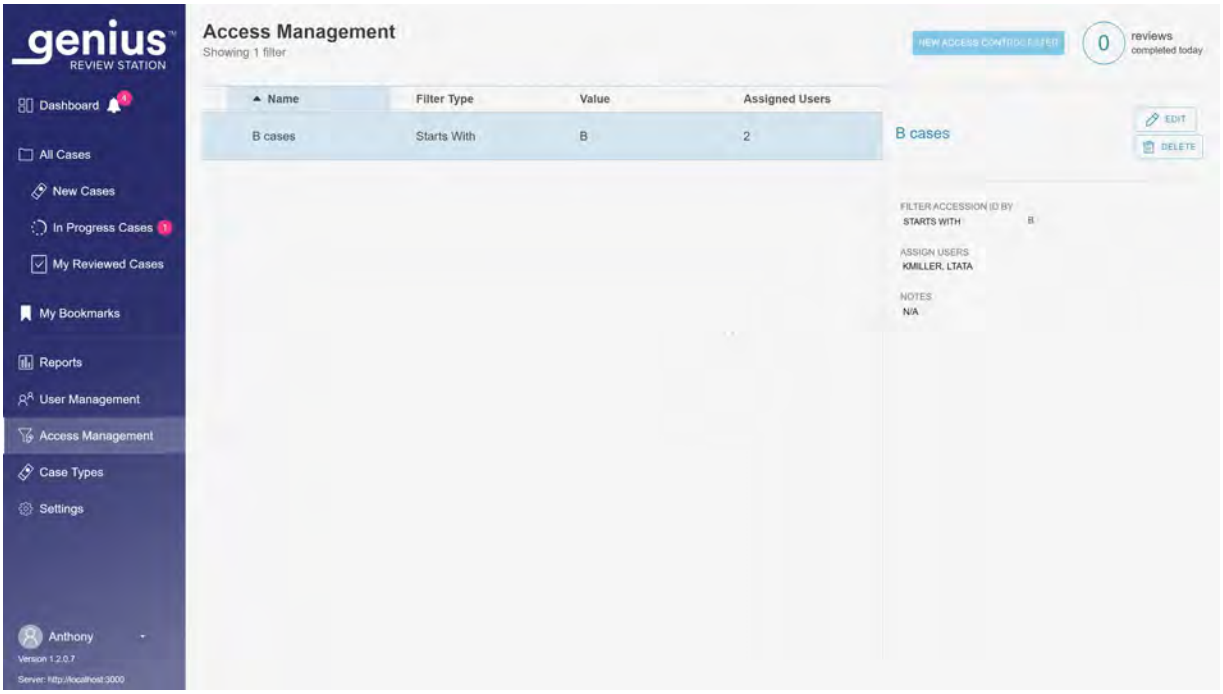

Figure 3-19 Edit or Delete an Access Control Filter

To edit an access control filter:

1. Select Access Management in the menu bar. The Access Managment 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 3.32.

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.

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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. Refer to "Open a case" on page 4.4.

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, then the case is available with read-only access to the reviewer(s) who completed the review of that case. Refer to "Open a case" on page 4.4.

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.

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



Figure 3-20 Review Station Dashboard, Default Widgets of Slides Imaged and Reviews Completed

Key to Figure 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 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 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.

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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. 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 to display can be segmented by reviewer. 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.
- **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.

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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 3-21 Review Station Dashboard, Widget Options Button

Key to Figure 3-21	
1	Use the **+Add Section** button on the Dashboard. See “Add a widget to the Dashboard” on page 3.51.
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.

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



Figure 3-22 Review Station Dashboard, Add Widget Section, Remove or Edit Widget

Key to Figure 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 3.50.
3	**Remove Widget** Click here to remove this widget from the Dashboard.

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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.

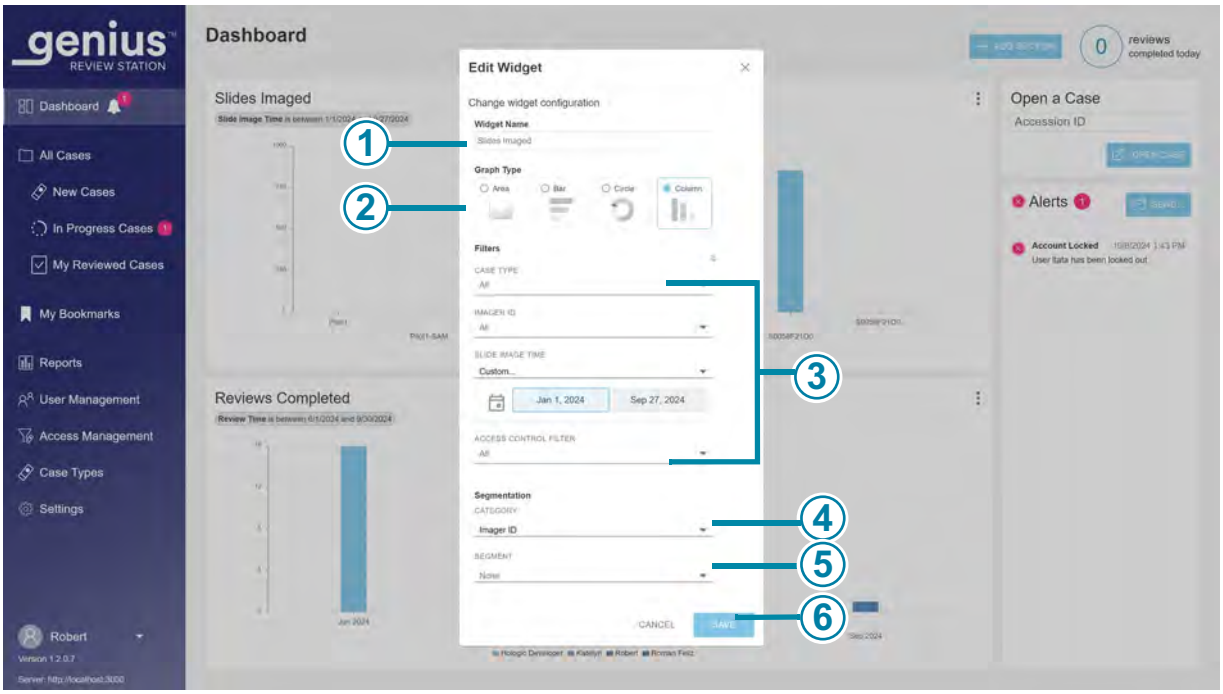

Figure 3-23 Review Station Dashboard, Edit a Widget

Key to Figure 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).

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Key to Figure 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 Digital Imager, by slide image time (for 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, when 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.

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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 3.50.

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 an 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 3.22.

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 **Search by tag...** 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 3.61.

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.

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- "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 "Search by Tag..." 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 "Search by Tag..." 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.

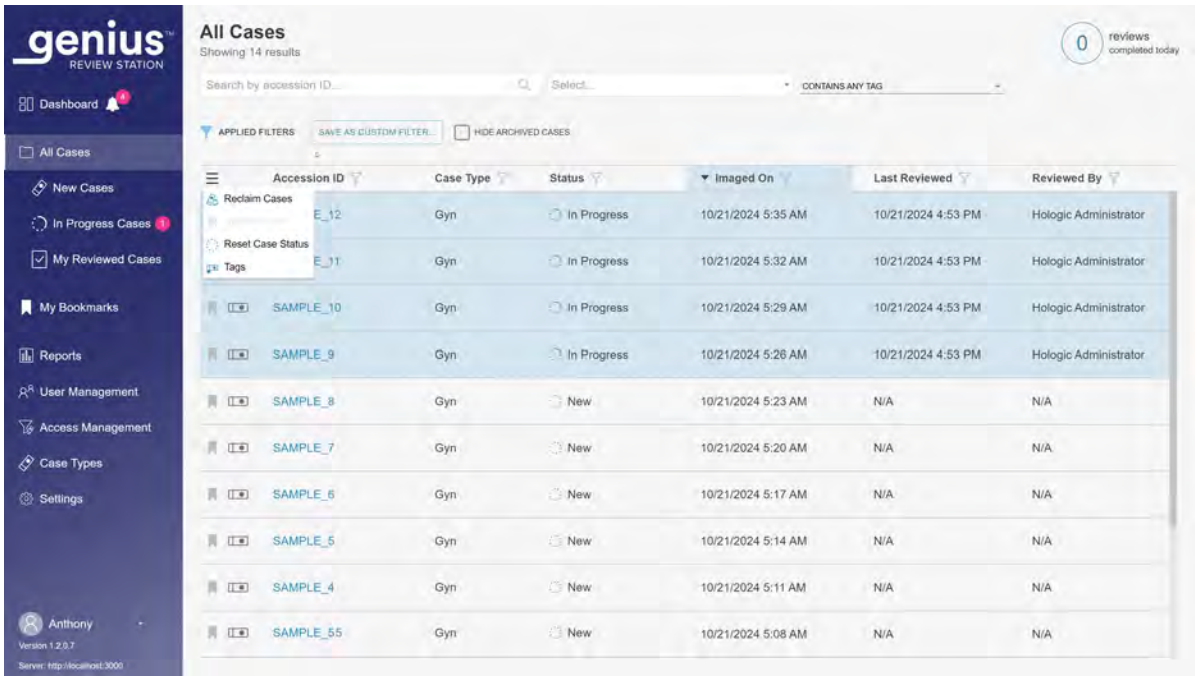

Figure 3-24 Select Multiple Cases (Administrator Role Shown)

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:

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- 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 3.56.
   - Delete slides (Manager or Administrator). Refer to "Delete a case" on page 3.58.
   - Reset cases (Manager or Administrator). Refer to "Reset a case" on page 3.57.
   - Tags. Refer to "Add a tag" on page 4.21.

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 to 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 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 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.

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For My Reviewed Cases, columns in the main pane can be filtered, similar to filtering “All Cases”. The Status 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.

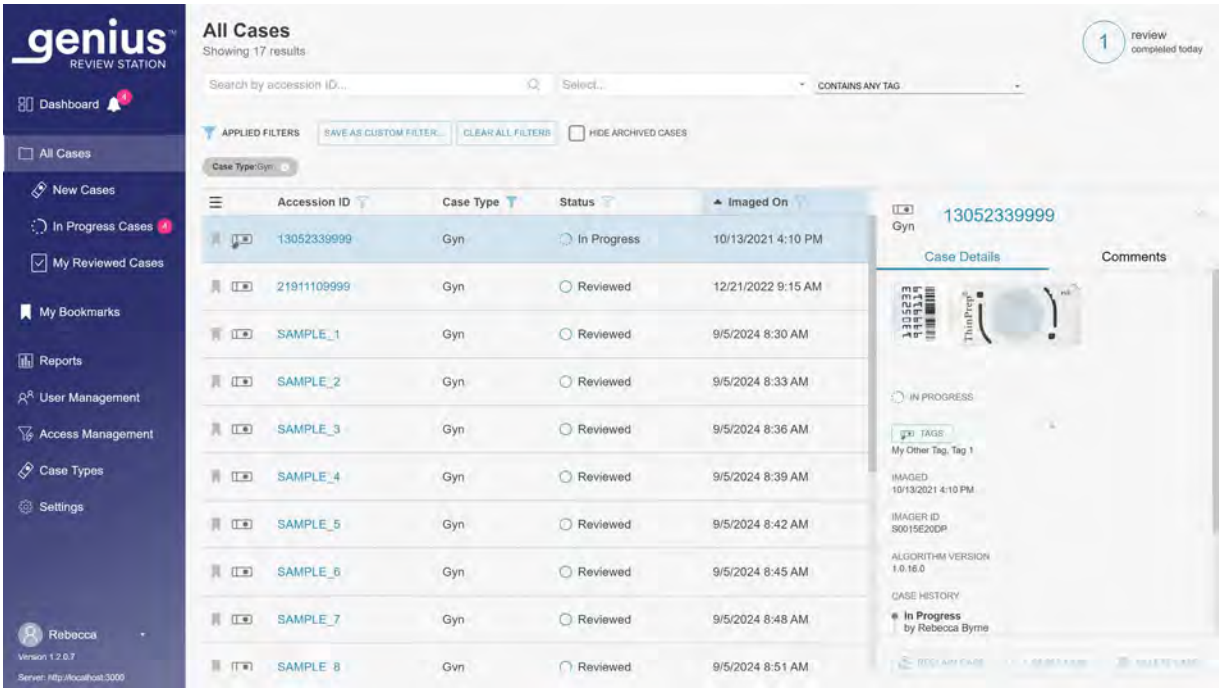

Figure 3-25 Case Detail - Gyn Example, Administrator Role Shown

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, the date the slide was imaged, a status indicator describing if any tags have been applied, 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.

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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.

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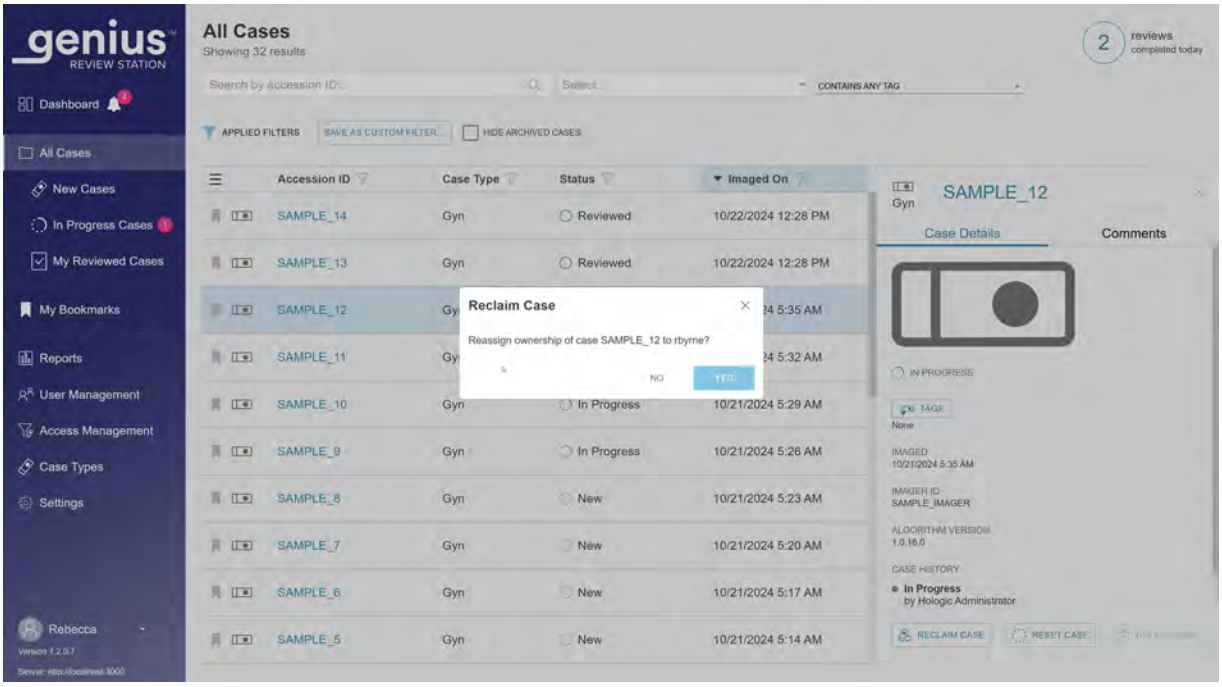

Figure 3-26 Reclaim an In-progress Case, Administrator Case Details View

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.

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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.

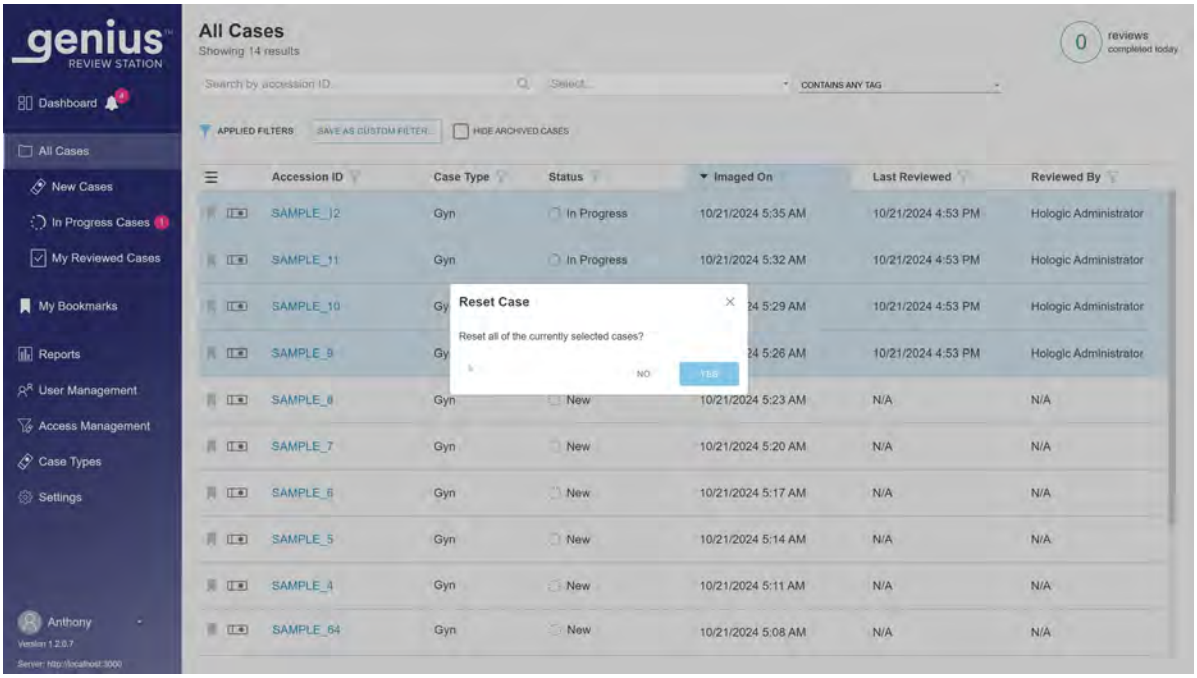

Figure 3-27 Reset a Case, Multiple Cases Selected from the Case List, Administrator View Shown

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.

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.

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Figure 3-28 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 can filter accession IDs by the name of the access control filter.



Figure 3-29 Accession ID Filter, Administrator Example

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Case Type Filter – There is an option to filter the case list by case type. All of the data is for the Gyn case type. so specifying the case type is not necessary.

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.

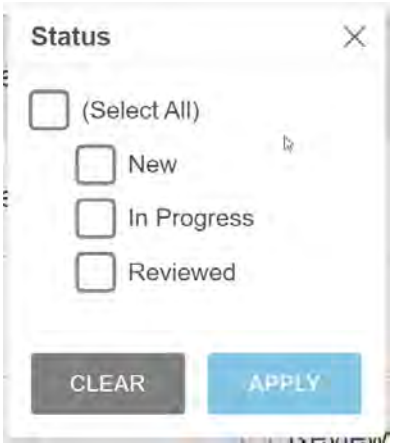

Figure 3-30 Status Filter

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.

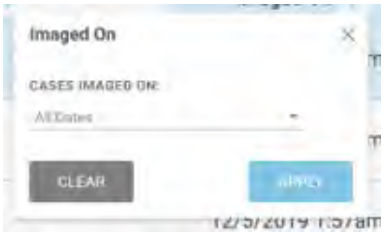

Figure 3-31 Imaged On Filter

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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.

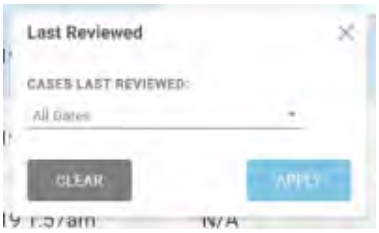

Figure 3-32 Last Reviewed Filter

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.

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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. Type in the text for the alert with the keyboard in the **Message** field.

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4. Click **Send** to send the alert. Or, to delete the alert without sending it, click the **Cancel** button.

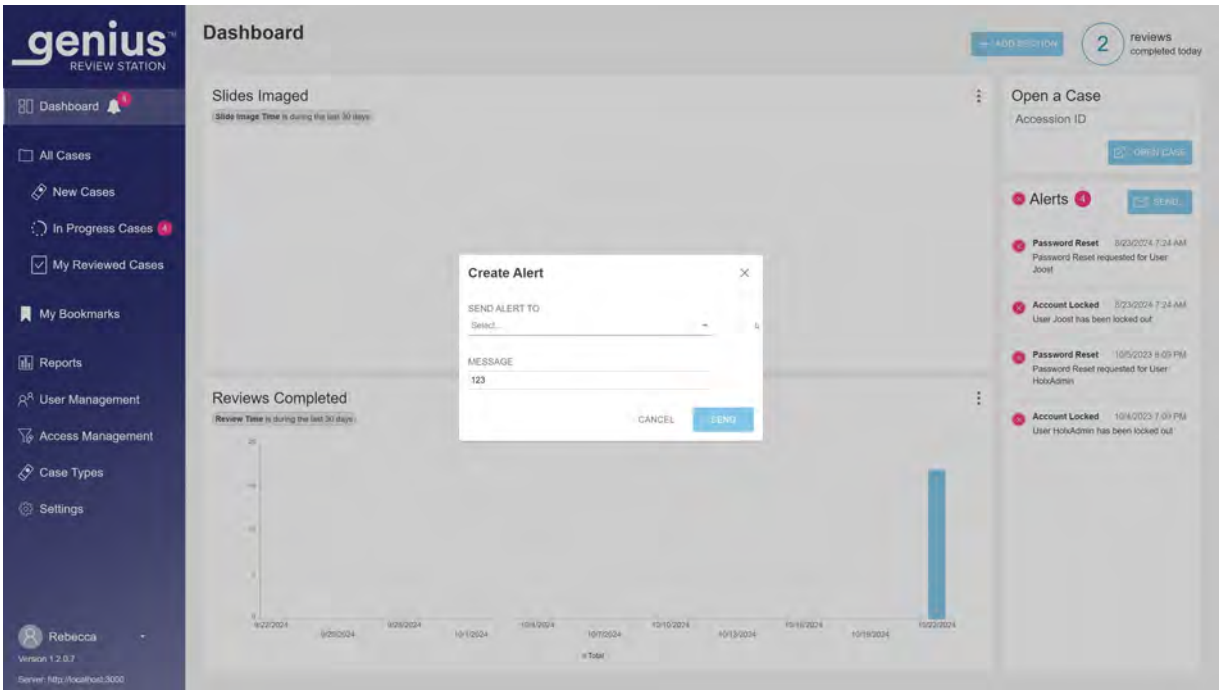

Figure 3-33 Send an Alert, Administrator Example

Key to Figure 3-33	
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

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Receive and read an alert

On the Dashboard, when a reviewer, lab tech, manager or 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.

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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.

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

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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.

Note: Some reports have options to select, sort or filter data by case type. All of the data is for the Gyn case type, so specifying the case type is not necessary.

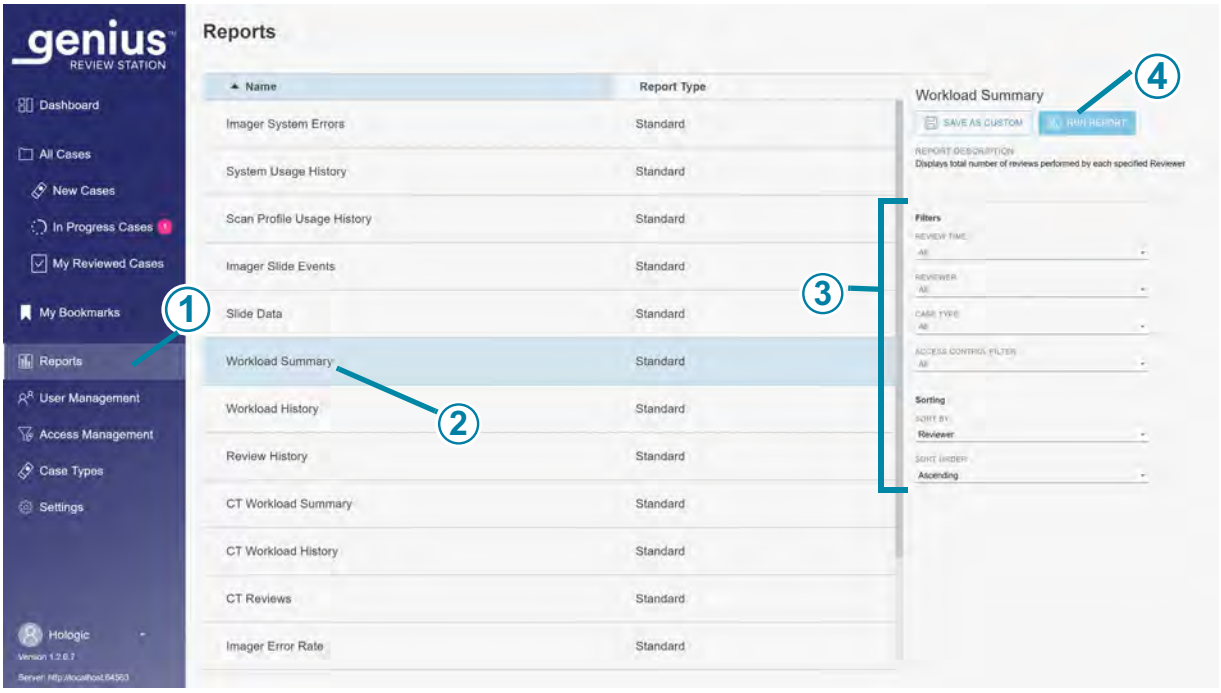

Figure 3-34 List of Reports, CT Reviews Selected

Key to Figure 3-34	
1	Click on **Reports**.

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Key to Figure 3-34	
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, and 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 Station reports for errors

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

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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 6.6.

Imager System errors are errors related to instrument performance. The Imager System error codes are described in “Imager Error Codes” on page 6.9.

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

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

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- 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.

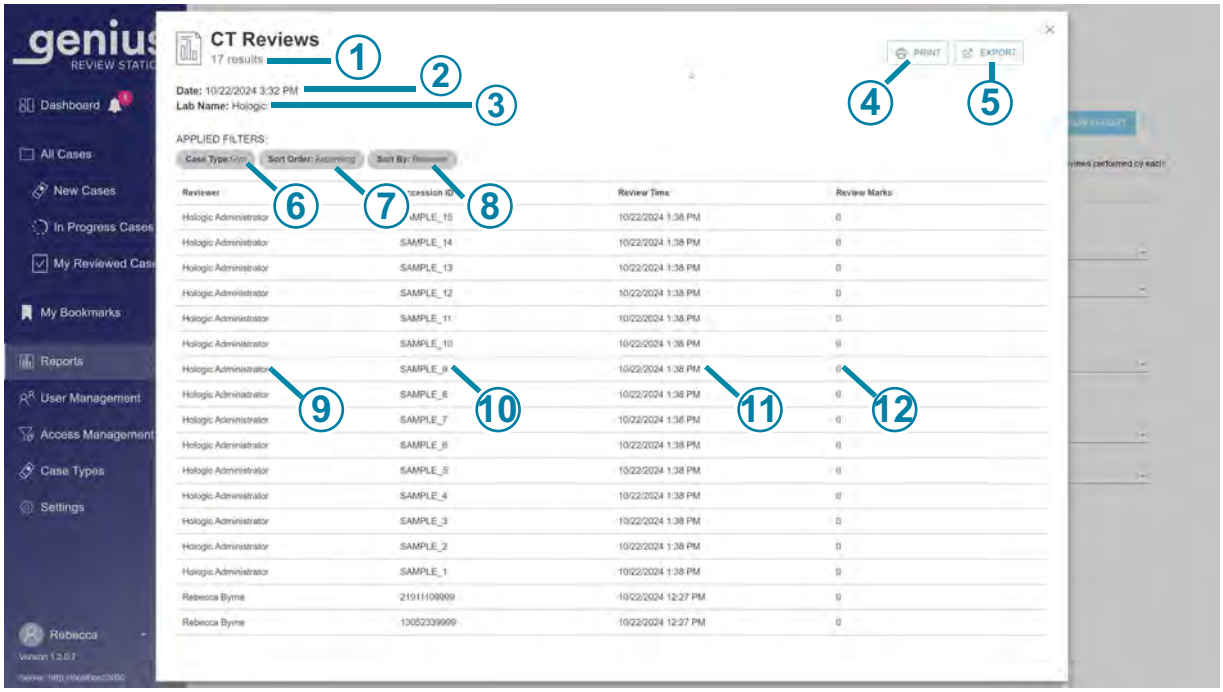

Figure 3-35 CT Reviews Report, Example

Key to Figure 3-35	
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

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Key to Figure 3-35	
④	Print to PDF
⑤	Export the data as a CSV file
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.

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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(s) 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.
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

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

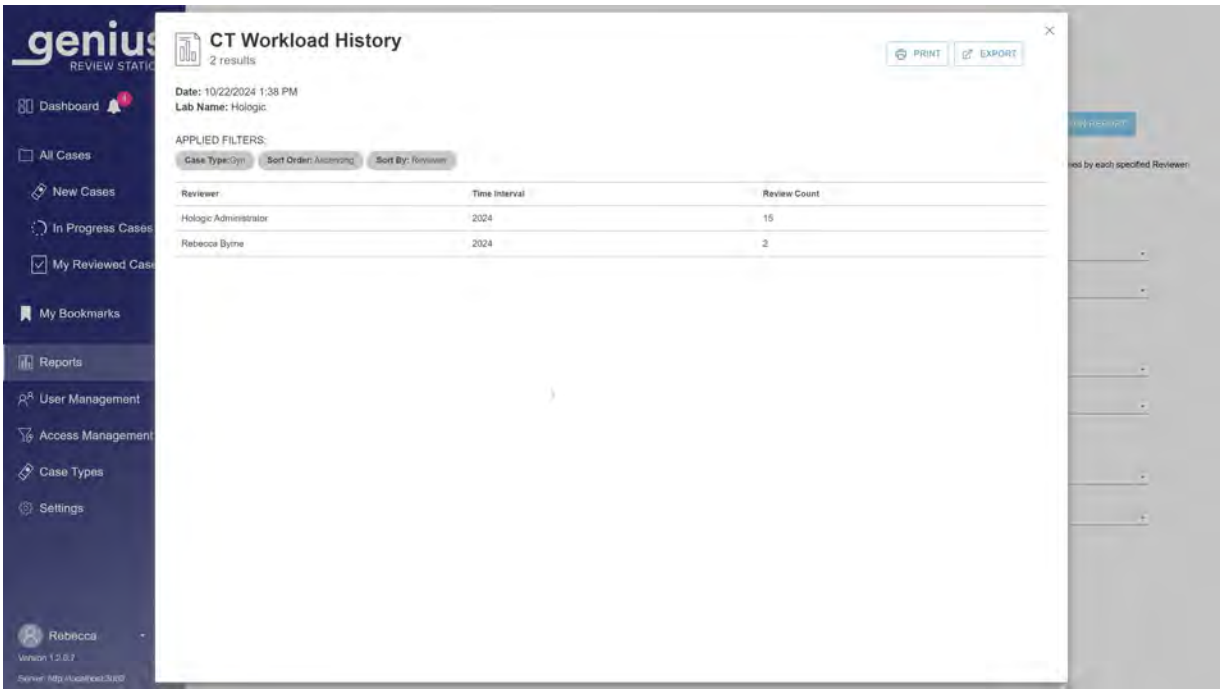

Figure 3-36 CT Workload History Report, Example

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

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- 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. 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 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 the number of completed reviews.
6. Choose the order in which the data will appear.

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- Sort the results in ascending or descending order.

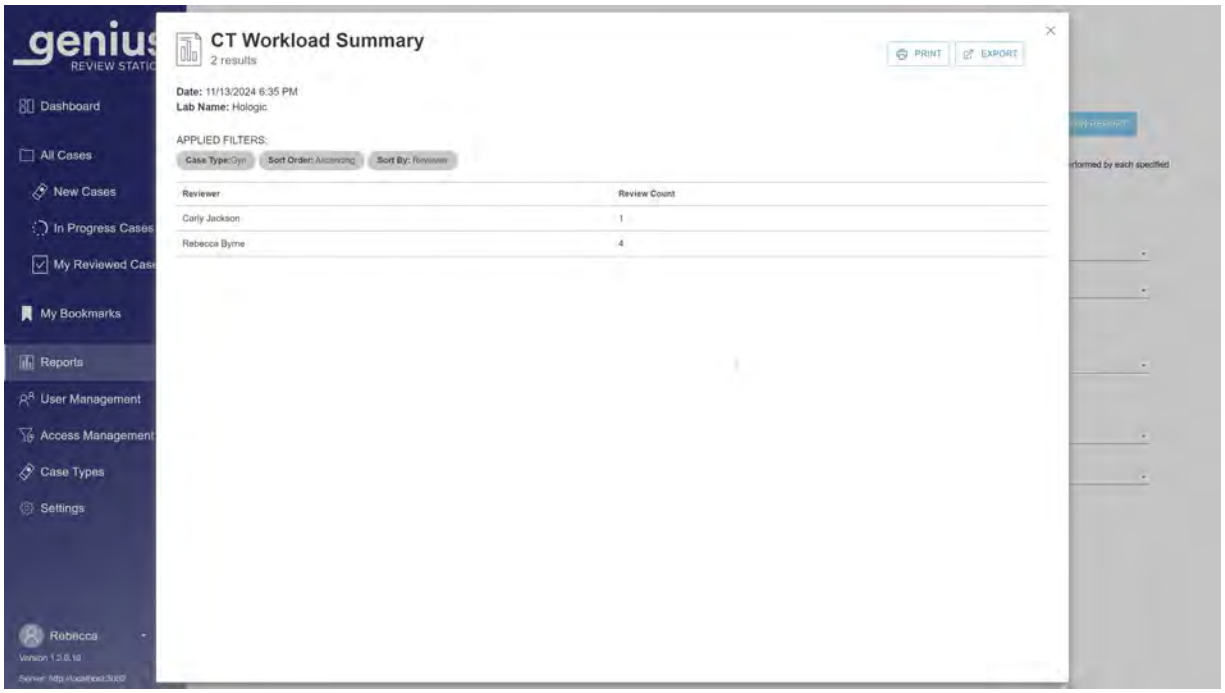

Figure 3-37 CT Workload Summary Report, Example

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

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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 3-38 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)

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

2. There is an option to select the case type. All of the data is for the Gyn case type, so specifying a case type is not necessary.
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 (Gyn)
   - 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.

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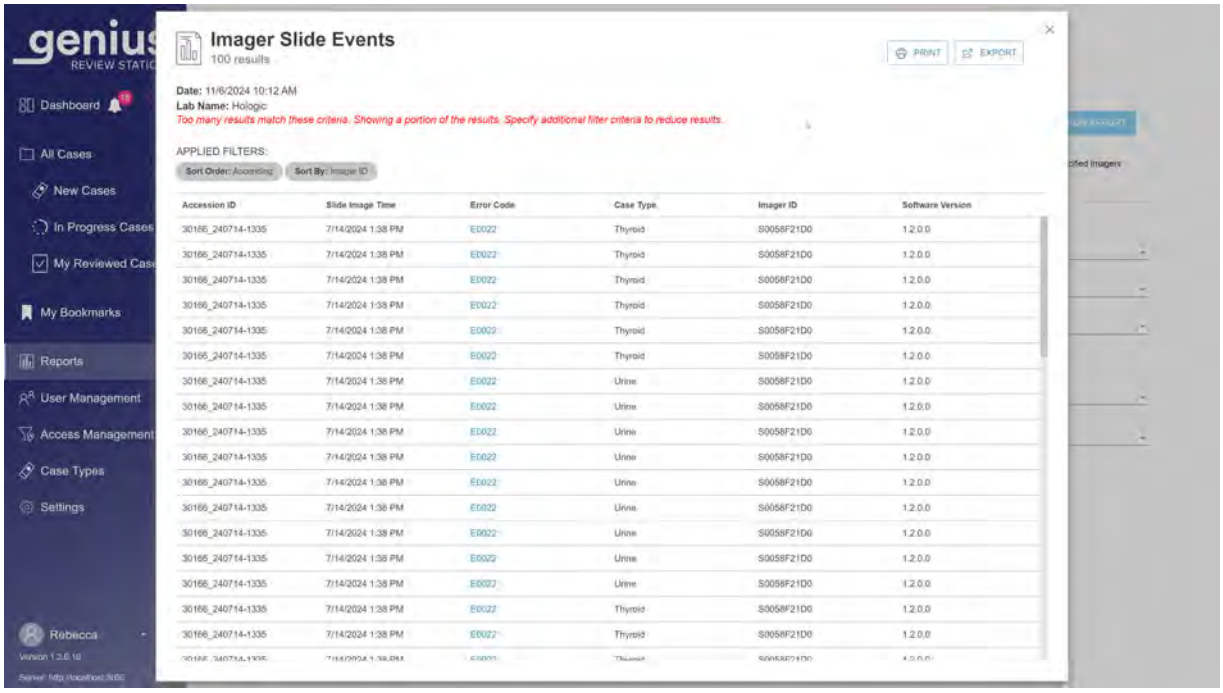

Figure 3-39 Imager Slide Events Report, Example

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

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- 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.

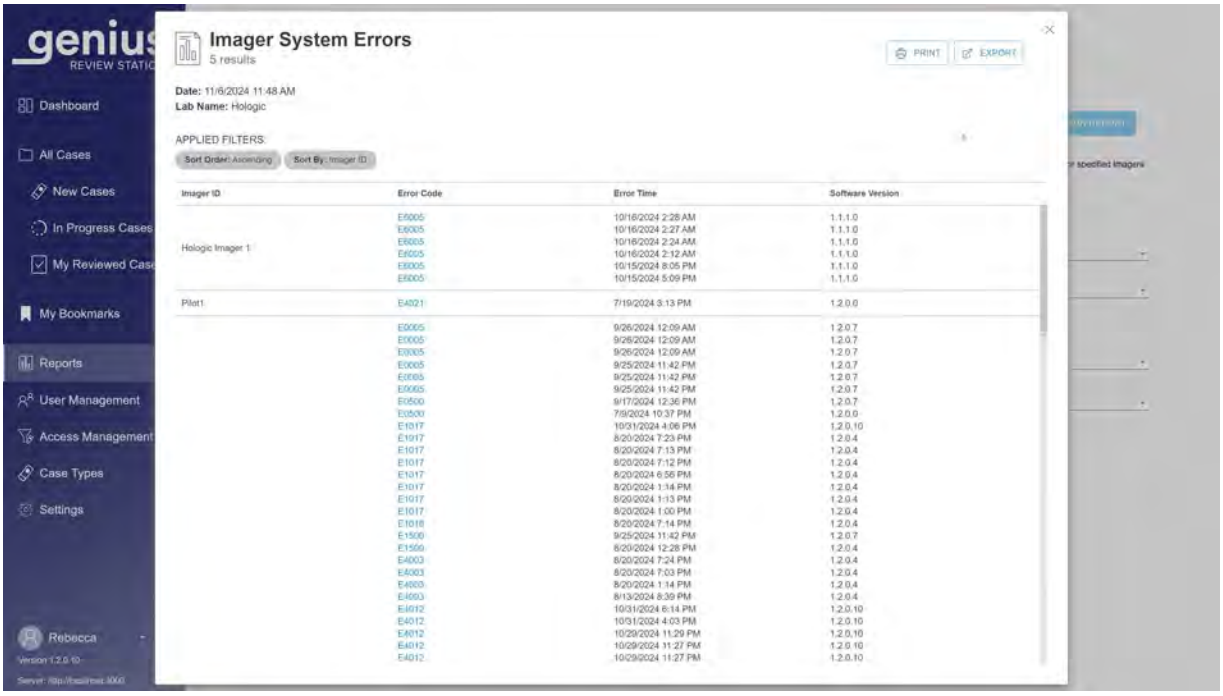

Figure 3-40 Imager System Errors Report, Example

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.

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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)

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

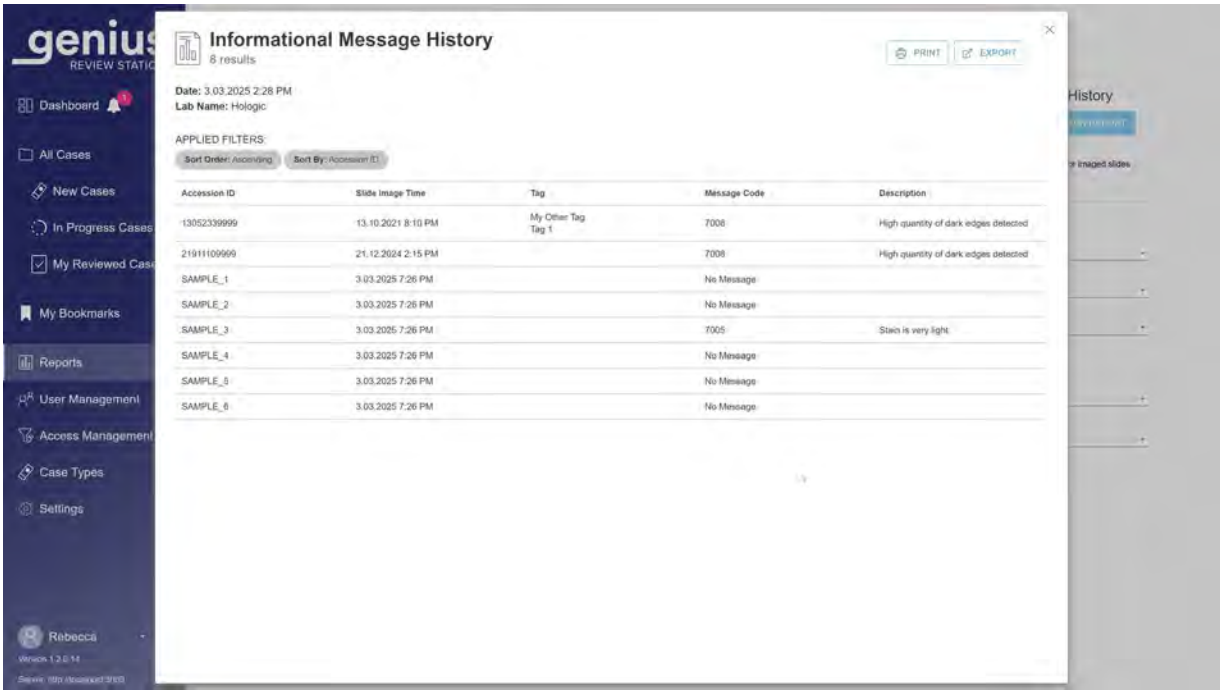

Figure 3-41 Informational Message History Report, Example

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

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- 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.

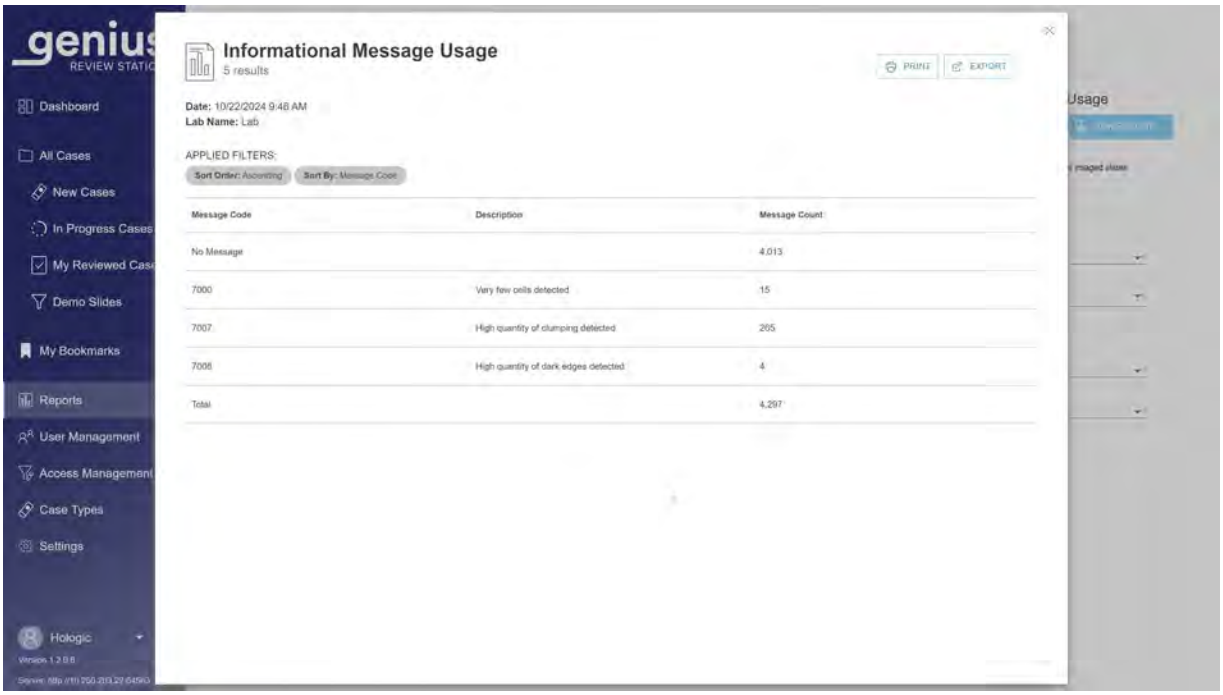

Figure 3-42 Informational Message Usage History Report, Example

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

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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.

Review History

The Review History Report is the same as the CT Reviews Report. Refer to "CT Reviews Report" on page 3.68.

Scan Profile Usage History

The Scan Profile Usage History Report lists Digital Imager activity for the Gyn scan profile.

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. There is an option to select the scan profile type. All of the data is for the Gyn scan profile, so specifying a scan profile is not necessary.
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 (Gyn)
   - 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)

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

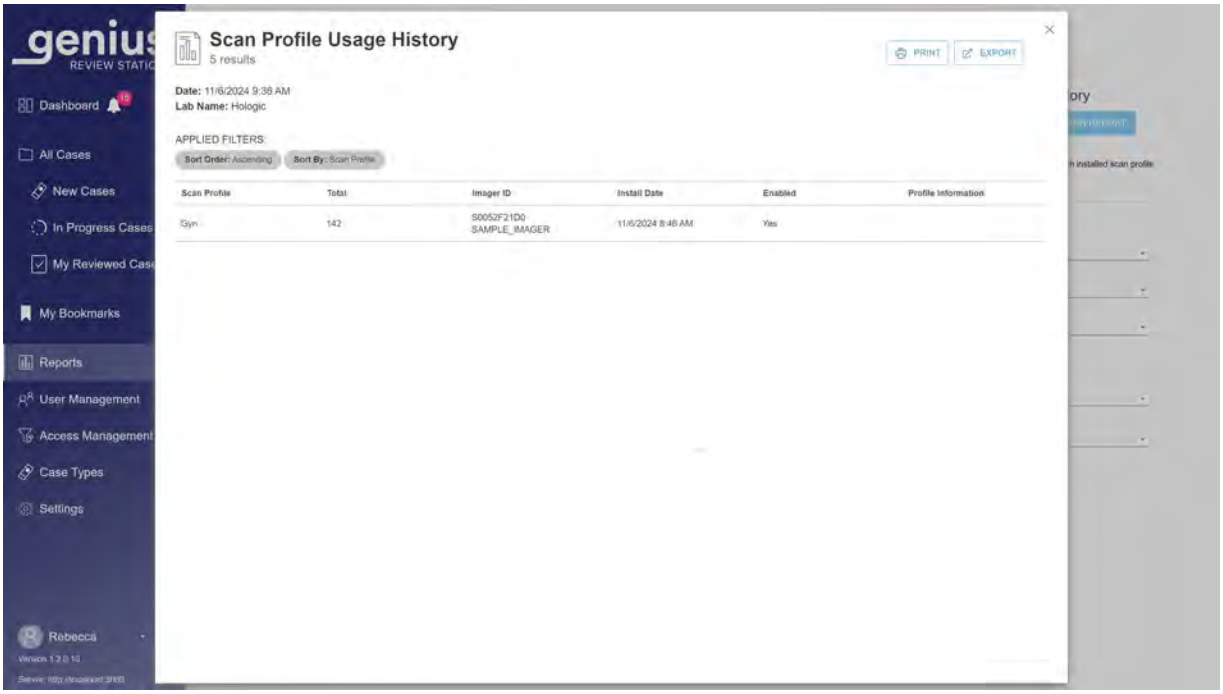

Figure 3-43 Scan Profile Usage History Report, Example

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.

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.

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Select the imaging criteria for the Slide Data Report

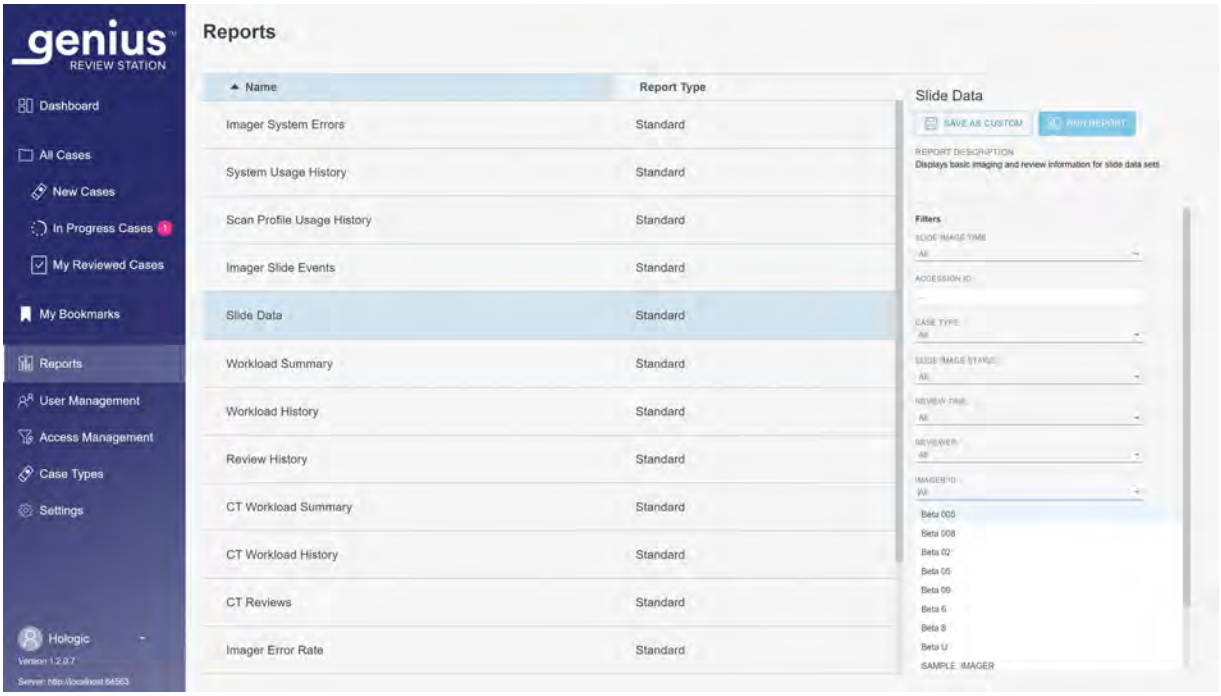

Figure 3-44 Select Criteria for Slide Data Report

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.
3. There is an option to select the case type. All of the data is for the Gyn case type, so specifying the case type is not necessary.
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:

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- **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.

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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.

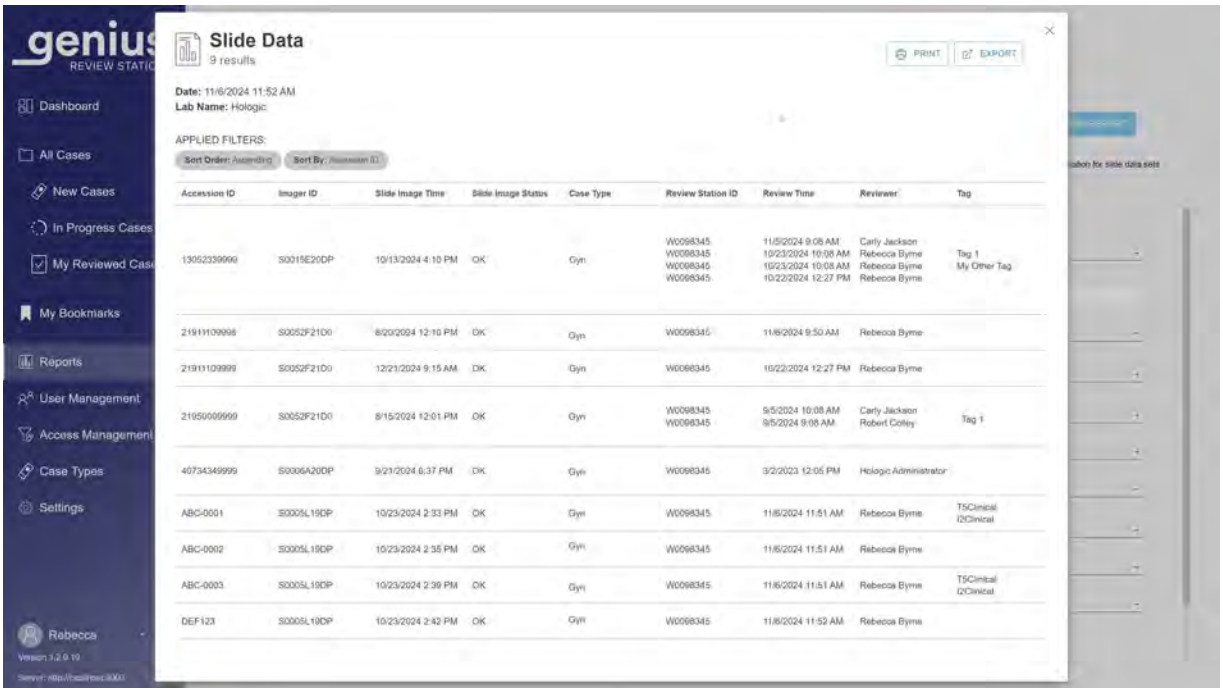

Figure 3-45 Slide Data Report, Example

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.

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- 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.

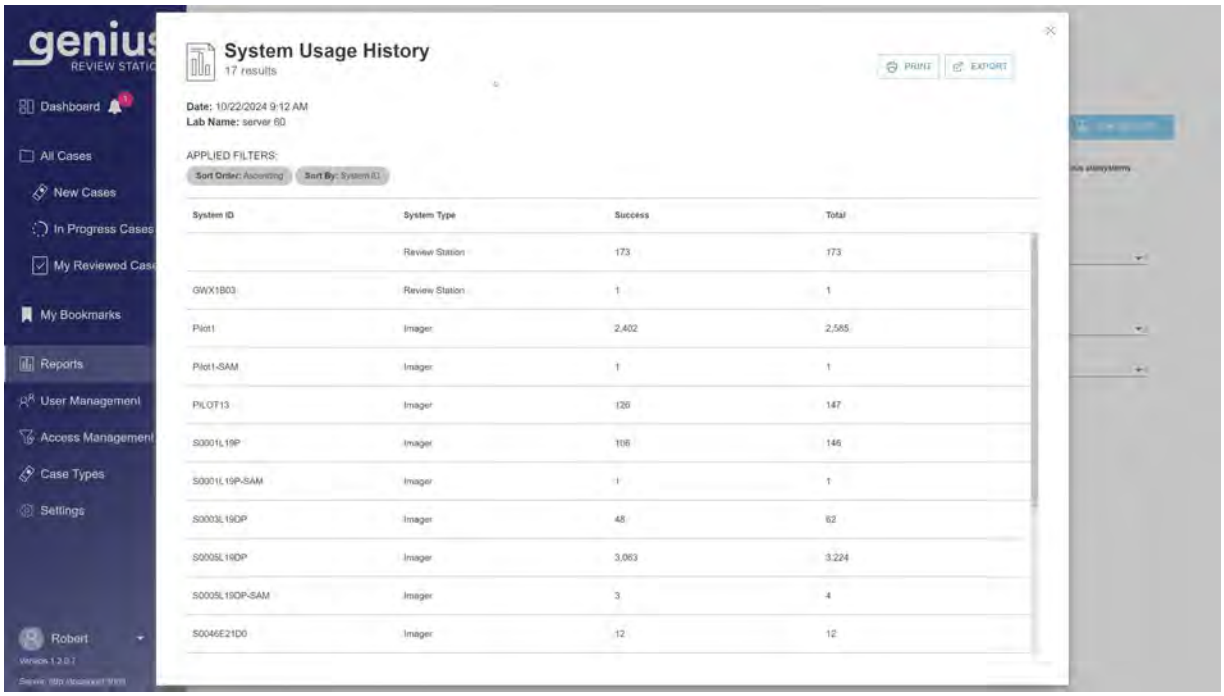

Figure 3-46 System Usage History Report, Example

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.

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.

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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:

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- 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.

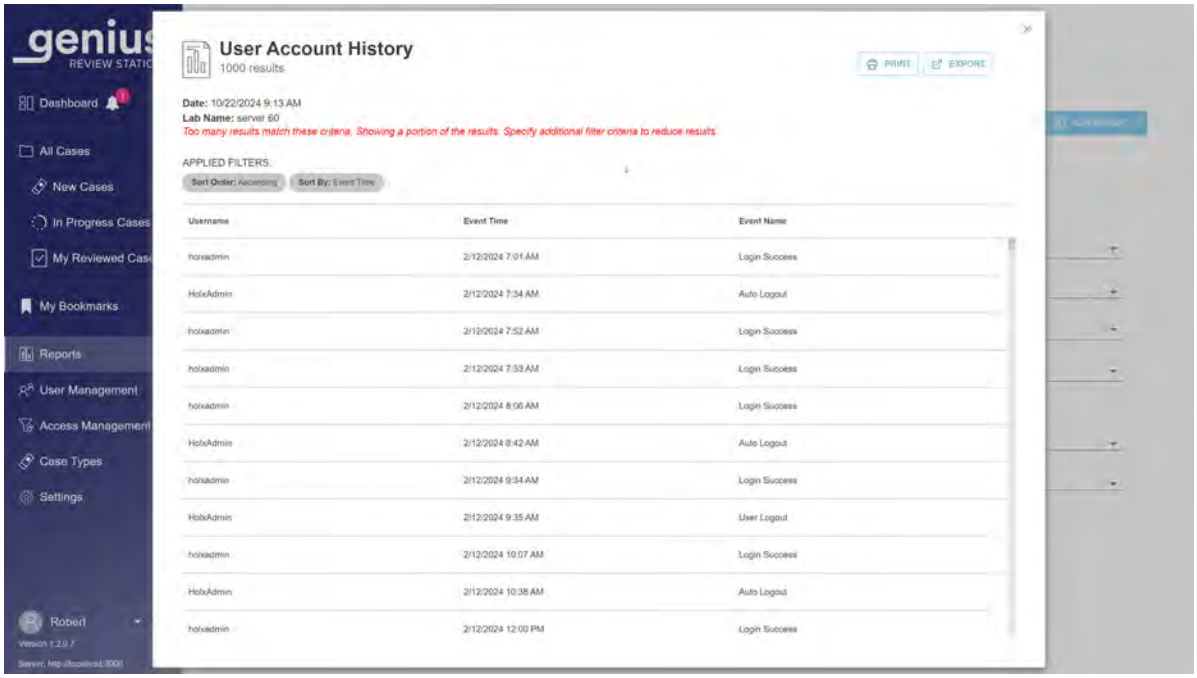

Figure 3-47 User Account History Report, Example

Workload History

The Workload History Report is the same as the CT Workload History Report. Refer to “CT Workload History” on page 3.70.

Workload Summary

The Workload Summary Report is the same as the CT Workload Summary Report. Refer to “CT Workload Summary” on page 3.72.

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4. Operation

Chapter Four

Operation

SECTION A OVERVIEW

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 Digital Diagnostics System with the Genius Cervical AI algorithm, the Review Station presents a gallery of images, additional images, and an image of the whole cell spot.

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 with Genius Event Bridge messaging. The event data can integrate with a compatible Laboratory Information System (LIS). Additional integration activities by the laboratory or the LIS provider are required.

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 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

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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 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

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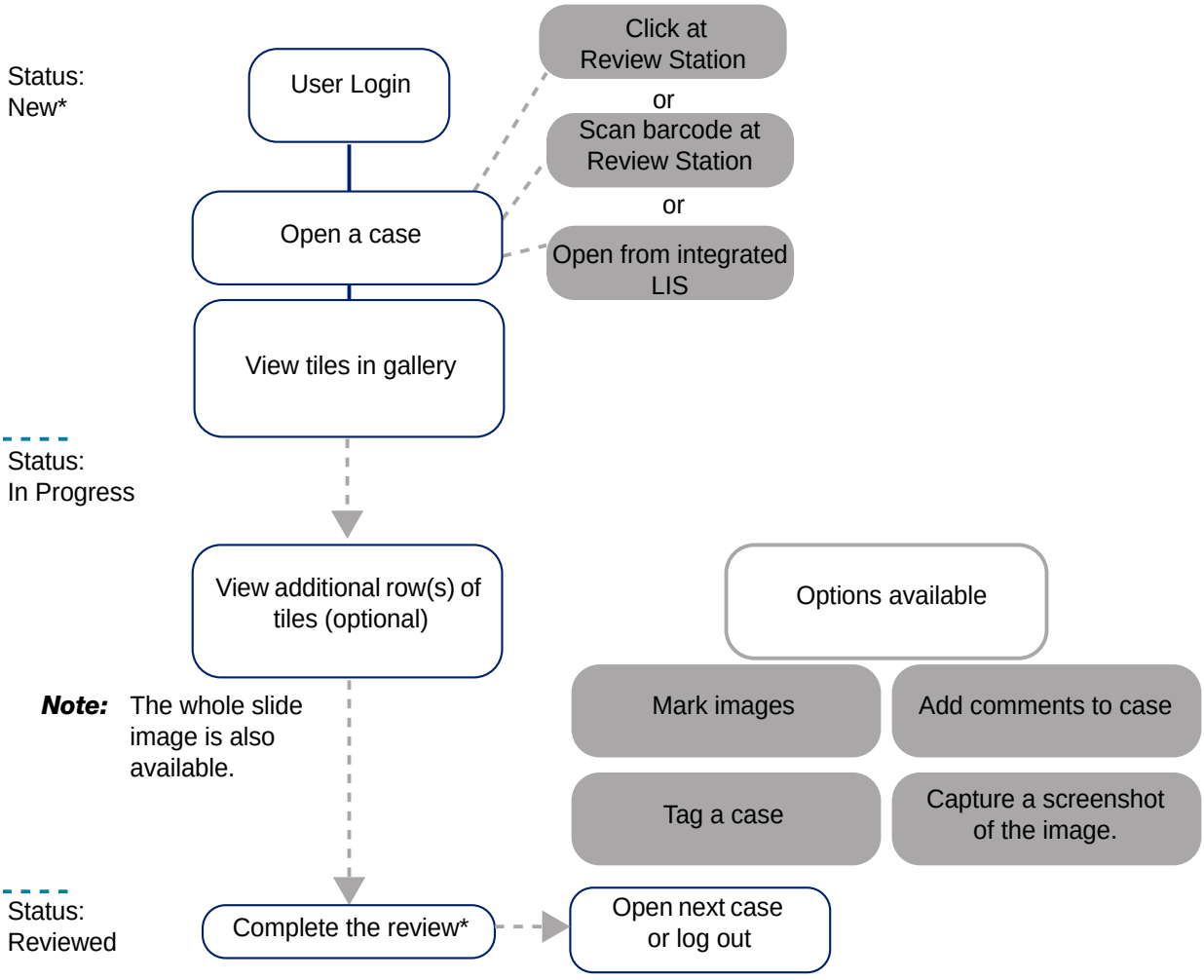

Figure 4-1 Typical Case Review Processes

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4 OPERATION

SECTION B MATERIALS REQUIRED PRIOR TO OPERATION

- Slide data on the Genius Image Management Server from imaged ThinPrep Imaging System slides
- Genius Review Station

Important Operational Notes:

- Examine the gallery of tiles, the five rows with six tiles per row, initially displayed at the Review Station.
- Marking images - the case images are digitally marked 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

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optional barcode scanner. Select **Open Case**, and the review screen displays. See Figure 3-6 on page 3.11.

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.

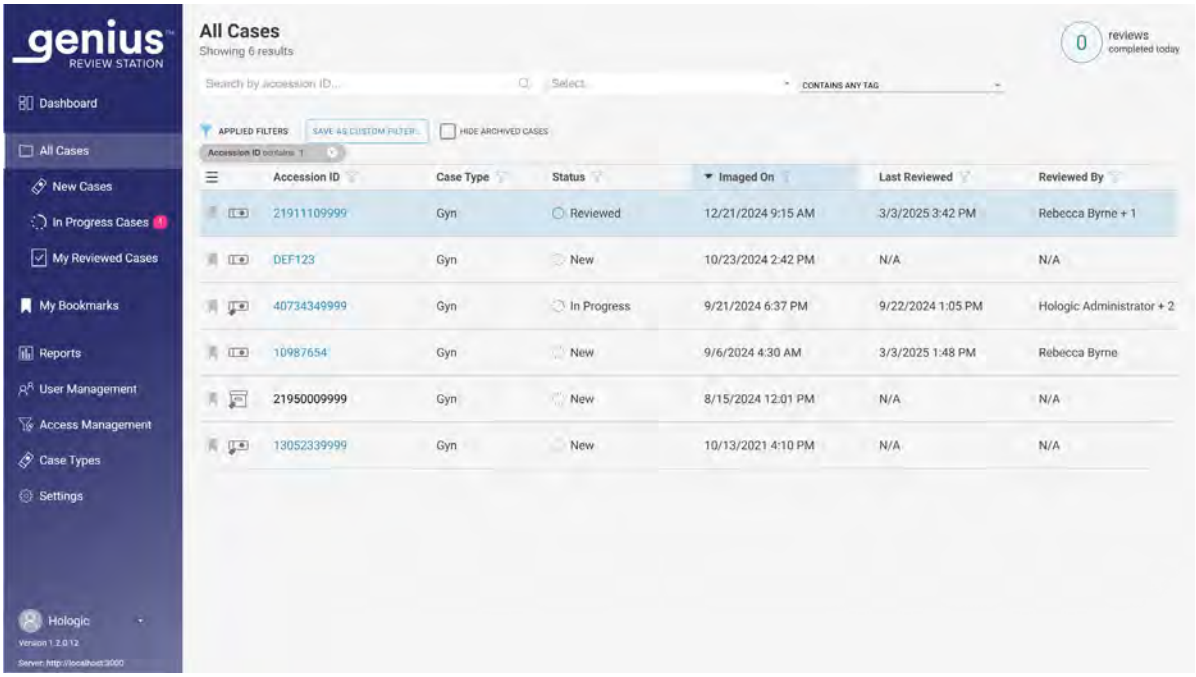

Figure 4-2 Case List - Click Accession ID to Open Case

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 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.

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Review Images

The review screen 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.

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
- The Case Type (Gyn)
- Your name “Reviewing Case As”
- **Cancel** button
- **Tags...** button
- **Complete Review** button

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Figure 4-3 New Case Opened for Review, Example

Key to Figure 4-3	
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 4-4. 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 4.11 for more details.

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Key to Figure 4-3	
③	The gallery of 30 tiles: five rows of six tiles. Refer to “Review the Gallery of Objects of Interest (OOIs)” on page 4.10 for more details.
④	Arrow to show or hide additional rows in the gallery. Refer to “The Genius Cervical AI Gallery” on page 4.11 for more details.
⑤	“Shortlist” of marked cells. Refer to “About Shortlists of marked objects” on page 4.23 for more details.
⑥	Arrow to show or hide additional rows in the Shortlist. Refer to “About Shortlists of marked objects” on page 4.23 for more details.
⑦	Whole Slide Image and tools for navigating the whole slide image. Refer to “The Whole Slide Image” on page 4.16 for more details.
⑧	Inset macroscopic view of the cell spot

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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.

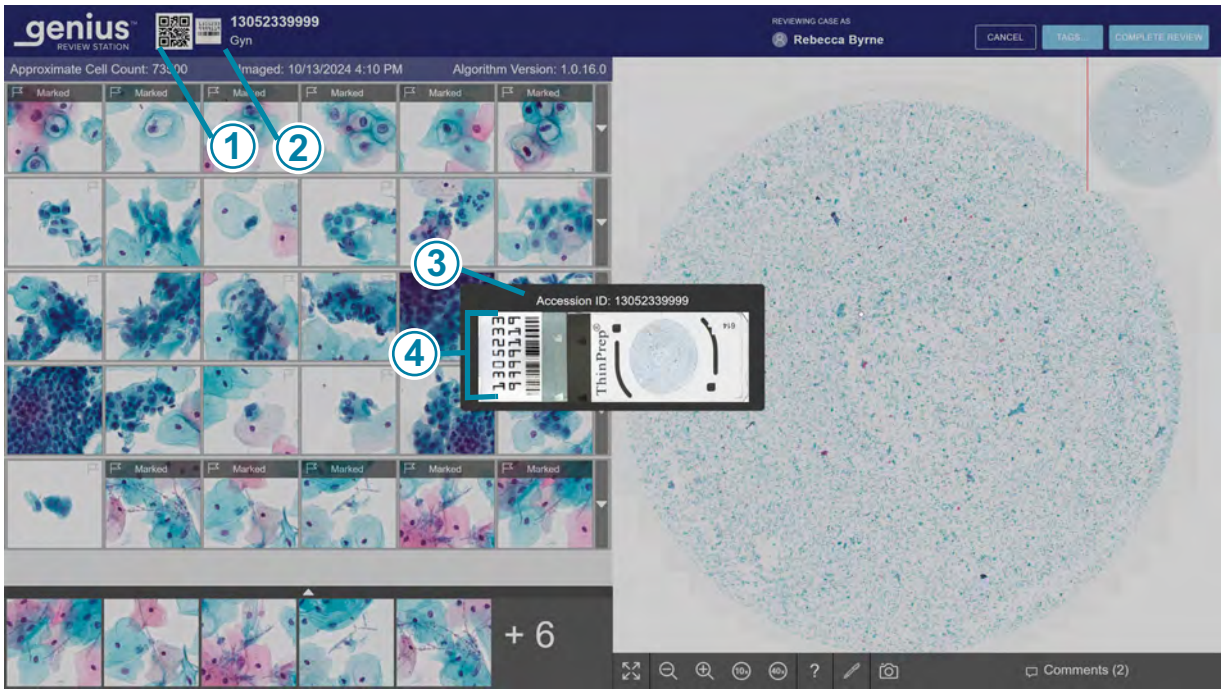

Figure 4-4 Macro Image Shows Slide Label Area, Example of a Case with Genius Cervical AI

Key to Figure 4-4	
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.

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Review the Gallery of Objects of Interest (OOIs)

The Genius Cervical AI algorithm in the Genius Digital Diagnostics System analyzes the images of the whole cell spot to identify the most 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 4-5 Genius Cervical AI Gallery Characteristics, Example

Key to Figure 4-5	
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, enlarged nuclei such as ASCU 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.

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Key to Figure 4-5	
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.

All rows may fill with normal cells or other objects of interest if the Genius Cervical AI algorithm has not identified objects of interest in the above categories for the designated rows.

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" on page 4.11 and "The Whole Slide Image" on page 4.16 for more information. The Review Station also provides the option of adding comments to a case. Refer to "Adding comments" on page 4.16.
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

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.

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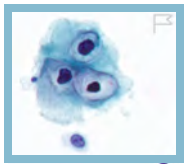
Tiles of objects of interest

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 mark is added to a tile, 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

The first step for navigating the gallery with the keyboard requires the use of a mouse. When the gallery opens, 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, click the mouse on the next tile.

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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, select 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. Use the arrow key to select 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, 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.

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Informational messages from the Genius Cervical AI algorithm

For some 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.

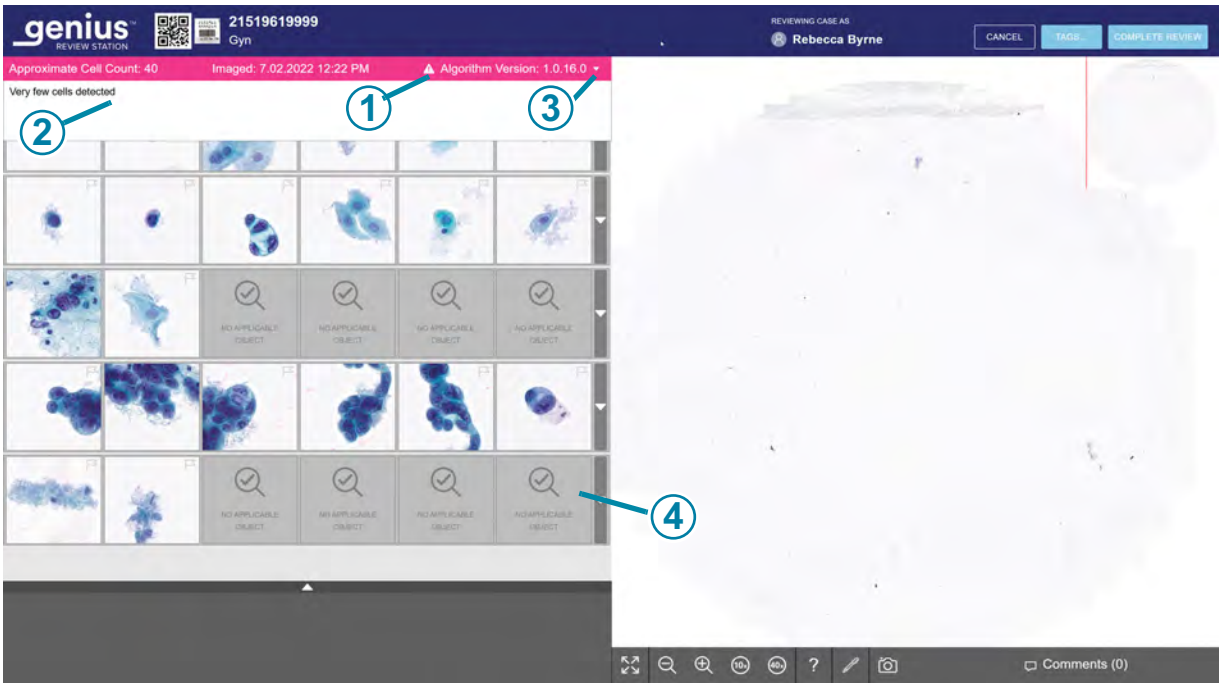

Figure 4-6 Case with an Informational Message, Text Displayed, Example

Key to Figure 4-6	
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

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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 3.78 and "Informational Message Usage Report" on page 3.80.

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

Table 4.1 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.
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.

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Table 4.1 Informational Messages

Message for Gyn Case	Possible Cause	Suggested Next Steps
High quantity of dark edges detected.	The case may have air bubbles, material retracted under the coverslip in the slide, or other hard-edged content, such as long strands of debris.	Review gallery. Check WSI. Check slide preparation.

The Whole Slide Image

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.

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3. Type in a comment, if any.

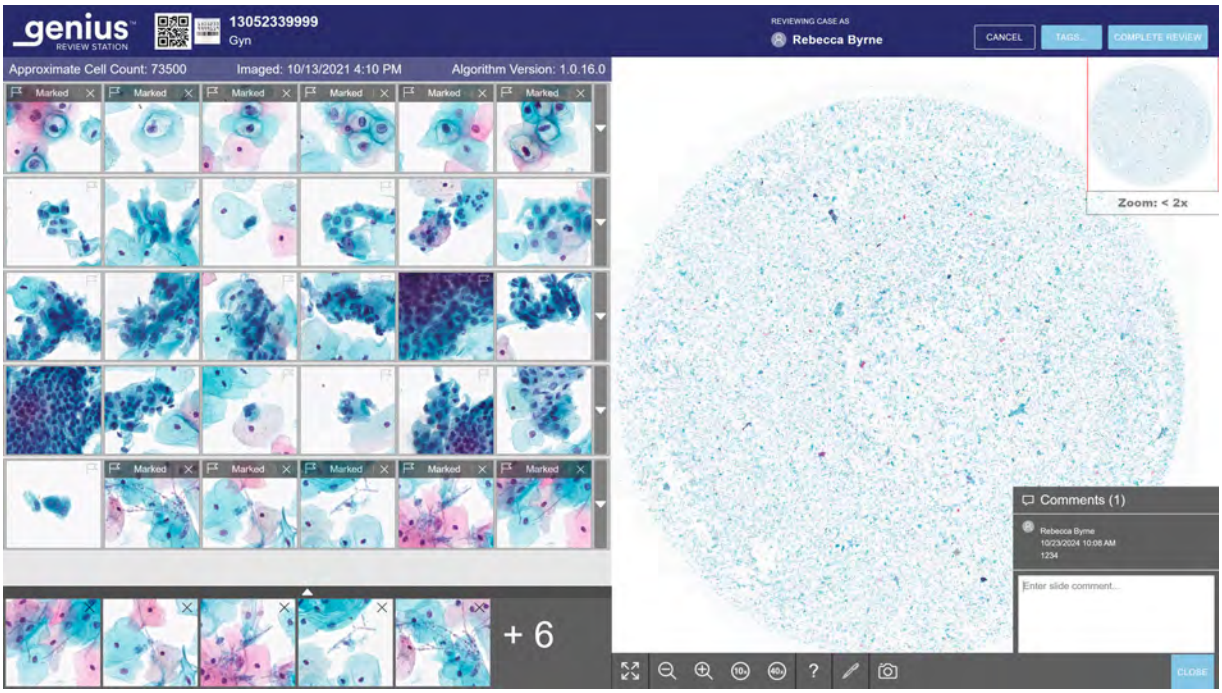

Figure 4-7 Add Comments, View Existing Comments, Gyn Example

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.

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The toolbar under the whole slide image has several tools.



Figure 4-8 Toolbar under the Whole Slide Image, Example

Key to Figure 4-8	
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, click the full screen tool again. To return to the gallery view and contract the view of the whole slide image, click the full screen tool again.
2	 Zoom out Click the mouse as many times as desired on the - button to zoom out.

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Key to Figure 4-8	
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.

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Key to Figure 4-8	
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 on the button.

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.

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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 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 administratorcan set up a tag using the Settings menu. Refer to"Tags" on page 3.23.
   Or, a manager or an administrator can set up a new tag from the **Tags...** button in a Case Review screen. Refer to "Review Images" on page 4.6.

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

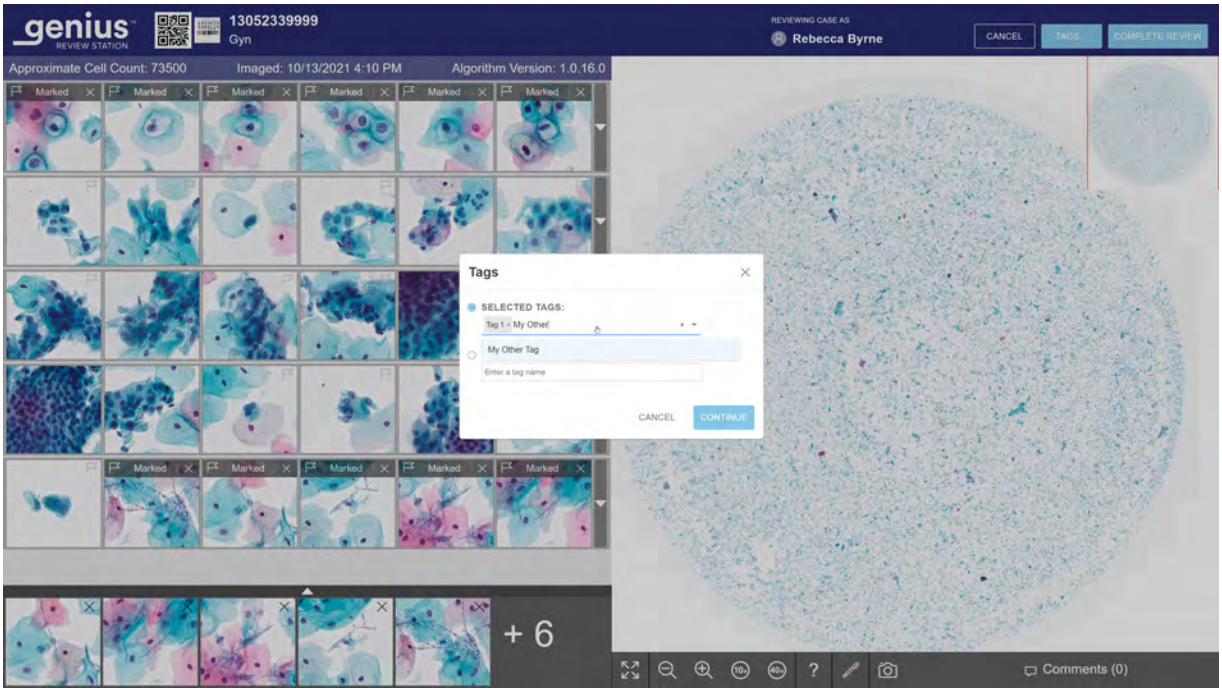

Figure 4-9 Tags, Manager Role Shown

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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.

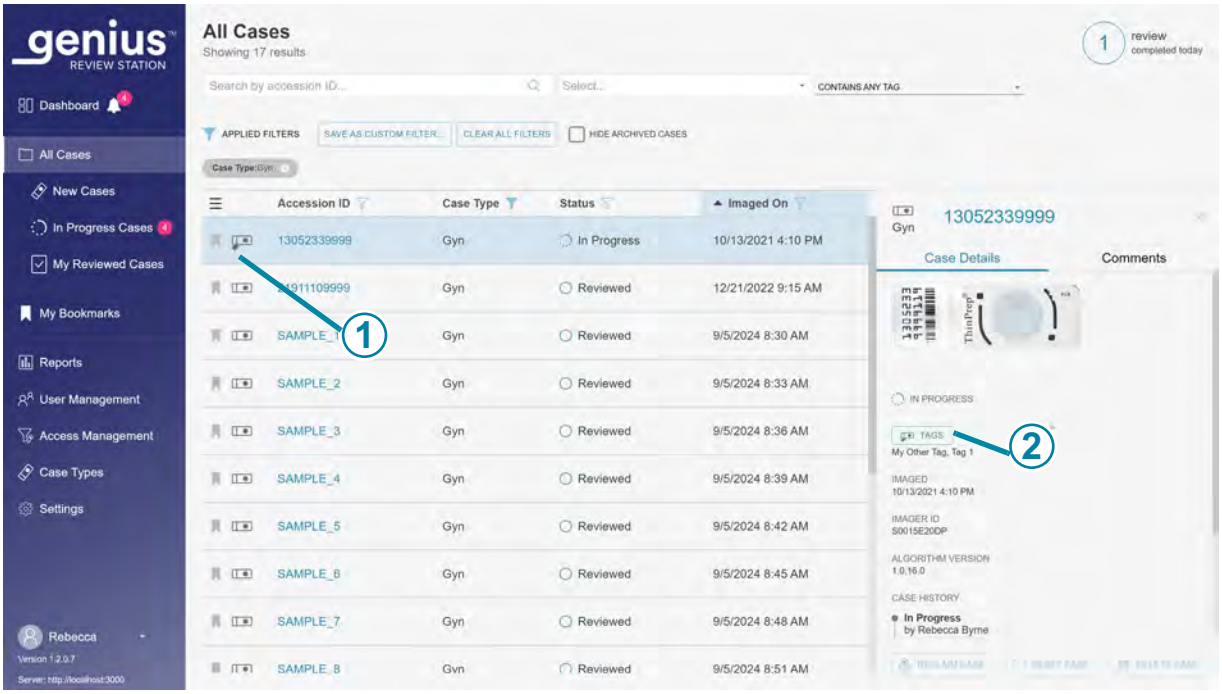

Figure 4-10 Case Details Screen for a Case with a Tag

Key to Figure 4-10	
1	The tagged case icon shows in the Case List.

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Key to Figure 4-10	
②	**Tags** button in the Case Details screen The name of the tag (or tags) associated with the case appears in the Case Details section. A reviewer can click this **Tags** button to add or remove a tag from the case. The steps are the same as adding a tag on the Case Review screen. If a manager or administrator changes the name of a tag, the name of the tag updates in the case details screen. If a manager or administrator deletes a tag from the Review Station network, that tag will no longer appear in the Case Details screen for a case.

Note: A tag can be added or removed from a case using the **Tags** button in the Case Details section. The tag selection steps are the same as using the **Tags** button in the Case Review screen.

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

After a slide 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 "**Search by tag**" on page 3.52.

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".

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The Shortlist is a gallery of marked tiles. 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" on page 4.11.

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 4-11 Shortlist of Marked Objects

Key to Figure 4-11	
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.

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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.

Note: If a user leaves the Review Station idle for 30 minutes, the Review Station logs the user out. 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.

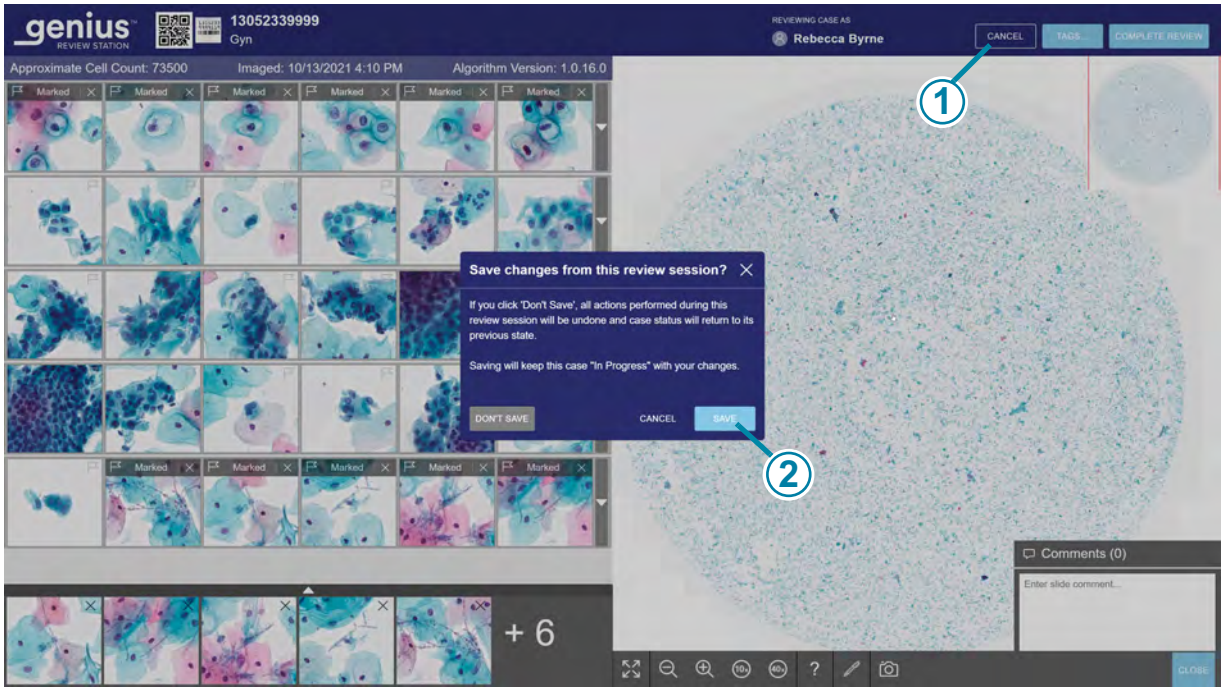

Figure 4-12 Save a Case as In Progress, Gyn Example

Key to Figure 4-12	
1	Click **Cancel**.
2	Click **Save**.

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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.

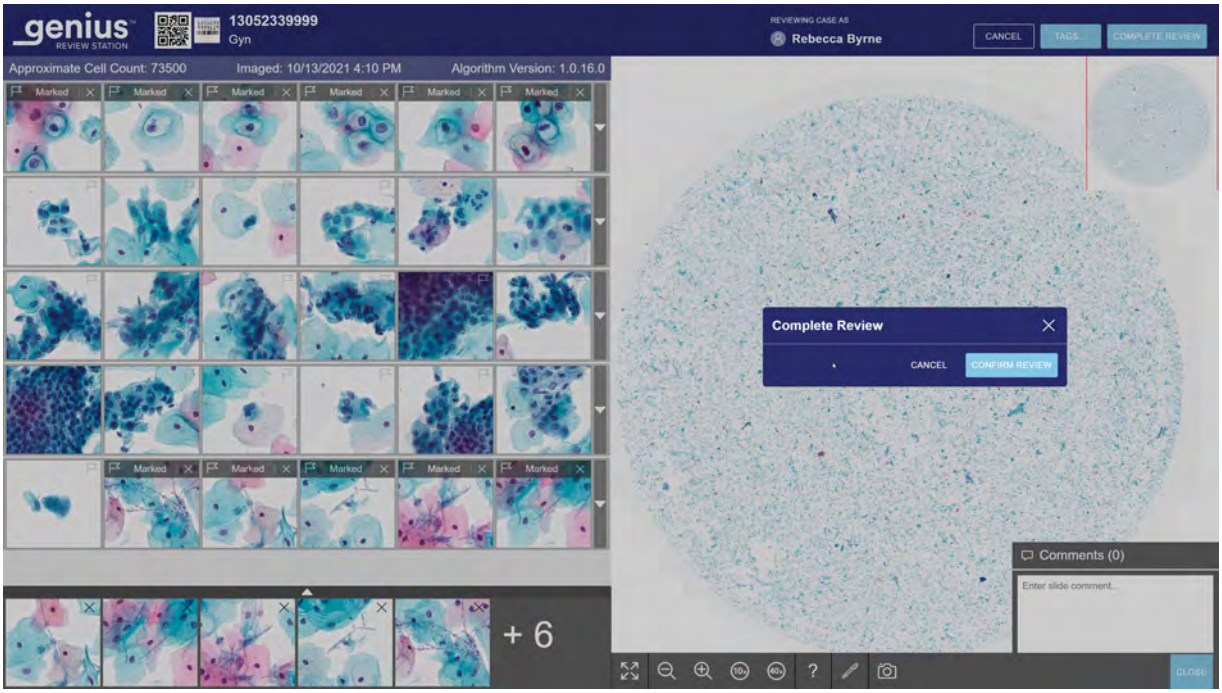

Figure 4-13 Complete the Review of a Case

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 status.

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Table 4.2 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
Zoom out, in small increments	Click the zoom out button as many times as desired: 	- (minus key) - zoom out

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	With the mouse	On the keyboard
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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5. Maintenance

Chapter Five

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 MAINTENANCE

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6. Troubleshooting

Chapter Six

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.

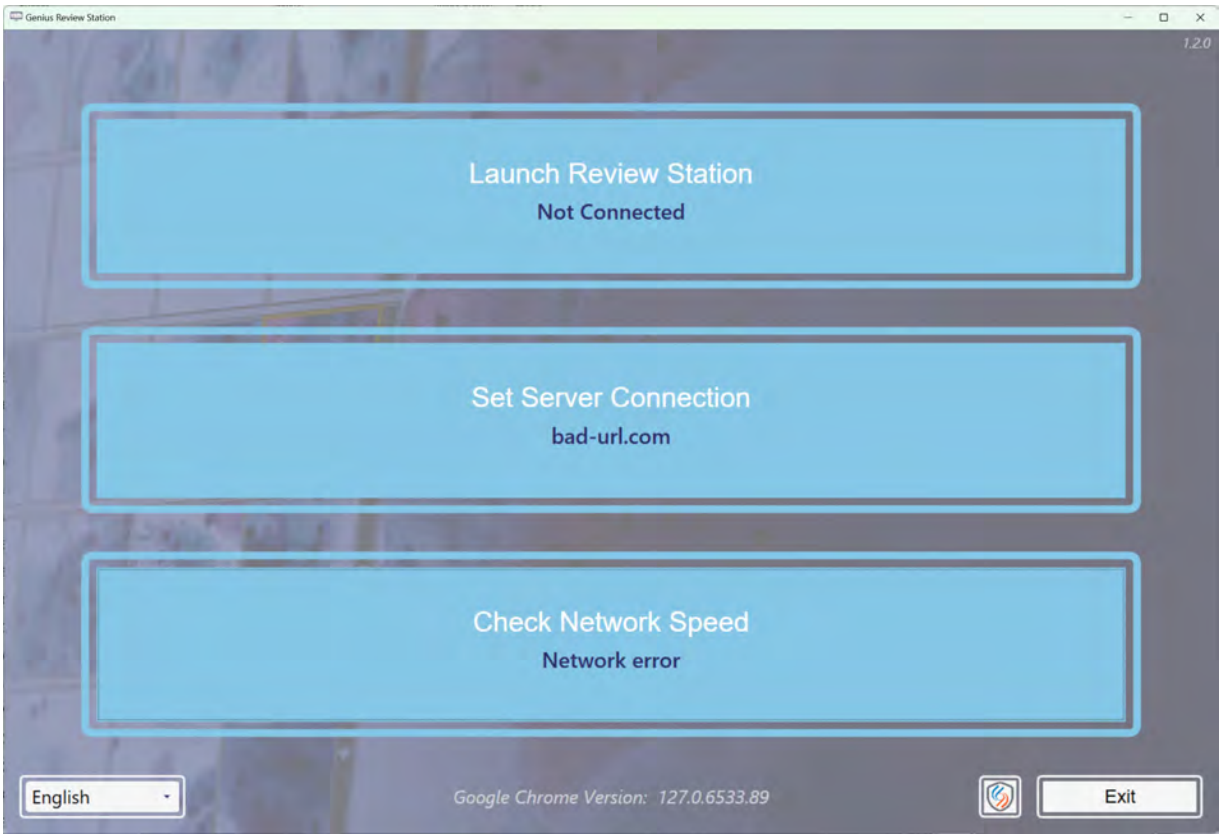

Figure 6-1 Review Station, Not Connected

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6 TROUBLESHOOTING

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 6-2 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.

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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.

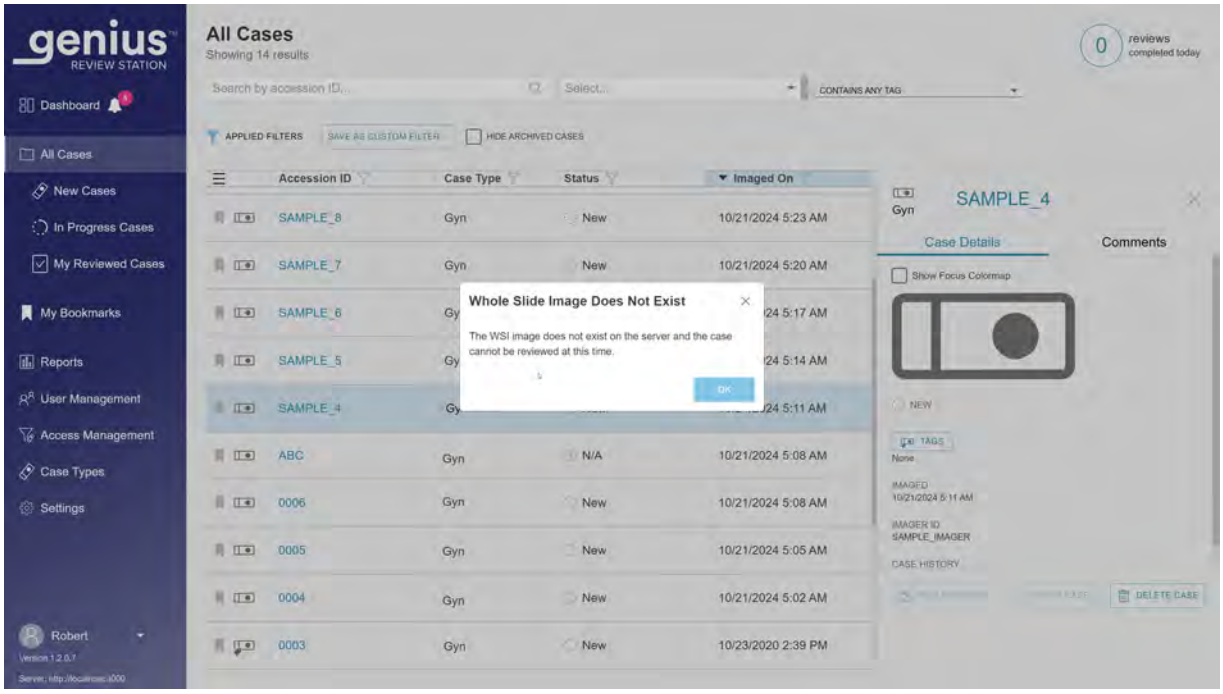

Figure 6-3 Review Station Notification of Image Management Server Error

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

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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 Image Management Server 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 7.1.
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.

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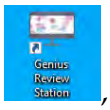
4. The Field Service personnel trained by Hologic disconnects their access when the service is complete.

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 7.1.
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.

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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 6.1 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.
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.

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Table 6.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E0003	**Slide fiducial verification failed.**	The slide is missing one or more of the ThinPrep Imaging System slide's fiducial marks.	ThinPrep Imaging System microscope 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.
			Check that the fiducial marks on the ThinPrep Imaging System microscope slide are not scratched or marred. Refer to the Genius Digital Imager Operator's Manual.
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.

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Table 6.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
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.
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 cell spot 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 through E0024	**Slide processing events**	---	Attempt to process the slide again. If the error persists, contact Technical Support.

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Table 6.2 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. If the error persists, contact Technical Support.
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.
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.

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Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
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 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.
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.

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Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
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. When the instrument is powered down, remove any obstruction. If the error persists, contact Technical Support.
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.
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.

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Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
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.
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.	Power cycle the system. 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.

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Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
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. 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 and the Image Management Server. If the error persists, contact Technical Support.
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 at the Genius Review Station. Ensure that slide management and archiving methods are in place and operational.

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6 TROUBLESHOOTING

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7. Service Information

7. Service Information

Chapter Seven

Service Information

Mailing Address

Hologic, Inc., 250 Campus Drive, Marlborough, MA 01752 USA

Remittance Address

Hologic, Inc., P.O. Box 3009, Boston, MA 02241-3009 USA

Business Hours

Hologic's business hours are 8:30 a.m. to 5:30 p.m. EST Monday through Friday excluding holidays.

Customer Service

To order products, and place or amend standing orders, call Customer Service at 1-844-465-6442 or 1-508-263-2900 during business hours or fax your order to the attention of Customer Service at 1-508-229-2795.

To order service contracts call Technical Support at 1-844-465-6442 or 1-508-263-2900 during business hours.

Technical Support

Technical service representatives are available to answer questions about your Genius Review Station at 1-844-465-6442 or 1-508-263-2900 from 7:00 a.m. to 7:00 p.m. Eastern Time Monday through Friday excluding company holidays.

Hologic technical service representatives are also available to address questions and concerns regarding cybersecurity.

Cytology application representatives are available to address application issues related to the Genius Digital Diagnostics System at 1-844-465-6442 or 1-508-263-2900 from 8:30 a.m. to 5:30 p.m. Eastern Time Monday through Friday excluding company holidays.

Returns

For returns related to warranty issues, please contact Technical Support at 1-844-465-6442 or 1-508-263-2900 and for questions regarding any other type of return, please contact Customer Service.

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7 SERVICE INFORMATION

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8. Ordering Information

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Chapter Eight

Ordering Information

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Ordering Information

To order products, and place or amend standing orders, call Customer Service at 1-844-465-6442 or 1-508-263-2900 during business hours or fax your order to the attention of Customer Service at 1-508-229-2795.

To order service contracts call Technical Support at 1-844-465-6442 or 1-508-263-2900 during business hours.

Terms

Net 30 days.

Shipping

All prices are F.O.B. Marlborough, Massachusetts, USA. All in-stock items are shipped on the next business day after the order is placed via UPS ground delivery. Second day and overnight delivery are available upon request.

Technical Support

Technical service representatives are available to answer questions about your Genius Review Station at 1-844-465-6442 or 1-508-263-2900 from 7:00 a.m. to 7:00 p.m. Eastern Time Monday through Friday excluding company holidays.

Cytology application representatives are available to address application issues related to the Genius Digital Diagnostics System at 1-844-465-6442 or 1-508-263-2900 from 8:30 a.m. to 5:30 p.m. Eastern Time Monday through Friday excluding company holidays.

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8 Ordering Information

Returns

For returns, please call Customer Service at 1-844-465-6442 or 1-508-263-2900 to obtain a Return Goods Authorization number. Hologic will not accept any returned items without this number.

For returns related to warranty issues, please contact Technical Support at 1-844-465-6442 or 1-508-263-2900 and for questions regarding any other type of return, please contact Customer Service.

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Table 8.1 Reordering Supply Items for the Review Station

Item	Description	Quantity	Part Number
Review Station Operator's Manual	Additional operator's manual	ea.	MAN-12121-001

Table 8.2 Optional Accessories

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

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8 ORDERING INFORMATION

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