HOLOGIC®

Genius™ Digital Diagnostics System Whole Slide Imaging

Instructions for Use

MAN-11759-002 Rev. 001

Genius™ Digital Diagnostics System

Instructions for Use

Whole Slide Imaging

IVD

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INTENDED USE/INTENDED PURPOSE

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

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

Patient population

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

For professional use.

SUMMARY AND EXPLANATION OF THE SYSTEM

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

A slide ID reader scans the slide's accession ID and locates the scan area. Then the Digital Imager scans the microscope slide, creating an in-focus, whole slide image.

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. 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 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 digital image of that slide.

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

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

LIMITATIONS

- Only personnel who have been appropriately trained should operate the Genius Digital Imager or Review Station.
- The laboratory Technical Supervisor should establish individual workload limits for personnel using the Genius Digital Diagnostics System, where applicable and in accordance with national or regional accreditation bodies, professional organizations, and regulations.
- 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 used with the Genius Digital Imager must contain properly formatted accession number identification information as described in the operator's manual.
- 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

- For *In Vitro* Diagnostic Use
- The Digital Imager generates, uses, and can radiate radio frequency energy and may cause interference to radio communications.
- Glass. The Digital Imager uses microscope slides, which 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.
- Service Installation Only. The system must be installed by trained Hologic personnel 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.

- If the “Auto” Case Type is not being used, make sure the Case Type selection on the Digital Imager is appropriate for the slides loaded into the slide carrier.
- The Digital Imager should be placed on a flat, sturdy surface away from any vibrating machinery to assure proper operation.

PERFORMANCE CHARACTERISTICS

CYTOLOGY SPECIMEN STUDY

A laboratory study was conducted to demonstrate that the Genius Digital Diagnostics System presents images of patient cases for slides that would otherwise be appropriate for manual visualization by conventional light microscopy. The study compared results from cases reviewed by cytologists (CT) using the Genius Digital Diagnostics System to the results of CT review of the same case slides on a microscope (manual review).

Four hundred (400) ThinPrep slides, including a range of specimen types, were enrolled in the study, including:

- **Fluid Samples (Effusions, Washings, etc.)** (e.g., ascites fluid, pleural fluid, peritoneal fluid, pelvic washing, bronchial washing, synovial fluid)
- **Brush/Swab Specimens** (e.g., anal Pap, bronchial brush, esophageal brush)
- **Fine Needle Aspirations of Solid Lesions** (e.g., breast FNA, thyroid FNA, lymph node FNA)
- **Urine Specimens** (e.g., bladder urine, renal urine)
- **Other Collections** (e.g., nipple discharge, stent discharge)

The specimens were a mix of normal, abnormal and non-diagnostic cases. The slides were interpreted first using a manual microscope. Then, the slides were imaged on a Genius Digital Imager. After a two-week washout period to minimize recognition bias, the case images were interpreted using the Genius Review Station. The digital review and the manual review of each case were performed by the same cytologist.

Cytology Study Results

Table 1 provides the overall results of the diagnostic screening of the specimens.

Table 1. Matched-Pair Diagnostic Categories

		Manual		
		Abnormal	**Normal**	**Non-Diagnostic**
Genius	**Abnormal**	111	12	0
	Normal	18	251	1
	Non-Diagnostic	0	0	7

In the study, “Abnormal” was defined as atypical or above for neoplasm.

Further analysis of the study data was performed to compare the diagnoses from the Genius case review versus the manual review of the glass slides. The eight (8) non-diagnostic cases were excluded from this analysis. The results are presented in Table 2.

Table 2. Proportions of Diagnoses of Abnormal Cases

	Proportion	**95% Confidence Interval**
Manual Review	0.329	[0.284 , 0.377]
Genius Digital Review	0.314	[0.270 , 0.361]
Difference, Genius - Manual	-0.015	[-0.045 , 0.018]

The study data show that the proportions of abnormal cases in a mix of specimens are equivalent when evaluated with the Genius Digital Diagnostics System and evaluated with manual review. Therefore, cytology specimens may be reliably reviewed for diagnostic evaluation using the Genius Digital Diagnostics System.

PATHOLOGY SPECIMEN STUDY

A descriptive laboratory study was conducted to demonstrate that the Genius Digital Diagnostics System presents images of patient cases for surgical pathology slides prepared from FFPE embedded tissue that would otherwise be appropriate for manual visualization by conventional light microscopy. The study evaluated the ability of the Sample Detect scan profile to reliably identify the areas of the slide that contain specimen, and the study evaluated the ability of the Genius Digital Diagnostics System to reliably create digital images of surgical pathology microscope slides suitable for digital review by pathologists.

Two hundred (200) slides, including a range of specimen types, were enrolled in the study. The study included the following types of tissue specimens: breast, colorectal, endocrine, gynecological biopsy, kidney, lymph node, prostate, respiratory, skin and stomach. Three Genius Digital Imagers were used in the study. Each slide was imaged on one Genius Digital Imager using the Sample Detect scan profile. The Sample Detect scan profile is a scan software option that locates and scans only the specimen on the glass slide, reducing scan time and file size compared to scanning the entire area of a glass slide. Each slide was also imaged on the same Genius Digital Imager using the Whole Slide scan profile. The Whole Slide scan profile is a scan software option that scans the 1” x 2” specimen area on the glass slide. Three (3) pathologists participated in the study. The slides were reviewed by a pathologist, using a Genius Review Station (digital review). First, each macro image of the slide was used by the pathologist as a

guide for determining if the image from the Sample Detect scan was suitable for review. In the event that the reviewing pathologist had any concern about the quality of the image from the scan with the Sample Detect scan profile, the pathologist reviewed the image from the scan with the Whole Slide scan profile. In the event that the reviewing pathologist had any concern about the image quality from the Whole Slide scan, the glass microscope slides were available to the pathologist for review with a microscope. The data collected included the instances when the pathologist referred to the glass slide, to confirm that the digital image was or was not suitable for review.

Pathology Study Results

Proportion of Slides Successfully Imaged

The proportion of slides successfully imaged was 100% in the study. The proportion of slides successfully imaged is the ratio of the number of successfully imaged slides to the total number of slides enrolled in the study. In the study, one slide had a scanning error reported and was re-run successfully. The data include cases reviewed from the digital image created with the Sample Detect scan profile and the Whole Slide scan profile.

Proportion of Slides Requiring Whole Slide Scanning

The proportion of slides that were scanned with the Whole Slide scan profile after they were scanned with the Sample Detect scan profile was 2.5% (5/200) in the study. The proportion of slides requiring Whole Slide scanning is the ratio of the number of cases reviewed as the image from the Whole Slide scanning to the number of slides successfully imaged.

Proportion of Slides Suitable for Digital Review

The proportion of slides suitable for digital review was 99.5% in the study. The proportion of slides suitable for digital review is the ratio of all slides with clarity and quality suitable for digital review to the number of successfully imaged slides. One case resulted in the pathologist asking to review the glass slide. In this case, no specific defect was noted in the digital image, but the pathologist wanted to review the glass slide to be fully confident in their review. The data include cases reviewed from the digital image created with the Sample Detect scan profile and the Whole Slide scan profile.

The study data show the Sample Detect scan profile reliably identifies the areas of the slide that contain specimen, and the Genius Digital Diagnostics System reliably creates digital images of pathology microscope slides that are suitable for review. Therefore, pathology specimens may be reliably reviewed for diagnostic evaluation using the Genius Digital Diagnostics System.

CONCLUSIONS

The data from the studies conducted on the Genius Digital Diagnostics System demonstrate that the Genius Digital Diagnostics System provides images that may be reliably reviewed for diagnostic evaluation of cytology and surgical pathology specimens.

MATERIALS REQUIRED

MATERIALS PROVIDED

- Genius Digital Imager
    - Digital Imager
    - Digital Imager computer
    - Slide carriers
- Genius Review Station
    - Monitor
    - 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 the 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 the Genius IMS Dashboard User's Manual for the minimum specifications for the server and network switch.

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.

TECHNICAL SERVICE AND PRODUCT INFORMATION

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

TScytology@hologic.com

And via the toll-free number below:

United Kingdom	0800 0323318

REVISION HISTORY

Revision	Date	Description
AW-32577-002 Rev. 001	8-2025	Initial release

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