HOLOGIC®

Genius™ Image Management Server Dashboard

User's Manual

MAN-12120-001 Rev. 001

Genius™
Image Management Server
Dashboard
User's Manual

HOLOGIC®

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

For Use With Version 1.2.x Software

MAN-12120-001

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.

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

This product may be covered by one or more U.S. patents identified at hologic.com/patentinformation

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™ Image Management Server not in accordance with these instructions may void the warranty.

Document Number: AW-33889-001 Rev. 001

5-2025

℞ only

Genius Digital
Diagnostics System

Genius Digital
Diagnostics System

Genius™ Digital Diagnostics System with the Genius™ Cervical AI Algorithm

Instructions for Use

℞ only

IVD

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 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.
- 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 493.1257 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.
- 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.

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)

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).

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).

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 (95% CI)**	**Manual (95% CI)**	**Difference (Genius – Manual) (95% CI)**	**Genius (95% CI)**	**Manual (95% CI)**	**Difference (Genius – 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.

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	Manual	Difference	Genius	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)

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	Manual	Difference	Genius	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)

ASC-H+

Sensitivity is a percent of "reference" ASC-H+ cases classified in Genius 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	Manual	Difference	Genius	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)

HSIL+

Sensitivity is a percent of "reference" HSIL+ cases classified in Genius 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	Manual	Difference	Genius	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)

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	Manual	Difference	Genius	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)

UNSAT

Sensitivity is a percent of "reference" UNSAT cases classified in Genius 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	Manual	Difference	Genius	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)

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	**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.

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	**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.

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	**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.

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	**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.

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	**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.

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	**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.

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	**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.

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	**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.

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	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–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	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–Manual	0.51% (19/3753)	0.45% (17/3753)	0.43% (16/3753)	0.11% (4/3753)	1.49% (56/3753)

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 (95% CI)**	**TIS (95% CI)**	**Difference (Genius – TIS) (95% CI)**	**Genius (95% CI)**	**TIS (95% CI)**	**Difference (Genius – 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 was greater than TIS 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.

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 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

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.

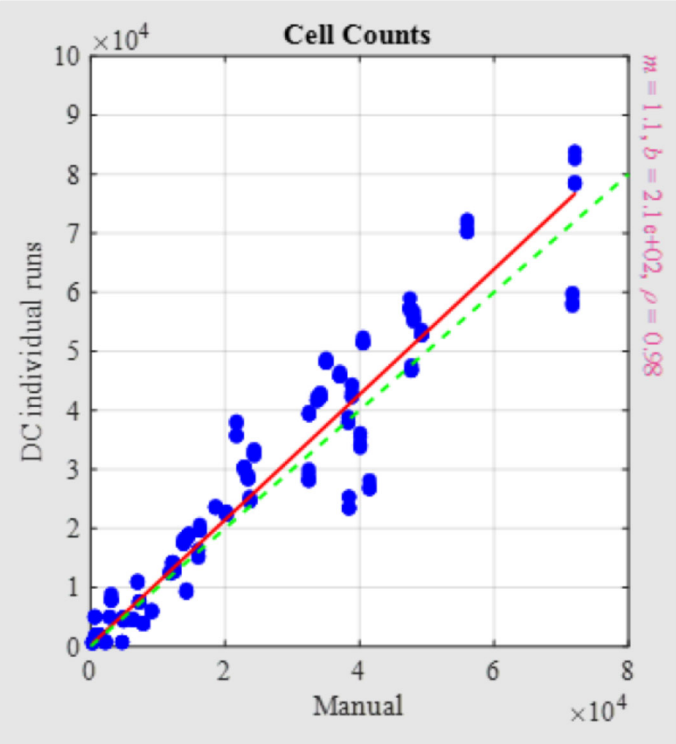
ThinPrep Pap test patient sample slides were prepared on a ThinPrep 5000 processor, stained and coverslipped. The same slides were imaged on three Genius Digital Imagers three separate times. To obtain the manual cell count for the slides in the study, a CT viewed the whole slide image presented on the 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.

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.

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 Evalua-tions	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

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%

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
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.

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) (5^{th} ; 95^{th} 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.

Figure 2. Sensitivity vs. Median Review Time

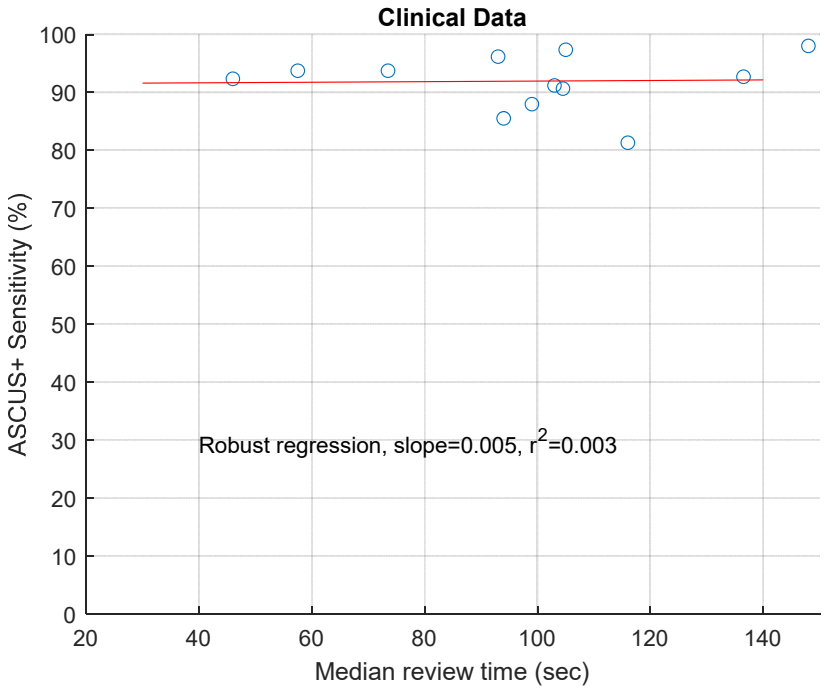
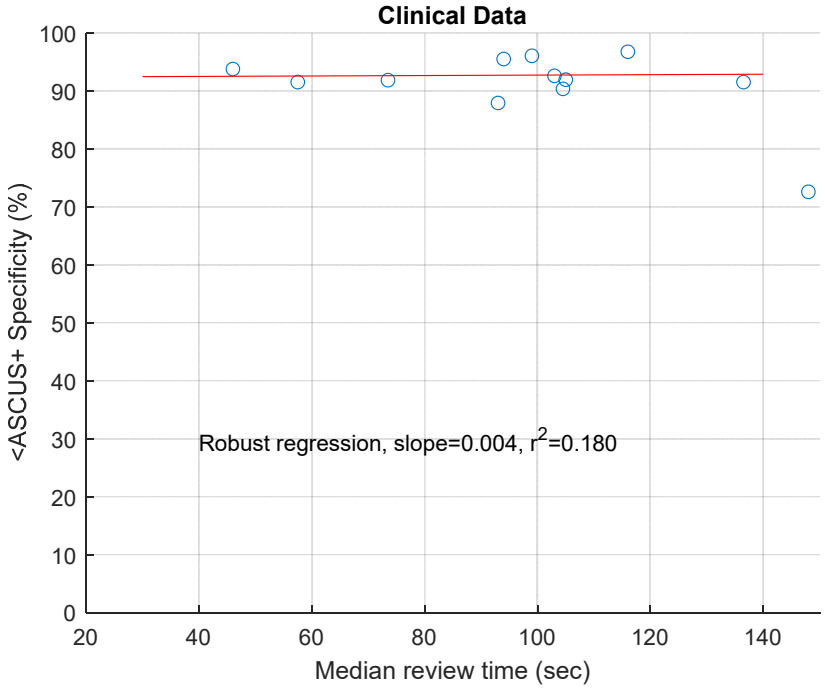


Figure 3. Specificity vs. Median Review Time



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.

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 ≤ 100 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.

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.

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)
    - Digital Imager computer (CMP-01687)
    - Slide carriers (ASY-14299)
- Genius Review Station
    - Monitor (CMP-01669)
    - Review Station computer*
- Genius Image Management Server
    - Server*
    - Network switch*

*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)

MATERIALS REQUIRED BUT NOT PROVIDED

- Slide staining racks
- Monitor, keyboard, mouse for the Image Management Server
- Keyboard and mouse for each Review Station

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.

Email: info@hologic.com

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
1-844-465-6442
www.hologic.com

Table of Contents

Table of Contents

Table of Contents

1. Introduction

Chapter One

Introduction

SECTION A

OVERVIEW

The Genius™ Image Management Server (IMS) is one component of the Genius™ Digital Diagnostics System with the Genius™ Cervical AI algorithm. The Image Management Server is a Windows-based server computer connected via wired Ethernet. The Image Management Server stores the image data set, maintains the image metadata database, and hosts web services for external Genius™ Review Stations. The Image Management Server has the capability to manage communication with an external archive. The Image Management Server provides a finite amount of storage and is intended as a cache to hold image files. The server capacity and lab data volumes will determine the time duration that the cache can support.

The Image Management Server is connected to a network switch, which connects the Genius™ Digital Imager to the Image Management Server, and connects the Review Station to the Image Management Server.

The Image Management Server stores the slide data set (imaging and review information) in a SQL database and stores the image files as a repository on disk. The Image Management Server facilitates the display of the images in the Genius Digital Diagnostics System for cytologists for review and QC reviews, as well as pathologists review as needed.

1 INTRODUCTION

Figure 1-1 Genius Image Management Server

Note: The hardware shown in this operator's manual may differ from the appearance of the hardware used at your site.

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.

It is the customer's responsibility to comply with all applicable record retention procedures. It is also the customer's responsibility to establish and implement policies and practices for maintaining storage capacity on the Genius Image Management Server. The Genius Image Management Server acts as a short-term cache for the slide data sets. The Genius Image Management Server can be configured to transfer slide data sets to a laboratory's archive storage system, and the Genius Image Management Server can be configured to delete older slide data sets. The system monitors the available storage capacity of the Genius Image Management Server. Users can view the IMS storage capacity from the IMS dashboard, the Review Station and the Digital Imager.

Indication for Use

The Image Management Server 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.

SECTION B THE GENIUS DIGITAL DIAGNOSTICS SYSTEM WITH THE GENIUS CERVICAL AI ALGORITHM

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

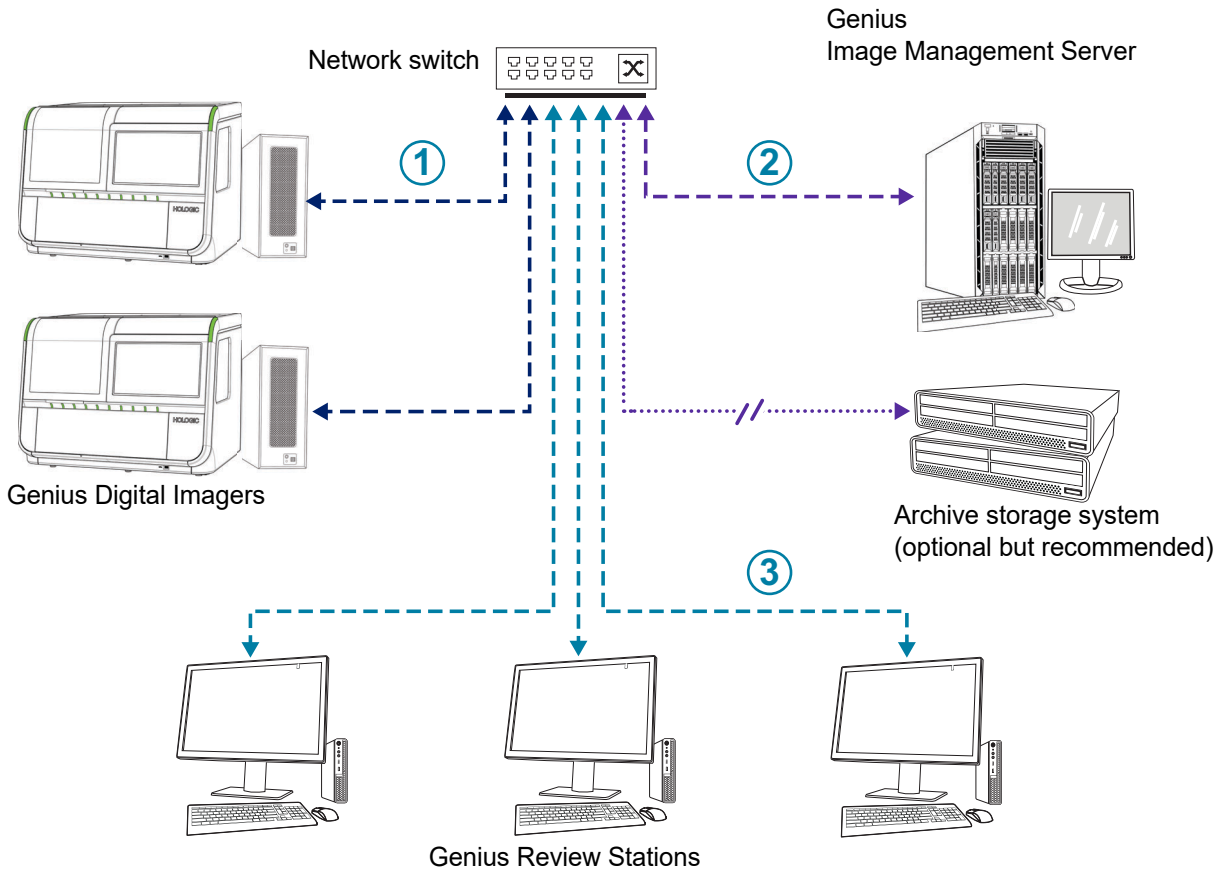
The Image Management Server acts as the central data manager for the Genius Digital Diagnostics System with the Genius Cervical AI algorithm. As slides are imaged by the Digital Imager and

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

reviewed at the Review Station, the server stores, retrieves and transmits information based on the accession 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 specimen on the slide for examination.



Note: Throughout this manual, illustrations of the Image Management Server, an archive storage system and other components are representative. The appearance of the actual equipment may differ from the illustrations.

Figure 1-2 Genius Digital Diagnostics System Network

Key to Figure 1-2	
①	Connection between a Genius Digital Imager and the network switch The recommended network speed between the Genius Digital Imager and Genius Image Management Server is 1 Gbps or faster.
②	Connection between the network switch and a Hologic-provided Genius Image Management Server The minimum speed required for this connection is the aggregate of the speeds required for the all of the Genius Digital Imagers and Genius Review Stations connected to the same Genius Image Management Server. For example, the connection for a Genius Image Management Server in an installation of six Genius Digital Imagers (6 x 1 Gbps=6 Gbps, minimum) and twenty Genius Review Stations (20 x 200 Mbps = 4 Gbps, minimum) would need to a speed of 10 Gbps or higher.
③	Connection between a Genius Review Station and the network switch The recommended network speed between the Genius Review Station and Genius Image Management Server is 200 Mbps or faster.

Required Materials

- Genius Digital Imager
- Genius Review Station
- Network switch – available from Hologic, or provided by customer
- Server – available from Hologic, or provided by customer

Required but not provided

- Computer monitor, keyboard, and mouse (for customers using a Hologic-supplied server)

Recommended but not provided

- Archive storage system

A network connection between the Image Management Server and the other components of the Genius Digital Diagnostics System is required.

Because the Genius Image Management Server handles all of the communication between the system components, the Genius Image Management Server connection requires a minimum of cat 6 cabling. Additionally, another network connection to the site's archive storage system is required.

For the cabling requirements for the connections to the Genius Review Station and the Genius Digital Imager, 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

Additionally, another network connection to the site's archive storage system is required.

A user must have System Administrator rights in Windows to access the Image Management Server dashboard. And, to change any archive settings, a user must have the proper credentials to access both the archive storage system and the Image Management Server.

If Hologic has not supplied the server, a user must have access to the server. Field service personnel trained by Hologic will install the Genius Image Management Server software on the server.

A laboratory must have a secure lab firewall and strong network security before the Image Management Server can be installed.

SECTION C IMAGE MANAGEMENT SERVER TECHNICAL SPECIFICATIONS

Overview of Components

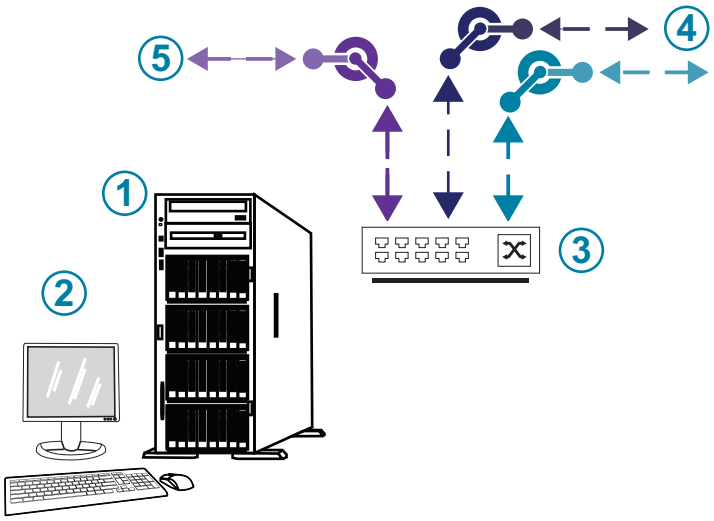


Figure 1-3 Image Management Server Components

Key to Figure 1-3	
1	Server The hardware shown may differ from the appearance of the hardware used at your site.
2	Monitor, keyboard, and mouse (for customers using a Hologic-supplied server)

Key to Figure 1-3	
③	Network switch
④	Connections to the Digital Imager and Review Station
⑤	Connection to the archive storage system

Image Management Server Specifications

The Genius Image Management Server software supplied by Hologic is required.

The hardware can be supplied by Hologic or supplied by your facility, provided it meets the required minimum specifications. The hardware configuration will vary, depending on the quantity and type of slides imaged in your facility. The minimum specifications for the hardware are:

Server Hardware:

- Dual Intel Xeon Silver 4214 2.2 GHz processor
- 64GB memory
- 240GB SSD for OS (boot)
- Raid 10 Array configuration
- 30 Terabytes configured storage capacity
- 2 10 GE ports
- 3 USB 2.0 (or faster) ports (not applicable to a virtual machine environment)
- Video graphics display interface of type VGA, HDMI, or display port (not applicable to a virtual machine environment)
- Dual, hot-plug, redundant power supply (1+1), 750 W

Operating System:

- A minimum of 64-Bit Windows Server is required. Windows Server 2016 is recommended.

Note: To properly display the dashboard, the minimum recommended display resolution for a monitor is 1366 by 768 ppi.

Operating temperature range

Refer to the documentation provided with the server and computer.

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

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

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

Pollution Degree
Refer to the documentation provided with the server and computer.

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

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

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

Power
Refer to the documentation provided with the server and computer.

Fuses
Refer to the documentation provided with the server 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.

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

SECTION D

INTERNAL QUALITY CONTROL

The Image Management Server hosts the Review Station application, hosts applications and services, and provides data storage for the Review Station and Digital Imager.

The Genius Digital Diagnostics System uses secure communications protocols to protect the integrity of the slide data set (digital slide images and case data record) transferred between the Digital Imager, the Review Station, and the Image Management Server. The use of the customer's Windows domain ensures secure communications between the IMS and the customer's archive repository (NAS). In addition, The Genius Digital Diagnostics System uses a Secure Hash Algorithm (SHA)-256 to verify the integrity of data being returned to the system. A hash manifest containing SHA-256 checksum information is generated for each file in a slide image data set. The hash manifest is stored in the Genius IMS database. The Genius Image Management Server software verifies the hash each time that slide image data set is retrieved from the customer's archive.

The Genius Digital Diagnostics System continuously checks for a proper connection between the Image Management Server and its clients: the Review Station and Digital Imager. If the connection to the server is broken, a message is shown on the Review Station or Digital Imager.

The Image Management Server continuously monitors the storage capacity available for storing new data from the Digital Imager. If the Image Management Server approaches full capacity, a message is shown on the Digital Imager.

The Review Station cannot be used until connection with the Image Management Server is reestablished.

The Digital Imager cannot image slides or generate reports until connection with the Image Management Server is reestablished. The Digital Imager cannot image slides until sufficient storage capacity is available on the Image Management Server.

1 INTRODUCTION

SECTION E

GENIUS IMAGE MANAGEMENT SERVER HAZARDS

The Image Management Server 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 installation and configuration of the Image Management Server must not be altered after installation by qualified Field Service personnel trained by Hologic and your facility's IT staff. Proper installation and configuration 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.

Symbols Used on the Instrument

Refer to the documentation provided with the server for a description of any symbols used on the hardware. The following symbols may appear on the labels supplied by Hologic.

Symbol	Title	Description	Standard information
 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
	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
	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

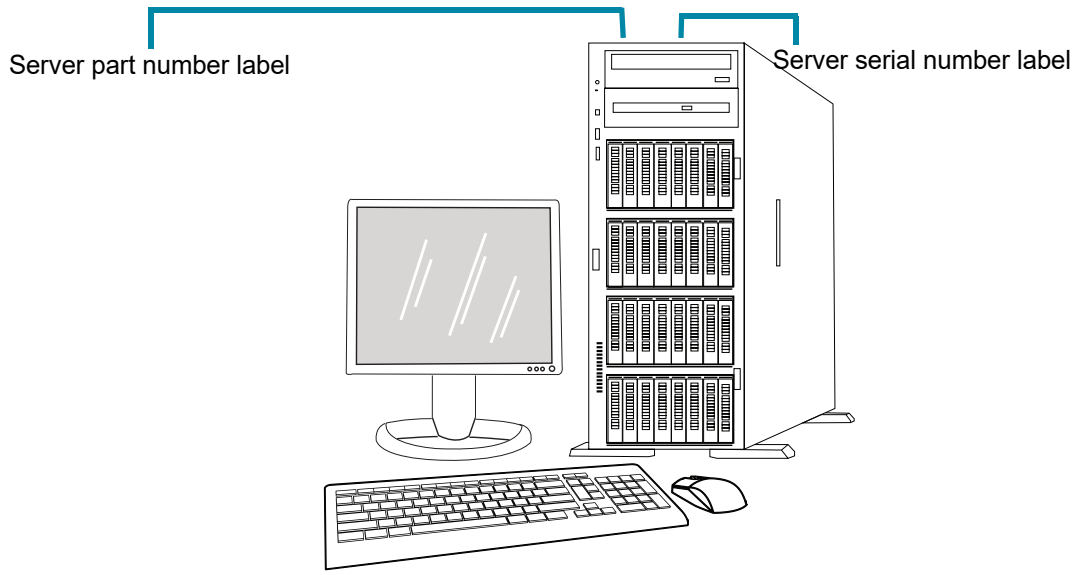
1 INTRODUCTION

Symbol	Title	Description	Standard information
	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 port	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	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
	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
	Unique Device Identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1 Medical devices—Symbols to be used with medical device labeling and information to be supplied, Section 5.7.10
	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

Figure 1-4 Symbols used on the server

Location of Labels

Refer to the documentation provided with the server and computer for additional information on the location of labels on the hardware. Labels on the hardware supplied by Hologic are shown in Figure 1-5:



Note: The appearance of the server in this illustration may differ from the server installed at your site, depending on the model of Hologic-supplied hardware you have.

Note: If the server hardware is not supplied by Hologic, the serial number may be in a different location and the server part number label will not be present.

Figure 1-5 Location of Labels on the Server

Warnings

WARNING: For professional use only.

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

WARNING: Grounded Outlet. To ensure safe operation of the instruments, use a three-wire grounded outlet. Refer to the documentation provided with the server.

Limitations

The server must meet the specifications in this manual. The Image Management Server is designed specifically for the Genius Digital Diagnostics System. The Image Management Server must be

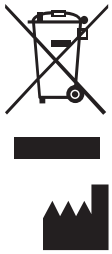
running the Hologic-supplied software for proper performance of the system and the software cannot be substituted.

SECTION F DISPOSAL

Disposal of the device

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

Do not dispose in municipal waste.



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

2. Installation

Chapter Two

Installation

WARNING: Service Installation Only

SECTION A GENERAL

The Genius Image Management Server must be installed and configured by Field Service personnel trained by Hologic.

The duration of the installation is dependent on the complexity of integration with the laboratory information technology (IT) infrastructure and connected systems. When installation and configuration are complete, Field Service personnel trained by Hologic trains the laboratory's information system staff, using the user's manual as the training guide.

In addition to the Hologic-installed components, a laboratory must provide a method for maintaining storage capacity on the Image Management Server, to allow the Genius Digital Diagnostics System to continue to image slides. A laboratory must establish their own policies and practices for maintaining storage capacity on the Image Management Server. The Genius Digital Diagnostics System can be configured to permanently delete older slide data set records, and the Genius Digital Diagnostics System can be configured to transfer slide data set records to a laboratory's archive storage system. The laboratory is responsible for the installation and configuration of the archive storage system. Field Service personnel trained by Hologic collaborate with a laboratory's IT staff to connect the Image Management Server to the archive storage system.

The Image Management Server dashboard 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

For installations with hardware supplied by Hologic, inspect the packing cartons for damage. Report any damage immediately to the shipper and/or Hologic Technical Support as soon as possible. (Refer to Chapter 6, Service Information.)

Leave the server in the packing cartons for installation by Field Service personnel trained by Hologic.

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

2 INSTALLATION

Note: The server 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 Field Service personnel trained by Hologic. The site assessment requires networking considerations with your laboratory's IT (Information Technologies) personnel. Be sure to have prepared any and all site configuration requirements as instructed by the qualified Field 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.

Physical location requirements for the server

- The Image Management Server supplied by Hologic is a Windows-based tower server. The dimensions of the hardware vary with the model of server for your facility. The Image Management Server must be easily accessible from all sides to accommodate proper servicing.
- The Image Management Server must be staged in a location suitable for IT infrastructure components. The Image Management Server is networked with the Genius Digital Imager and the Genius Review Station.
- As a general best practice, an uninterruptible, conditioned power supply as well as environmental conditioning, are recommended with proper regard for physical dimensions, power requirements and BTU output. The power requirements and environmental conditioning vary with the model of server for your facility.

Network requirements for the server

- The recommended network speed between the Genius Digital Imager and the Genius Image Management Server is a minimum of 1 Gbps.
- 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.
- Connectivity can be accomplished utilizing facility infrastructure or direct connection through the 10-Gbps network switch following applicable standards for 10 Gbps Ethernet.
- Each facility must provide a static IP address for the customer network interface.

- The Image Management Server runs web services on port 443.

  Note: If utilizing remote review stations firewall access must be configured accordingly.

Physical requirements for the network switch

- The network switch should be staged in a location suitable for IT infrastructure components, such as a rack in a network closet or suitable countertop with appropriate power and environmental controls.
- If placed on a countertop, the rubber-footpads provided with the network switch must be installed to prevent movement and improve airflow.
- Network switch must be easily accessible on all sides to accommodate proper servicing.

Network requirements for the network switch

- The network switch is a Layer 2 type switch.
- The network switch has a minimum of twelve RJ-45 Ethernet ports with 10 Gbps.

Security

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

Limit access and back-up off-system

As part of normal operation, data is saved to the Genius IMS in the following directories:

- **Hologic Main Application Folder**

  C:\Program Files\Hologic
  Hologic application files for IMS dashboard, Archiver, etc., as well as SQL Server MDF/LDF database files
- **Default Database Backup Folder**

  D:\Hologic\DC\Database
  Default location for creating nightly database backups. This is a user-definable folder location.
- **Image Repository Folder**

  D:\SlideData
  Location of main image repository. As this is a user-definable location, it may be different on an installed system.

Limit direct access to these directories, and follow your site's best practices for backing up this data (off-system).

Cybersecurity and Data Protection

Use the information in this section as well as your site's best practices for cybersecurity and data protection.

- The computer USB ports should only be used in accordance with the instructions provided with the system. Always ensure the external USB flash drive or portable storage medium is virus-free and not used on public or home computers.
- If the instrument is connected to a network, Hologic requires a firewall be placed between the system and the network to protect against malicious network threats.
- Ensure all external storage devices are kept in a secure location and only available to authorized personnel.
- If your laboratory uses images and slide data generated by the Genius Digital Diagnostics System outside the Genius Digital Diagnostics System, then your laboratory is responsible for maintaining the integrity of the data in those other applications. The slide data set generated by the Genius Digital Diagnostics System includes a hash manifest with SHA-256 checksum information. The Secure Hash Algorithm (SHA) can also be utilized by the laboratory's archiving system to check data integrity as the laboratory moves files throughout their long-term storage solution.

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. Failure to follow these recommendations could increase the risk of exposure to a virus, spyware, Trojan or other hostile code intrusion. If any of these are suspected, please contact Hologic Technical Support as soon as possible.

Windows Domain and Active Directory

The IMS supports the use of Active Directory as a mechanism for Windows authentication. Domain membership is permitted; however, care must be taken to ensure domain policies do not adversely affect system functionality or performance.

The IIS application pool runs under a single administrative account for all Hologic web services. As an IIS service-account, the password does not expire.

The Genius IMS database is SQL Server® 2022. Applications use Windows authentication for SQL access.

Genius Review Station users are independent and not integrated with Active Directory. Review Station usernames and passwords are stored in the IMS SQL database. Review Station user passwords are encrypted in the SQL database.

Third party software packages

Genius IMS software may come preinstalled on the Genius IMS server 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.

Antivirus

The use of antivirus software is recommended on the IMS. Installation instructions provided with the antivirus software product should be used for installation and configuration.

Exclude the following parent directories and subdirectories from antivirus scanning. Failure to exclude these directories may result in degraded system performance:

- **Hologic Main Application Folder**

  C:\Program Files\Hologic
  Hologic application files for IMS dashboard, Archiver, etc., as well as SQL Server MDF/LDF database files

- **Hologic Web Services Folder**

  Application files for all three Hologic web services (.\ImagerService, .\ReviewStation, and .\SlideRetriever subdirectories)

  For installations that use Genius Event Bridge, the application files for the Hologic Genius Event Bridge web service (.\GeniusEventBridge subdirectory) are also in this folder.

- **Default Database Backup Folder**

  D:\Hologic\DC\Database
  Default location for creating nightly database backups. This is a user-definable folder location.

- **Image Repository Folder**

  D:\SlideData
  Location of main image repository. As this is a user-definable location, it may be different on an installed system.

Hologic recommends the use of antivirus software on the computer that will run the IMS Server. Hologic has tested the following antivirus software on the computer that will run the IMS Server:

- Microsoft Defender Version 1.417.647.0
- ESET – 11.0.12012.0
- MalwareBytes – 4.6.9.314

Antivirus software other than those listed has not been tested. The impact of antivirus software other than those listed has not been established.

Intrusion detection

Real-time intrusion detection monitoring software is not recommended to be run when the IMS is active as it may affect performance of the application. Intrusion detection could be run in an offline manner on the system when the IMS application is idle.

Encryption

Software-encryption may adversely affect system performance. If encryption is desired, hardware-based disk encryption is recommended. Installation instructions provided with the encryption product should be used for installation and configuration. It is recommended to consult Hologic Technical Support to better understand the implications of such encryption on performance.

Operating system patching

The IMS software runs on Microsoft Windows Server 2016, Microsoft Windows Server 2019, Microsoft Windows Server 2022 (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.

IMS tasks are set to run in the Windows Task Scheduler. Source files for these tasks reside in the Hologic Main Application Folder. Refer to "Hologic Main Application Folder" on page 2.3.

- "Hologic IMS Archiver" – Nightly image archiving function
- "Hologic IMS Database Backup" – Powershell to execute database backup script.

Cybersecurity assessment

A cybersecurity assessment of the Genius IMS running Windows Server 2016 was performed. The results are presented in Table 2.1.The same assessment has been run with Windows Server 2019 and Windows Server 2022.

Table 2.1 Cybersecurity Assessment, IMS Running Windows Server 2016, Windows Server 2019 or Windows Server 2022

Number	Severity	Vulnerability Description	Affected (ports)
1	Severe	**SMB signing disabled** - This system does not allow SMB signing. SMB signing allows the recipient of SMB packets to confirm their authenticity and helps prevent man in the middle attacks against SMB. SMB signing can be configured in one of three ways: disabled entirely (least secure), enabled, and required (most secure).	446
2	Severe	**SMB signing not required** - This system enables, but does not require SMB signing. SMB signing allows the recipient of SMB packets to confirm their authenticity and helps prevent man in the middle attacks against SMB. SMB signing can be configured in one of three ways: disabled entirely (least secure), enabled, and required (most secure).	446
3	Severe	**SMB: Service supports deprecated SMBv1 protocol** - The SMB1 protocol has been deprecated since 2014 and is considered obsolete and insecure.	446
4	Severe	**SMBv2 signing not required** - This system enables, but does not require SMB signing. SMB signing allows the recipient of SMB packets to confirm their authenticity and helps prevent man in the middle attacks against SMB. SMB 2.x signing can be configured in one of two ways: not required (least secure) and required (most secure)	446

Number	Severity	Vulnerability Description	Affected (ports)
5	Moderate	**DNS Traffic Amplification** - A Domain Name Server (DNS) amplification attack is a popular form of distributed denial of service (DDoS) that relies on the use of publicly accessible open DNS servers to overwhelm a victim system with DNS response traffic.	53
6	Moderate	**TCP timestamp response** - The remote host responded with a TCP timestamp. The TCP timestamp response can be used to approximate the remote host's uptime, potentially aiding in further attacks. Additionally, some operating systems can be fingerprinted based on the behavior of their TCP timestamps	N/A
7	Moderate	The remote service accepts connections encrypted using TLS 1.0. TLS 1.0 has a number of cryptographic design flaws. Modern implementations of TLS 1.0 mitigate these problems, but newer versions of TLS like 1.2 and 1.3 are designed against these flaws and should be used whenever possible.	N/A

To address potential vulnerabilities, Hologic recommends:

- Keep SMB signing disabled (SMB signing is disabled by default on Windows Server® 2016, Windows Server® 2019, and Windows Server® 2022)
- Disable SMB1 by using Windows® Powershell® Administrator commands.
- Use a series of standard information systems' security practices, such as Source IP verification for network devices, disabling recursion on applicable name servers or limiting recursion to authorized clients, and implementing rate limiting on DNS Server as needed.

  Note: TCP timestamp responses are a common function inherent to the TCP protocol itself. Disabling this feature can cause TCP communication to malfunction. McAfee® and other security organizations consider this a low vulnerability and recommend keeping this feature enabled.

- Enable support for TLS 1.2 and 1.3 and disable support for TLS 1.0.

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 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. The lab can disable access at any time from a Genius Review Station.

Access through the SecureLink remote diagnostics support platform facilitates efficient diagnosis and resolution of issues that may arise during operation of the Genius Digital Diagnostics System.

2 INSTALLATION

The remote support session allows authorized service personnel trained by Hologic to securely access the system to provide system service, view the desktop GUI, or provide guidance to a local instrument operator. In addition, the system allows for remote file transfer of files needed to troubleshoot an instrument error.

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 Genius Review Station Operator's Manual describes the procedure for enabling a session for authorized support personnel trained by Hologic to access your Genius Digital Diagnostics System remotely, if SecureLink software has been installed.

Technology Description

The SecureLink remote support platform is an optional service that can be installed once customer approval has been received by Field Service personnel trained by Hologic. Upon approval, the SecureLink GateKeeper will be installed as a Windows Service on the IMS server. When the service is not running, a remote support connection is not available.

The installation package used by the Field Service personnel trained by Hologic will modify the Windows Firewall Outbound Rule Set on the firewall installed on the Image Management Server. This modification allows a connection to be established from the GateKeeper to Hologic's SecureLink Application Server appropriate for your region. As a final step, the customer firewall must allow outbound connections using the outside interface IP of the Cisco ASA as the source IP.

The SecureLink GateKeeper service establishes a secure, end-to-end outbound connection from the GateKeeper host system to the Hologic-maintained SecureLink Application Server using SSHv2. The GateKeeper is locked from modification and only allows connection to the Hologic-maintained SecureLink Application Server.

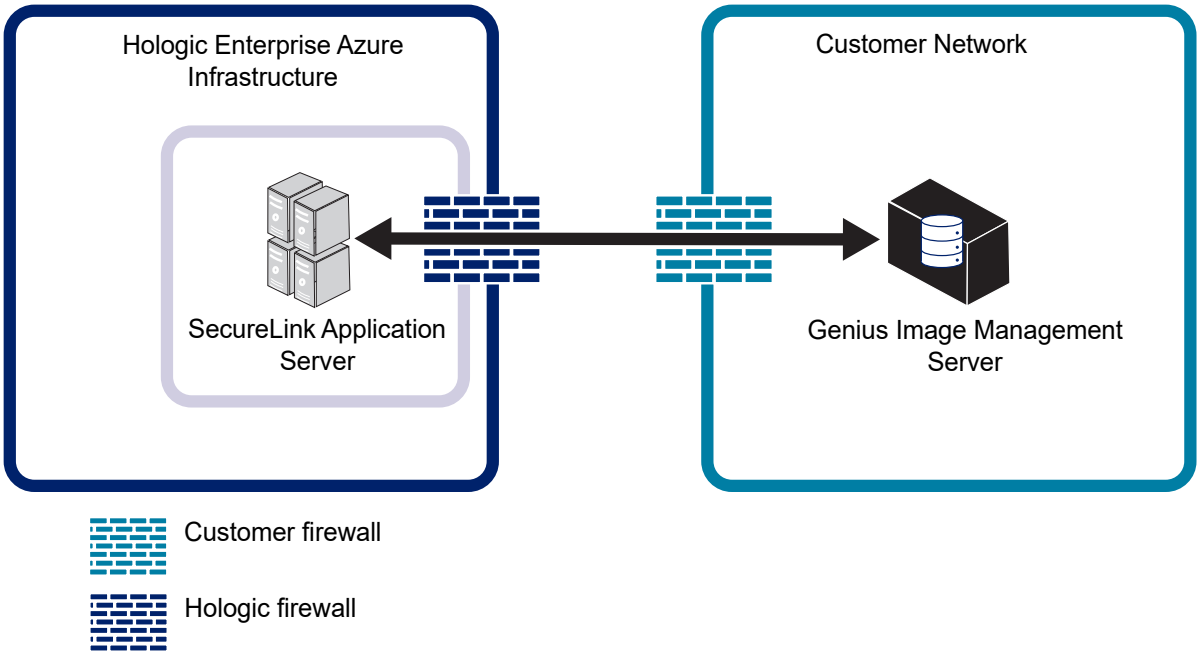


Figure 2-1 Network Diagram for SecureLink Remote Access

Refer to Table 2.2 on page 2.10. It is the customer's responsibility to select the appropriate IP address from the Table 2.2.

The SecureLink service is set to start automatically with Windows by default when SecureLink is initially installed. However, as part of the installation of the Genius Digital Diagnostics System software, the SecureLink GateKeeper service is automatically disabled. For Field Service personnel trained by Hologic to access a customer's system, a customer must enable the remote connection as described in the operator's manual for the Genius Review Station.

Note: Hologic does not currently support the use of a customer's existing SecureLink GateKeeper or SecureLink Nexus infrastructure.

Authentication into the SecureLink Application Server for Hologic service personnel is managed through Hologic Active Directory, and authenticated using Okta® with multi-factor authentication, ensuring only authorized personnel trained by Hologic have system access. Details of each remote support session (including a record of the employee ID) are archived indefinitely for audit purposes. The remote support connection activity can be made available upon request to Hologic Technical Support.

Each SecureLink GateKeeper instance is uniquely identified by a registration code that is entered during installation by Field Service personnel trained by Hologic, allowing for granular control of GateKeeper systems that are authorized to connect to the SecureLink Application Server.

The SecureLink GateKeeper is capable of automatically updating itself to a new version to ensure vulnerabilities are addressed and allow product enhancements to be delivered without requiring a site visit by Field Service personnel trained by Hologic. Once a connection has been established to the SecureLink Application Server, a version check will be performed. If a higher version is found, the GateKeeper will download the necessary components for the upgrade, perform the upgrade, and restart the service.

The SecureLink Application Server resides in Hologic's Enterprise Azure Infrastructure and is isolated onto its own network segment. The server instance Operating System is hardened to reduce attack vectors by disabling and removing unnecessary services and tools. All SecureLink session connections utilize the SSHv2 protocol for data transport with AES-256 for bulk encryption, and RSA (2048-bit key length) for key exchange. Every key is uniquely generated per session and mutual authentication is enforced to mitigate Man-In-The-Middle attacks.

Configuration Information

It may be necessary to configure the customer's enterprise firewall to allow the Genius Digital Diagnostics System to utilize SecureLink depending on the current Outbound Rule Set. No Inbound rules need to be added for a remote support connection to be established. The following connections must be allowed to enable a successful remote connection.

Table 2.2 Connectivity Guidance

Application	URL	IP Address*	Protocol and Port	Connection Type
SecureLink US	connect.hologicsecurecare.com*	168.62.215.126	TCP 22	Outbound

*** The IP addresses have been provided however, Hologic recommends utilizing the URL in any firewall configuration to support additional server deployments in the future as well as disaster recovery.**

SECTION D

MOVING THE IMAGE MANAGEMENT SERVER

If it becomes necessary to change the location of your Image Management Server, contact Hologic Technical Support or your local Hologic representative. Collaboration between your IT staff and Hologic is required, and a service visit may be necessary.

Unit Shipped to New Location

If the Image Management Server is to be shipped to a new location, please contact Hologic Technical Support or your local Hologic distributor. Refer to Chapter 8, Service Information.

SECTION E

CONNECTING IMAGE MANAGEMENT SERVER COMPONENTS

If it becomes necessary to change the archive storage system connected to your Image Management Server, contact Hologic Technical Support or your local Hologic distributor. A service visit is required.

The Genius Digital Diagnostics System components must be fully assembled before turning on the power and using the instrument. Field Service personnel trained by Hologic will install and configure the system components.

A network connection (see Figure 1-5) connects the Review Station to a networking device, enabling communication to the Genius Image Management Server.

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

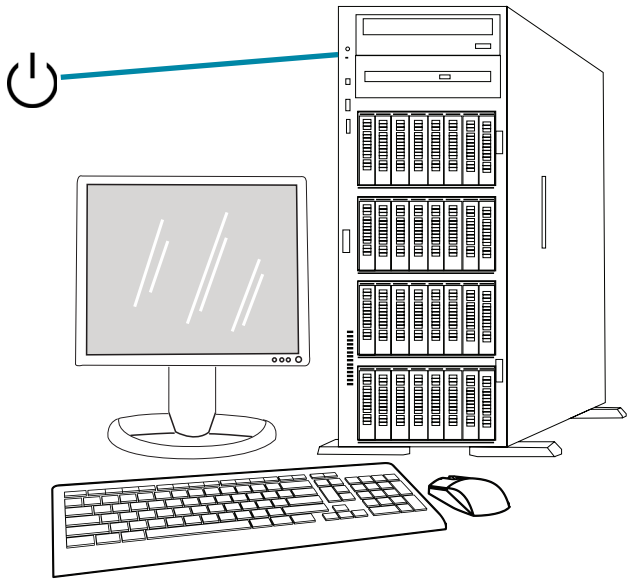
SECTION F

POWER ON THE SERVER

WARNING: Grounded Outlet

To ensure safe operation of the instrument use a three-wire grounded outlet. Typically, the server is always powered on, left running.

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



Note: The appearance of the server in this illustration may differ from the server installed at your site, and the position of the power button may differ.

Figure 2-2 Power Switch

Launch the application

The Image Management Server dashboard application can be left running. If the dashboard application is closed, to launch the application, click on the desktop shortcut.

SECTION G STORAGE AND HANDLING - POST INSTALLATION

The Image Management Server must be stored in the location where it was installed. Typically, the server is left running. Follow your laboratory's policy for handling computer equipment.

SECTION H SYSTEM SHUTDOWN

Normal and Extended Shutdown

Typically, the Image Management Server is left running.

Because the Image Management Server hosts services and applications necessary to the operation of the Digital Imager and the Review Station, shutting down the Image Management Server shuts down the operation of the Genius Digital Diagnostics System. Notify the staff using the Digital Imagers and Review Stations before shutting down the server.

Caution: If the Image Management Server needs to be shut down, ensure that the Digital Imagers and Review Stations are idle, to avoid disruptions.

In the event that the server must be shut down:

1. Close the application.
2. Shut down Windows.
3. Press the power button on the server (The location of the button varies with the model of server.)
4. Completely remove power by unplugging the monitor power cord and the computer cord from the power outlet.

2 INSTALLATION

This page intentionally left blank.

3 .Image Management
Server Dashboard

3 .Image Management
Server Dashboard

Chapter Three

Image Management Server Dashboard

SECTION A

OVERVIEW

The user interfaces with the Genius Image Management Server through the Image Management Server dashboard. The dashboard presents a quick confirmation or error notification for the services and applications necessary to store and retrieve data for the Digital Imager and the Review Station.

It is recommended that the IT support staff for a laboratory acquaint themselves with the material in this chapter using the Image Management Server dashboard.

This chapter describes each of the dashboard's tabs:

3 IMAGE MANAGEMENT SERVER DASHBOARD

SECTION B SYSTEM

The System dashboard shows an overview of the entire Image Management Server services, applications and connections.

Status Indicators

The System dashboard displays a summary of each of the other tabs in the dashboard. Each of the services and applications on the left of the System dashboard are described in more detail further in this chapter.

A green circle indicates that the services and applications are running. In normal operating conditions, all circles are green.

A red circle indicates that a service or application is not running. Hover over the status to see more information.

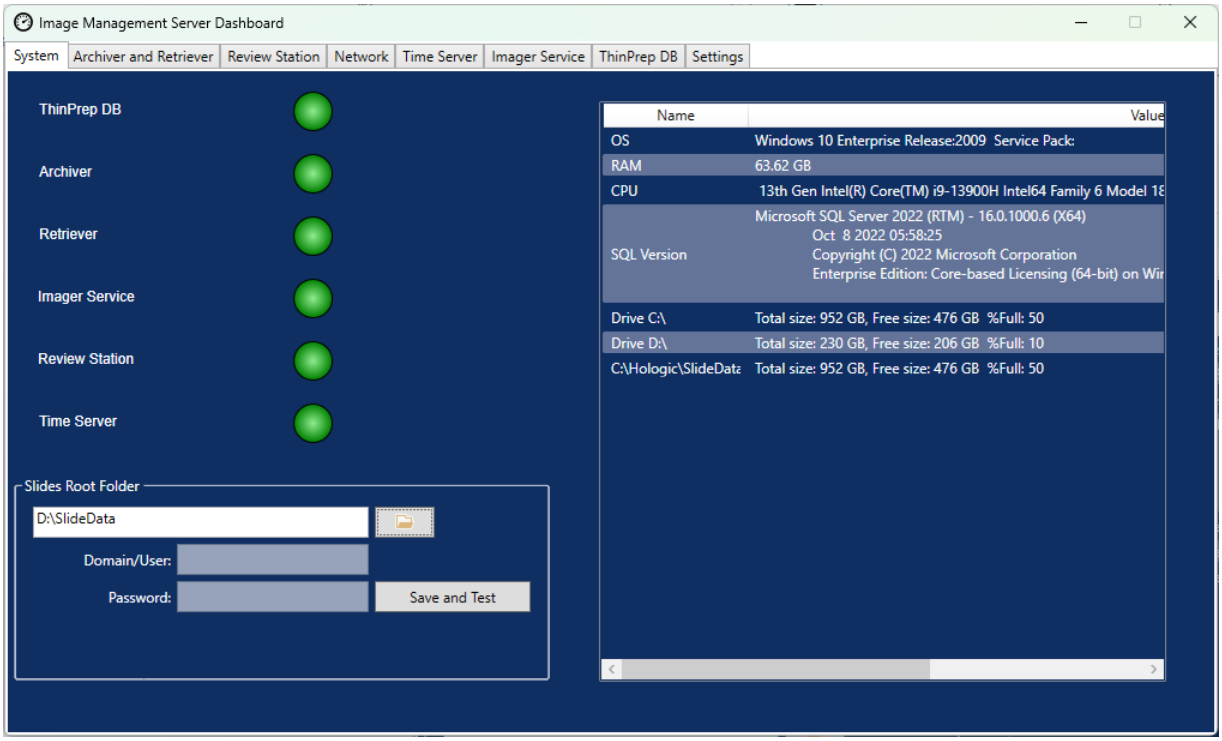


Figure 3-1 System dashboard

Slides Root Folder

The Slides Root Folder is the storage location for the images sent by the Digital Imager and reviewed at the Review Station. The Slides Root Folder is set up during the system installation. Only qualified Field Service personnel trained by Hologic should change the domain name or IP address for the Slides Root Folder.

When the amount of data saved to the Slides Root Folder approaches the limit of its storage capacity, a notification message appears. The notification appears when 10% of the storage capacity remains. Refer to “Unable to Archive or Approaching Full Capacity” on page 5.3.

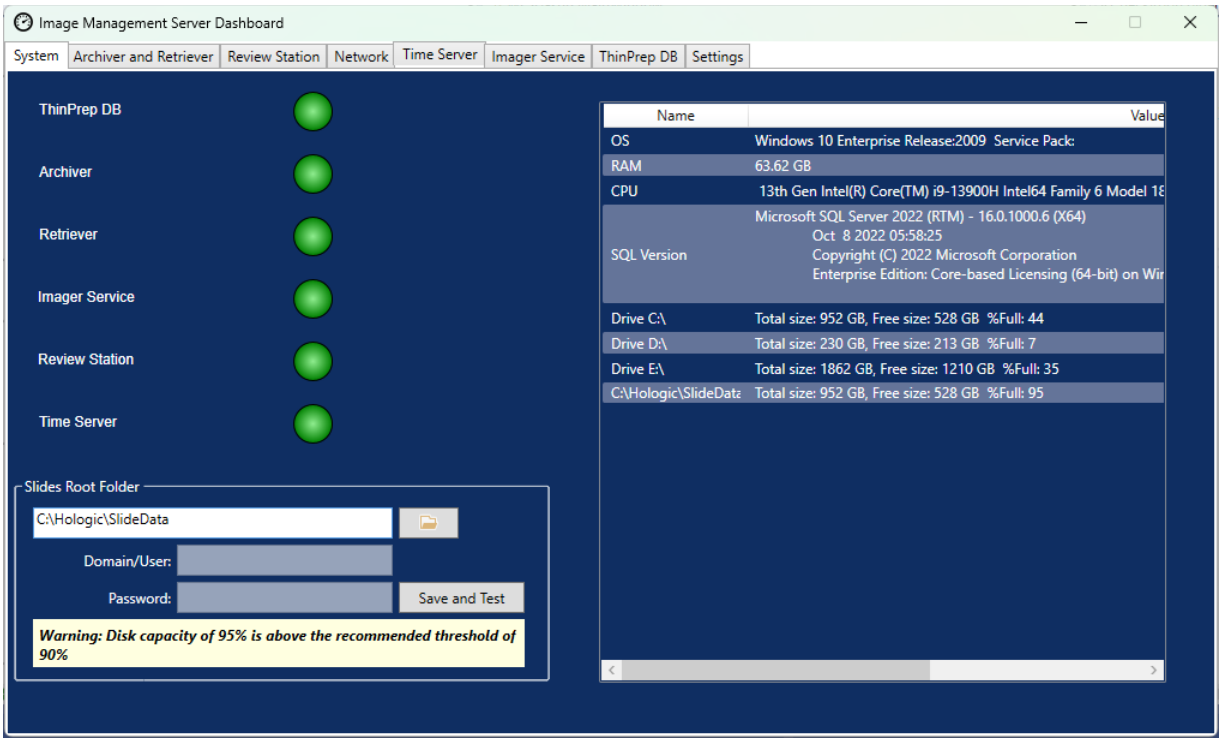


Figure 3-2 Slides Root Folder Approaching Full Storage Capacity

Adequate storage capacity is necessary to continue to image slides at the Digital Imager. The amount of storage capacity varies with Imager usage.

Data clean-up

It is the customer’s responsibility to perform a regular data clean-up to create free space on the Genius Image Management Server, to enable the continued addition of new images and case data.

The Genius Digital Diagnostics System features listed below support your data clean-up:

- Use an archive storage solution and routinely archive cases. Refer to “Archiver and Retriever” on page 3.7 and to the Genius Review Station Operator’s Manual for instructions.

- Delete unnecessary slide data sets. Refer to "Slide Management" on page 3.4 and to the Genius Review Station Operator's Manual for instructions.
- Deactivate user accounts when the user leaves the organization. Refer to the Genius Review Station Operator's Manual for instructions.
- Delete unused tags. Refer to the Genius Review Station Operator's Manual for instructions.

The Slides Root Folder is only changed by qualified Field Service personnel trained by Hologic. Hologic Technical Support may ask for the Slides Root Folder file path to assist with support.

Slide Management

The Genius Digital Diagnostics System can be set up to permanently and routinely delete slide images and case data records (slide data sets) 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.

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 gallery of OOIs, marks and comments, cannot be recovered once deleted. There is no way to retrieve the deleted data.

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

When enabled by the lab manager at the Review Station, the Slide Management tasks run nightly in the background on the Genius IMS and require no user interaction. Slide Management is a task within the Windows Task Scheduler on the Genius IMS.

The system monitors the available local disk space, and, if slide management is set to delete slides, the system deletes the oldest image files to free up storage capacity to store the newly scanned image files.

In the settings for Slide Management at the Review Station, a manager chooses if cases that have been tagged or bookmarked by a Review Station user will be included in the delete operation, or if tagged or bookmarked cases will be retained on the system.

- If the free storage capacity (disk space) in the image repository is lower than the threshold set by the lab manager, Slide Management will exit and perform no action.
- If the free disk space in the image repository meets or exceeds the threshold set by the lab manager, Slide Management will delete the oldest slides (slide image files from the repository and corresponding internal database records) until the storage capacity threshold is met. Slide Management operates on blocks of 1,000 slide data sets at a time and not individual image files. This may result in freeing up slightly more storage capacity than the threshold percentage.

Note: While Slide Management runs nightly, it may not need to delete image files every night. Deletion volume depends on the volume of new slides scanned in the Genius Digital Diagnostics System since the last run of Slide Management and a laboratory's long-term storage archiving schedule.

If the Slide Management utility on the Image Management Server fails to delete any of the eligible images from the slides root folder, the Review Station users with a manager role or an administrator role receive an alert at the Review Station. The alert instructs the user to contact the site network administrator.

If the slides root folder approaches the slide management threshold and some of the eligible images are successfully deleted each night, no alert is sent to the manager or administrator at the Review Station.

Storage capacity considerations

Hologic recommends considering the archiving criteria and the local repository size (image cache) of the Genius IMS in your lab when setting the storage capacity threshold for Slide Management to run.

For example, if the slide management is set to delete slide data sets when 90% of the Genius IMS storage capacity is full, then the number of slides whose data is stored on the Image Management Server will reach a steady state when the lab has consumed over 90% of repository storage. At the 90% threshold, the system deletes the oldest slide data sets to maintain sufficient free space. As more slides are imaged, the oldest slide data sets (digital slide images and case data) will be deleted.

The number of slide data sets at this steady state can be estimated based on the storage size of the repository on the IMS. The table below provides an example of server capacity and number of slides:

IMS Storage Capacity	Estimated Number of Slides Stored Locally*
72 TB	48,000
*Calculation based on an estimate of 1.5 GB file size per case. The actual size of the slide image files is variable based on multiple factors, including cellularity.	

A server with 72 TB of storage can store approximately 48,000 of the most recently imaged slides (and related internal database records) in the local repository. The time duration that this spans is directly proportional to the lab's scanning volume. The greater the volume, the

shorter the duration of slides kept in the cache. The table below illustrates approximate durations for a 72-TB server to reach 90% storage capacity:

Weekly Lab Slide Volume (slides)	Estimated Duration of Local Repository Cache*
500	96 weeks
1,000	48 weeks
2,000	24 weeks
3,000	16 weeks
4,000	12 weeks
5,000	9.6 weeks
*Calculation based on an estimate of 1.5 GB file size per case. The actual size of the slide image files is variable based on multiple factors, including cellularity.	

A manager or administrator at the Review Station can adjust the Slide Management Settings and the Archive Settings to adjust to a change in lab slide volume. Refer to the Review Station Operator's Manual for details.

Re-imaging slides

Case data records are internal database entries of each slide's imaging and review activity. Case data records and images (slide data sets) are deleted by the slide management feature. The deletion of the database entry allows the slide to be scanned again in the future if required.

After a case is deleted from the Genius IMS, it is possible to re-image the ThinPrep slide to produce another digital image of the slide. Due to environmental factors such as fading, drying, lighting, and system variability, re-imaging a ThinPrep Pap test slide 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.

And, due to environmental factors such as fading, drying, lighting, and system variability, re-imaging a a slide may not produce an identical whole slide image. Refer to the Instructions for Use for the performance characteristics of the Genius Digital Diagnostics System.

Hologic recommends that customers enable a solution for long-term storage and archiving 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 IMS.

Impact of deleting slides

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 and CT Reviews) 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.

Notes: 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.

Reports that are run on the Genius Digital Imager are not affected by the Slide Management file deletion activity.

List of Network Hardware

The System dashboard displays information about the network hardware, installed and configured at the time of the system installation. The storage capacity and free space on each network drive is shown along with the percentage of used storage capacity (%Full).

SECTION C ARCHIVER AND RETRIEVER

The Archiver and Retriever dashboard shows information about the archiver service and the retriever service hosted on the Image Management Server.

In the Genius Digital Diagnostics System, slide data sets (images and case data records) are stored on the Image Management Server from the time a slide is imaged until the time a case is archived or deleted. Each day, the Image Management Server checks for cases whose images are eligible to be archived. The criteria for archiving cases is set up at the Review Station. When a case is archived, its slide images are moved from the Image Management Server to a laboratory's archive storage system.

Note: Case data records continue to reside on the Image Management Server after the images for the case are archived. To view images from an archived case, a reviewer at a Review Station must retrieve the images from the archive first, as described in the operator's manual for the Review Station.

Information relating to the Archiver status appears on the left of the screen. Information relating to the Retriever status appears on the right side of the screen.

3 IMAGE MANAGEMENT SERVER DASHBOARD

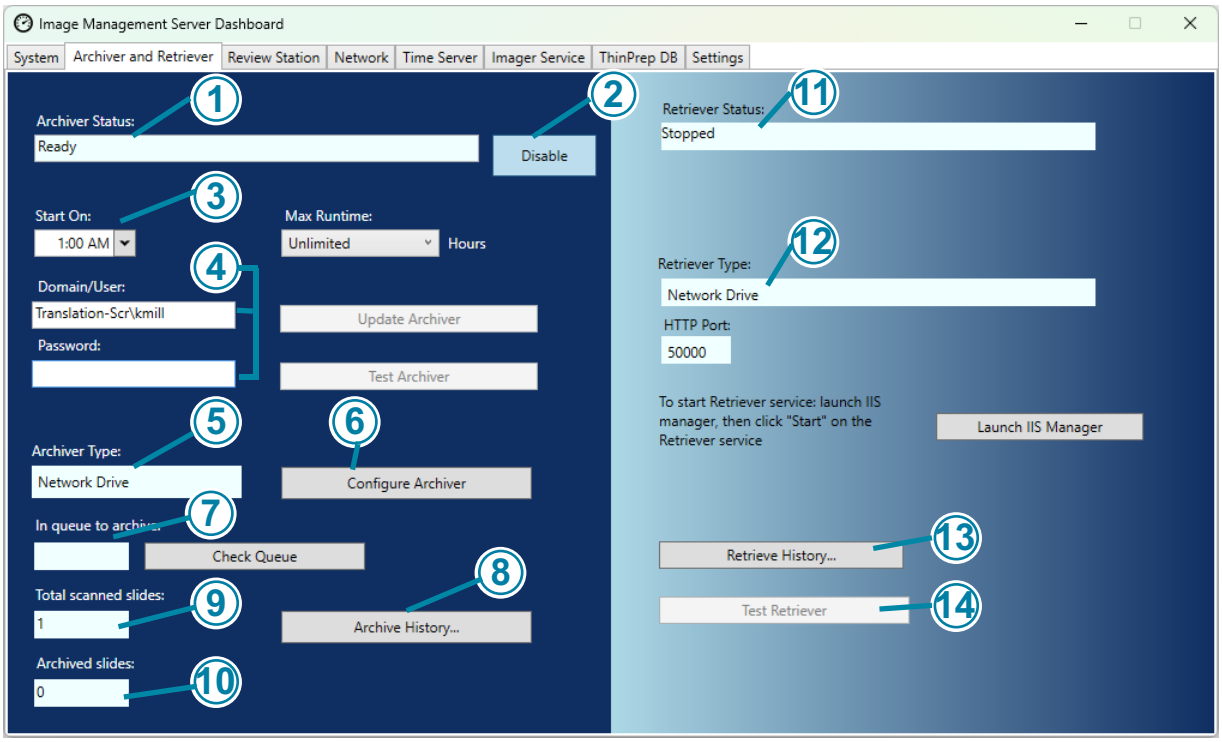


Figure 3-3 Archiver and Retriever dashboard

Key to Figure 3-3	
1	Archiver Status Refer to “Archiver Status” on page 3.10.
2	Enable/Disable Archiver Refer to “Enable or Disable existing archiver” on page 3.10.
3	Current time settings for the daily archive Refer to “Current time settings for the daily archive” on page 3.10.
4	Username and password to apply and test changes to the time settings for the daily archive Refer to “Change start or duration of daily archive” on page 3.10.

Key to Figure 3-3	
⑤	Archiver The Archiver information on the dashboard describes the archived storage device configured with this Image Management Server. The archiver is configured by qualified Field Service personnel trained by Hologic.
⑥	Configure For use by Field Service personnel trained by Hologic. The archiver is configured by qualified Field Service personnel trained by Hologic.
⑦	Archive queue To display the quantity of slides that are eligible to be archived at the current point in time, click the **Check queue** button. The number in the **In queue to archive** field updates each time the **Check queue** button is clicked.
⑧	Archive History button Refer to “Archive History” on page 3.11.
⑨	Total scanned slides This is the quantity of slides whose data has been saved to the server, from all of the Digital Imagers connected to the server, since installation of the Genius Digital Diagnostics System.
⑩	Total archived slides This is the quantity of slides whose images have been archived from the server, since installation of the Genius Digital Diagnostics System.
⑪	Retriever status Refer to “Retriever Status” on page 3.12.
⑫	Retriever and http port The **Retriever** information on the dashboard describes the archive storage system device configured with this Image Management Server. When configured correctly, the retriever is the same device as the archiver. The **http port** in the retriever section of the dashboard displays the name of the port through which the retriever transfers data from the archive storage system to the Image Management Server. The archiver and retriever are configured by qualified Field Service personnel trained by Hologic.
⑬	Retrieve History Refer to “Retrieve history” on page 3.13.
⑭	Test Retriever The Test Retriever is used by qualified Hologic service personnel after an archiver is set up. The test confirms that the current settings are properly set up for retrieving slides from the archive storage system.

3 IMAGE MANAGEMENT SERVER DASHBOARD

Archiver Status

Under normal operating conditions, when the **Archiver Status** is **Ready**, there are no actions required to archive data from the Image Management Server.

Enable or Disable existing archiver

In order to archive data, the archiver service must be configured, installed and enabled.

- If there is a need to disable the archiver configured for and connected to the Image Management Server, the setting can be changed to Disable here.
- To enable a disabled archiver, change this setting to Enable.

Configure archiver

The Archiver and Retriever dashboard has a Configure field, to be used only by qualified Field Service personnel trained by Hologic. The field has the network storage location for the archiver.

Current time settings for the daily archive

The **Start On** field on the dashboard is the time that the daily archive starts.

The **Max runtime** on the dashboard is the duration that the daily archive will run. An unlimited max runtime will continue archiving until all of the eligible cases are archived. The max runtime can be set to a specific number of hours.

For example, if the Start On time is 2 a.m. and the Max runtime is 4 hours, the Image Management Server will stop archiving eligible images at 6 a.m. each day. If the Start On time is 2 a.m. and the Max runtime is unlimited, the Image Management Server will run until all of the eligible images are archived.

Change start or duration of daily archive

After the initial system set-up, there may be no need to change any archive setting. However, a user with System Administrator rights on the server can change the start time and the runtime for the archiving service. In the event that the start time or runtime needs to change:

1. To change the starting time for the daily archive, click the down-arrow next to the current Start On time and select a new time.
2. To change the duration of the daily archive, click the down-arrow next to the Max Runtime and select a new time.
3. Enter your username. The user must have System Admin rights.
4. Enter your password.
5. Click the **Update Archiver** button. This applies the changed settings.
6. Click the **Test Archiver** button. This tests that communication between the archive storage system and the server is not disrupted by the changed settings.

7. Click **OK** when the "Archiver task updated successfully" message appears on the screen.

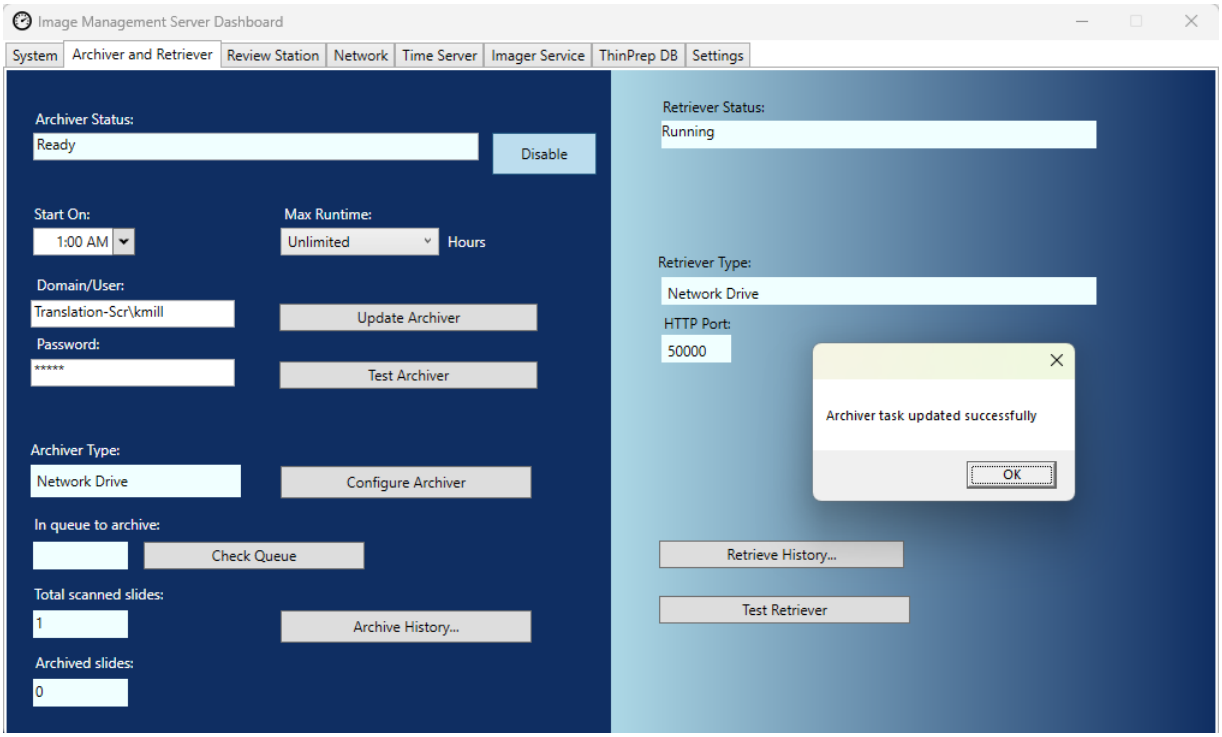


Figure 3-4 Archiver task updated successfully

Caution: If the archiver is not successfully updated and tested, images will not be archived from the server to the archive storage system. Daily archive is intended to keep sufficient server space available for imaging slides on the Digital Imager.

Archive History

The **Archive History** button on the dashboard generates a list of daily archive activity. When the quantity of cases listed in the **Planned** column equals the quantity of cases in the **Actual Archived** column, the server successfully transferred all of the images eligible for archive for that date from the Slides Root Folder to the archive storage system.

If the quantity of cases planned for the daily archive is lower than the quantity actually archived, something prevented all of the cases from transferring to the archive storage system. The difference could be caused by a max runtime that is too short, or it could be one of the indicators of a failure to archive. Refer to "Unable to Archive or Approaching Full Capacity" on page 5.3.

If all of the cases that are eligible for archive on a given day are not successfully archived because the max runtime is too short, the archive service attempts to archive the cases again the next day. The Archive History shows past activity. To see the queue of cases eligible for archive at the current time, click the **Check Queue** button, and the number of cases appears in the box for **In queue to archive**.

Note: If the volume of slides imaged or reviewed at your lab increases significantly, the Archive History list can be helpful in considering if the current archive criteria at your lab should change so that cases are archived more frequently.

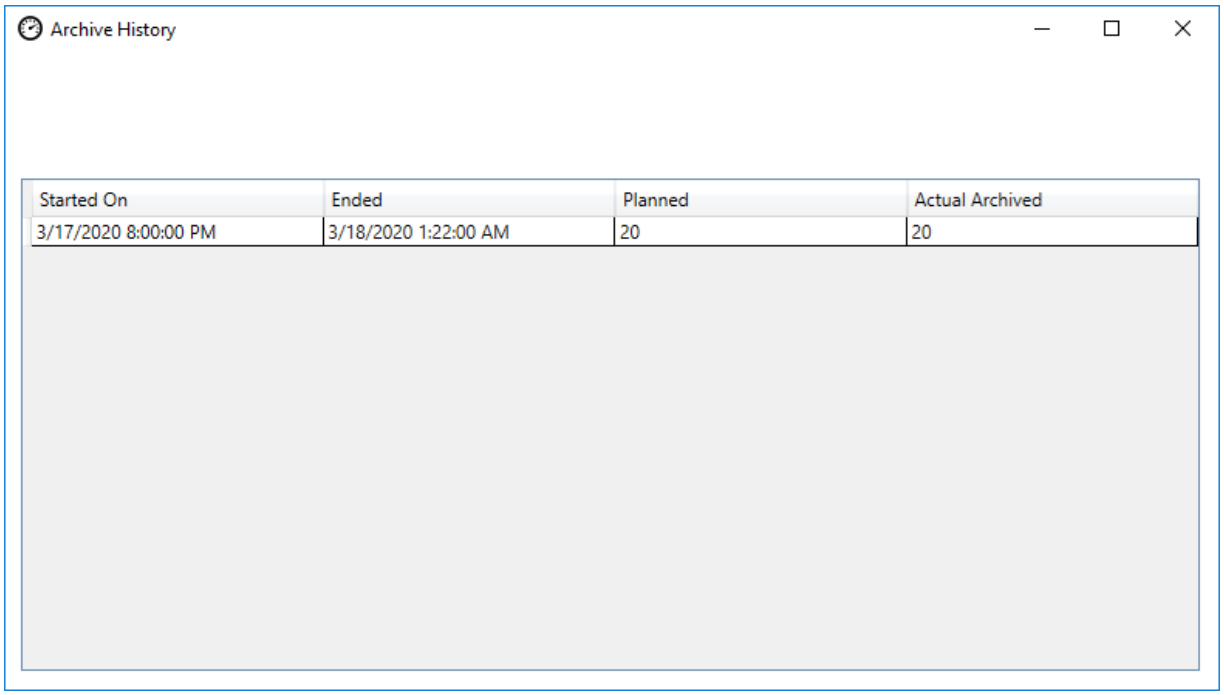


Figure 3-5 Archive History, example

Retriever Status

Under normal operating conditions, when the **Retriever Status** is **Ready**, there are no actions required to archive data from the Image Management Server.

Retrieve history

The **Retrieve History** button generates a list of the quantity of slides whose images were retrieved from the archive storage system each month.

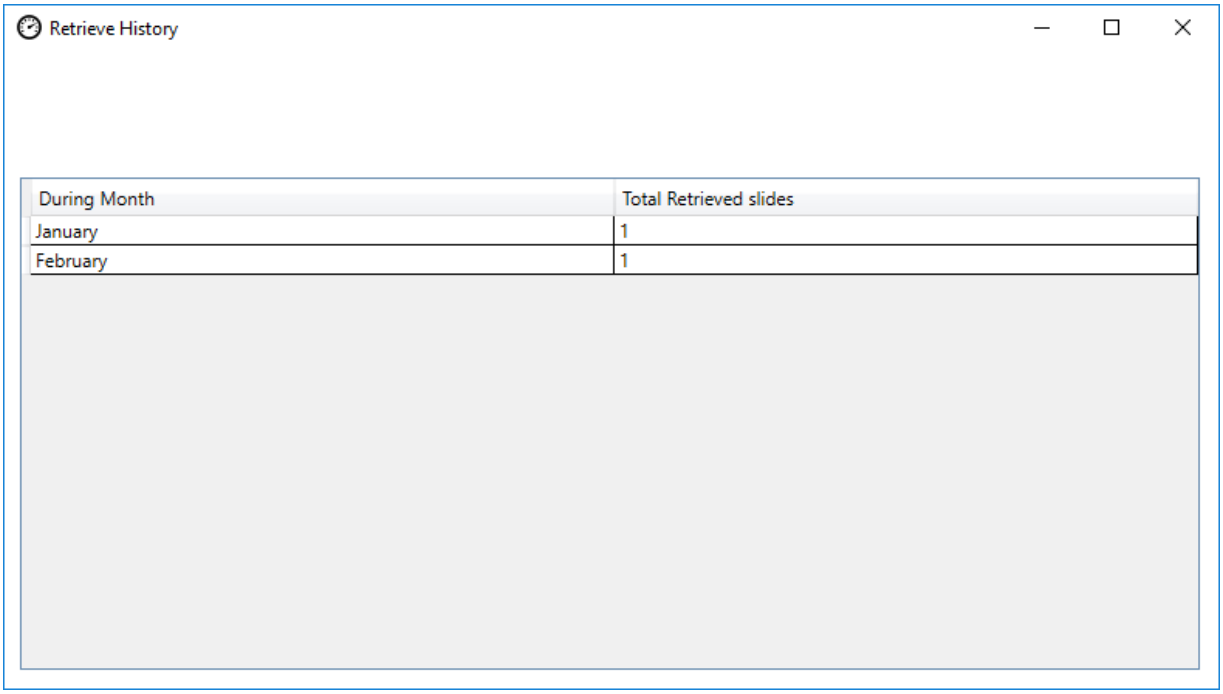


Figure 3-6 Retrieve History, example

3 IMAGE MANAGEMENT SERVER DASHBOARD

SECTION D REVIEW STATION

The Review Station dashboard displays the current status of the service that allows any Review Station on the network to launch and run the Review Station application. The status must be "Running" to use a Review Station in the Genius Digital Diagnostics System network.

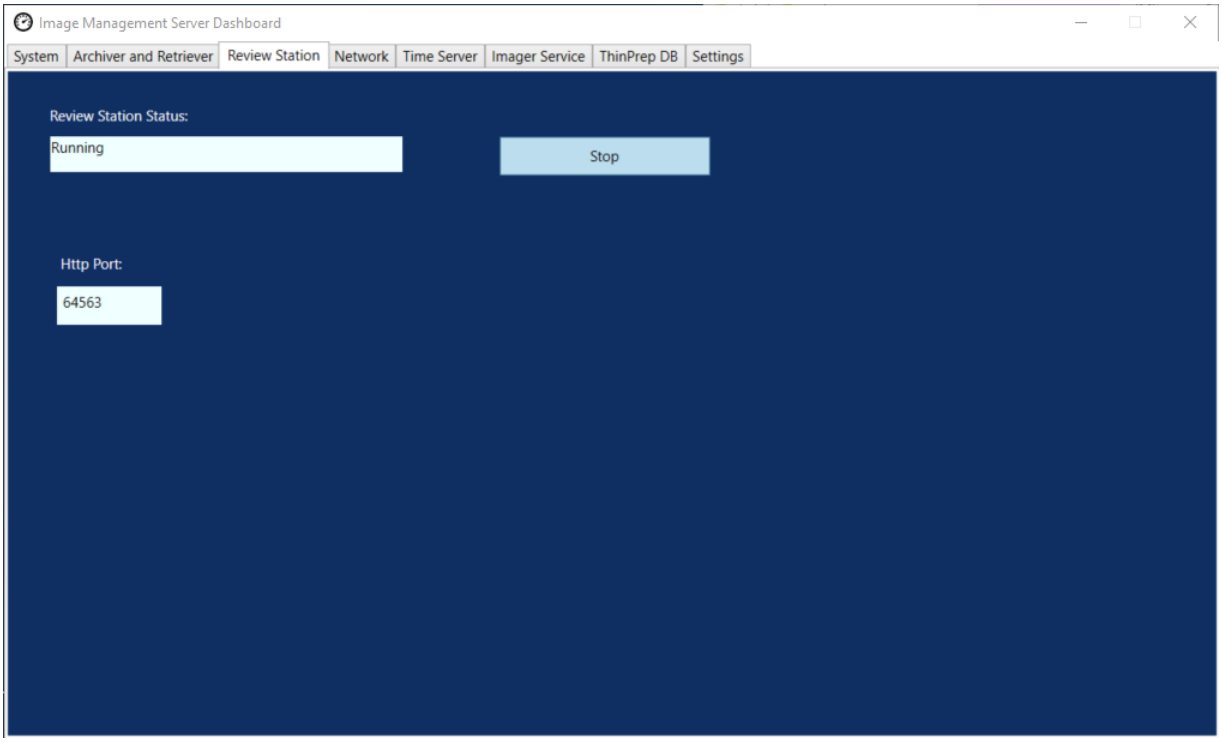


Figure 3-7 Review Station dashboard

The Http port is the name of the port through which the Image Management Server runs the Review Station service. The communication between the Review Station and the Image Management Server is set up by Field Service personnel trained by Hologic as part of system installation.

The Review Station dashboard has a **Start/Stop** button, to be used only by qualified Field Service personnel trained by Hologic.

SECTION E

NETWORK

The Network dashboard displays the current network connections for the Image Management Server.

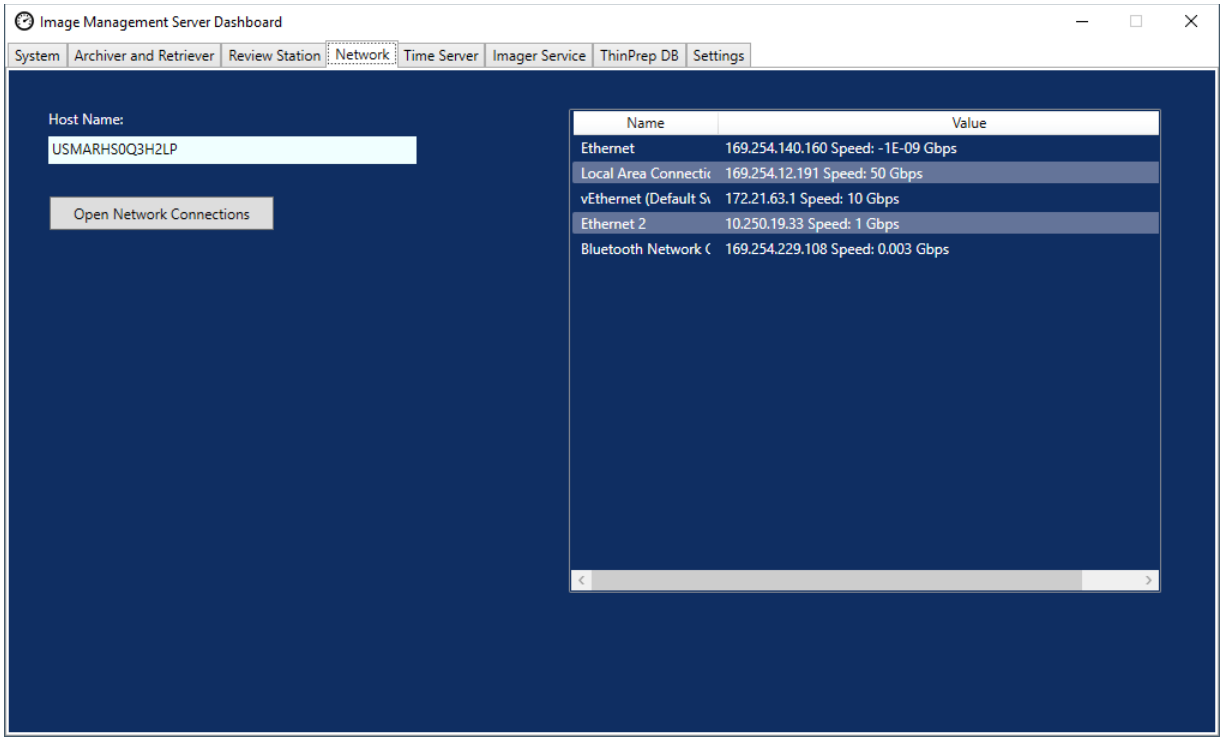


Figure 3-8 Network dashboard

The dashboard displays the name of the network on which the Image Management Server runs, along with the current network connections. The network information may be helpful in troubleshooting connection issues with Hologic Technical Support.

The Network dashboard has an **Open Network Connections** button, to be used only by qualified Field Service personnel trained by Hologic.

SECTION F

TIME SERVER

The Time Server dashboard displays the current status of the Windows time server. The time server on the Image Management Server governs the time set not only on the server, but also on the Digital Imagers and Review Stations in the network. The time server status must be "Running" in order for the Genius Digital Diagnostic System to operate.

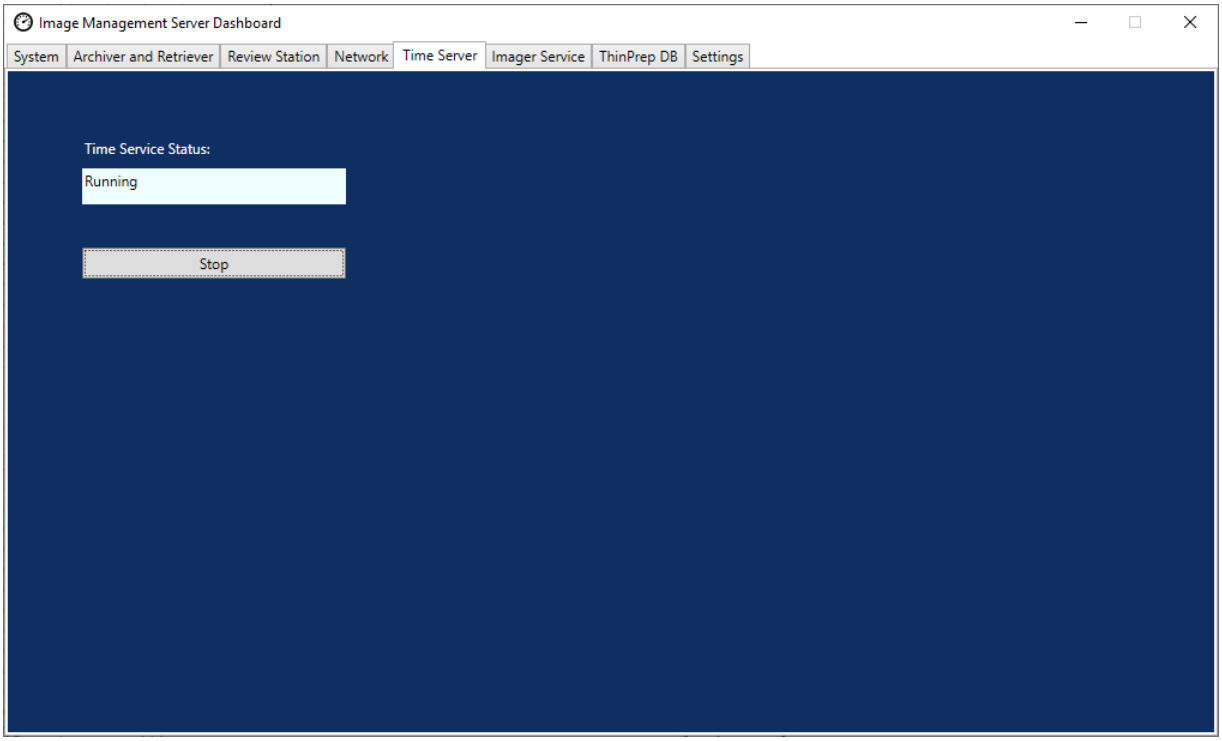


Figure 3-9 Time Server dashboard

The Time Server dashboard has a **Start/Stop** button, to be used only by qualified Field Service personnel trained by Hologic.

SECTION G

IMAGER SERVICE

The Imager Service dashboard displays the current status of the service that allows any Digital Imager on the network to image slides and run reports. The status must be “Running” for normal operation of a Digital Imager in the Genius Digital Diagnostics System network.

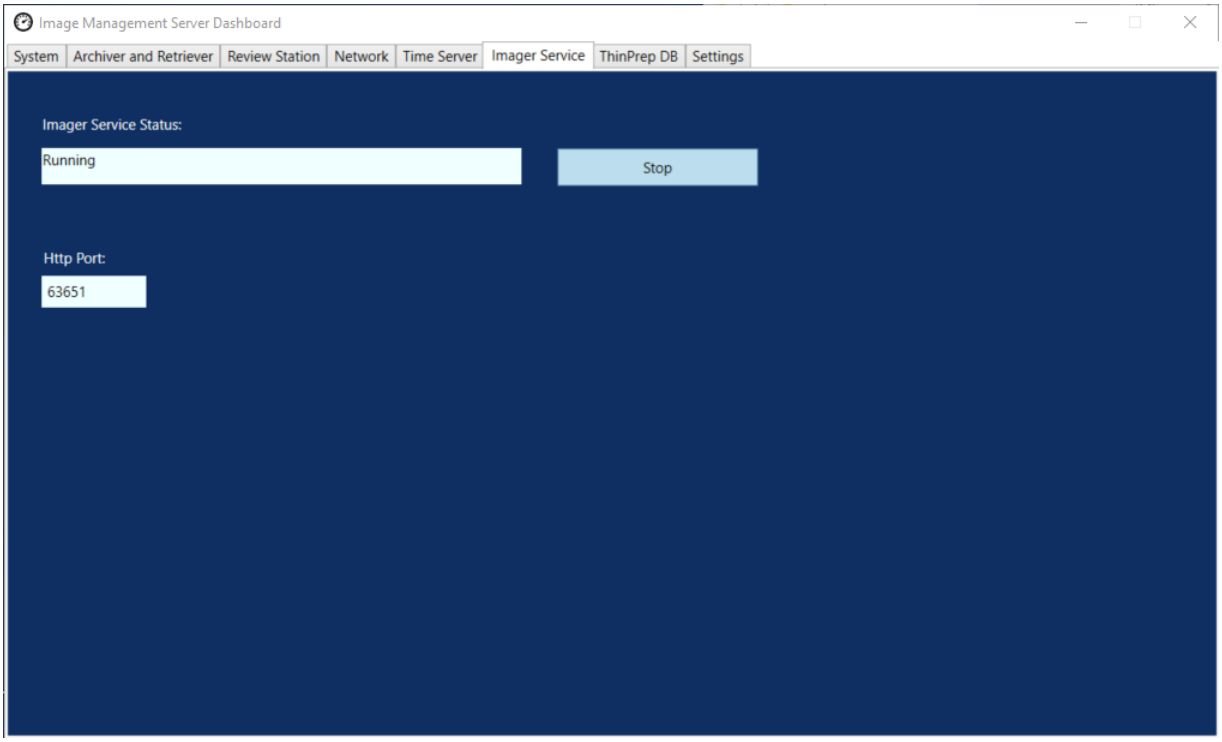


Figure 3-10 Imager Service dashboard

The Http port is the name of the port through which the Image Management Server runs the Imager service. The communication between the Digital Imager and the Image Management Server is set up by Field Service personnel trained by Hologic as part of system installation.

The Imager Service dashboard has a **Start/Stop** button, to be used only by qualified Field Service personnel trained by Hologic.

SECTION H

THINPREP DB

The ThinPrep DB dashboard displays information about the database containing slide image data. The slide image data stored on the Image Management Server includes the accession ID, the date and time the slide was imaged, and the date and time a case was reviewed, as well as other data. The accession ID is stored both as the barcode value scanned from the slide label and the ID used by the Genius Digital Diagnostics System. The slide image data is available on the Image Management Server even after a slide's images have been archived. This allows reports run from the Digital Imager or from the Review Station to include information about all slides, if the person running the report so chooses.

Note: Deleting slides removes data from the Image Management Server. Refer to "Impact of deleting slides" on page 3.6.

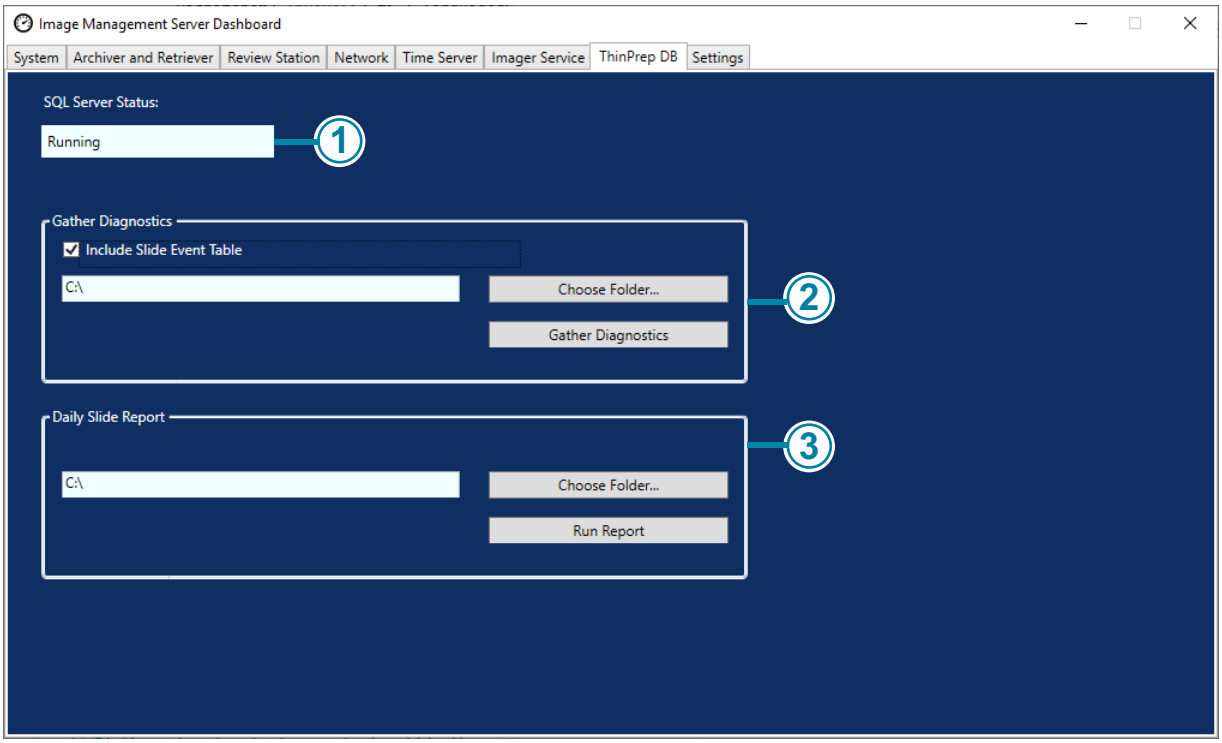


Figure 3-11 ThinPrep DB dashboard

Key to Figure 3-11	
1	SQL Server Status Displays the current status of the SQL server. The status must be “running” in order for the Genius Digital Diagnostics System to function.
2	Gather Diagnostics Refer to “Gather diagnostics” on page 3.19.
3	Daily Slide Report Refer to “Daily slide report” on page 3.20.

Gather diagnostics

Use the Gather Diagnostics feature to create a zip file of system data for troubleshooting. The system data in the Gather Diagnostics file is intended for instrument troubleshooting by Hologic Technical Support. It gathers and zips the error history log and other instrument operating information.

1. To gather that data, click the **Choose Folder...** button to navigate to the folder to which the zip file will be written, or type in a file path.
   By default, the box is checked for **Include Slide Event Data**. The slide accession IDs are included in the slide event data. To exclude slide event data, click to un-check the box.

   Note: To save the Gather Diagnostics file to a thumb drive, put a thumb drive into a USB port on the server and choose that drive in the Choose Folder option.

2. Click the **Gather Diagnostics** button to gather the data. The Image Management Server creates a "IMSDiagnostics" zip file whose file name contains the host name of the computer as well. If a file with the same name already exists in the same location, an error message displays, giving the option to overwrite the existing file.

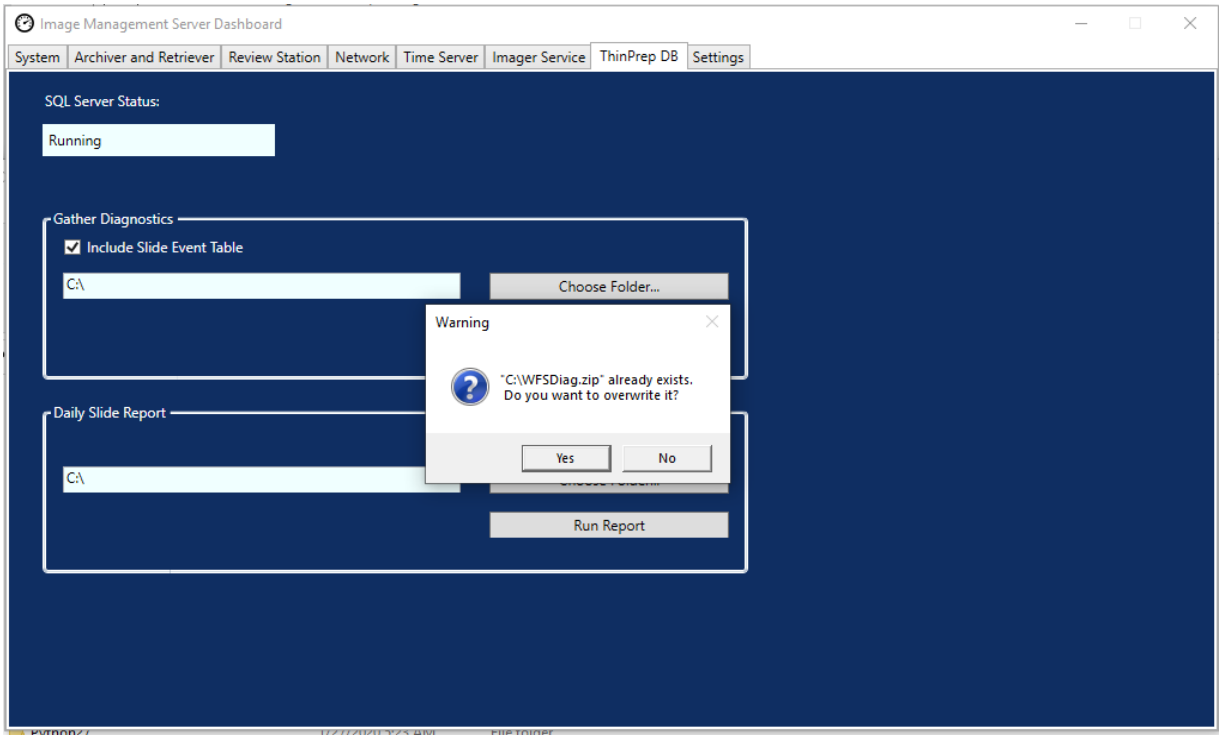


Figure 3-12 Gather Diagnostics, overwrite existing file?

3. To overwrite the existing file, select **Yes**, or select **No** and navigate to a different path using the **Choose Folder...** button.
4. Follow the instructions provided by Hologic Technical Support. Typically, the Gather Diagnostics file is small enough to send to Hologic Technical Support by e-mail.

Daily slide report

The Daily Slide Report is a .csv file showing the quantity of slides imaged each day for each sample type.

To generate a Daily Slide Report:

1. Click the **Choose Folder...** button to navigate to the folder to which the .csv file will be written, or type in a file path.

   Note: To save the Daily Slide Report file to a thumb drive, put a thumb drive into a USB port on the server and choose that drive in the Choose Folder option.

2. Click the **Run Report** button to generate the report. The .csv file is named "TotalSlidesByType.csv" and lists the date, the sample type for the slide, and the number of slides.

Date	SlideTypeName	NumOfSlides
7/8/2020 0:00	Gyn	280
7/11/2020 0:00	Gyn	80
7/12/2020 0:00	Gyn	40
7/13/2020 0:00	Gyn	400
7/14/2020 0:00	Gyn	400
7/15/2020 0:00	Gyn	400

Figure 3-13 Daily Slide Report, example

3 IMAGE MANAGEMENT SERVER DASHBOARD

SECTION I

SETTINGS

After the Image Management Server is installed by Field Service personnel trained by Hologic, there may be no need to change the language displayed on the dashboard. The Settings dashboard provides the option to change the language setting to a user with System Administrator rights on the server.

Figure 3-14 Settings dashboard

To change the language, use the down-arrow to select one of the available options.

4. Maintenance

Chapter Four

Maintenance

SECTION A GENERAL MAINTENANCE

Refer to the documentation provided by the server manufacturer. Hologic does not require preventive maintenance for the Genius Image Management Server.

4 MAINTENANCE

This page intentionally left blank.

5. Troubleshooting

Chapter Five

Troubleshooting

SECTION A

RED STATUS INDICATOR ON SYSTEM DASHBOARD

The Image Management Server System dashboard shows all green status indicators when all of the services and applications are running properly.

A red status indicator indicates that a service or application is not at the “running” or “ready” status. Hover over the status to see more information. On the corresponding tab, the same information displays.

Because the Image Management Server runs on a network at your site, troubleshooting some issues may require collaboration between your laboratory’s network IT staff and Field Service personnel trained by Hologic. The troubleshooting steps described in this manual are intended to resolve issues that arise from the Hologic-controlled components in the network. Additional troubleshooting by a laboratory’s network IT staff may be necessary. For example, if a laboratory’s network IT staff pings the archive storage system from the server, and the ping fails, then a laboratory’s network IT staff will need to troubleshoot the issue. Similarly, if something changes on the laboratory’s network, a laboratory’s network IT staff will need to help troubleshoot issues related to the changes.

5 TROUBLESHOOTING

Hologic Technical Support is usually required to resolve a “red status” and a service visit by Field Service personnel trained by Hologic may be required. Hologic Technical support will typically request information available on the dashboard to assist with troubleshooting.

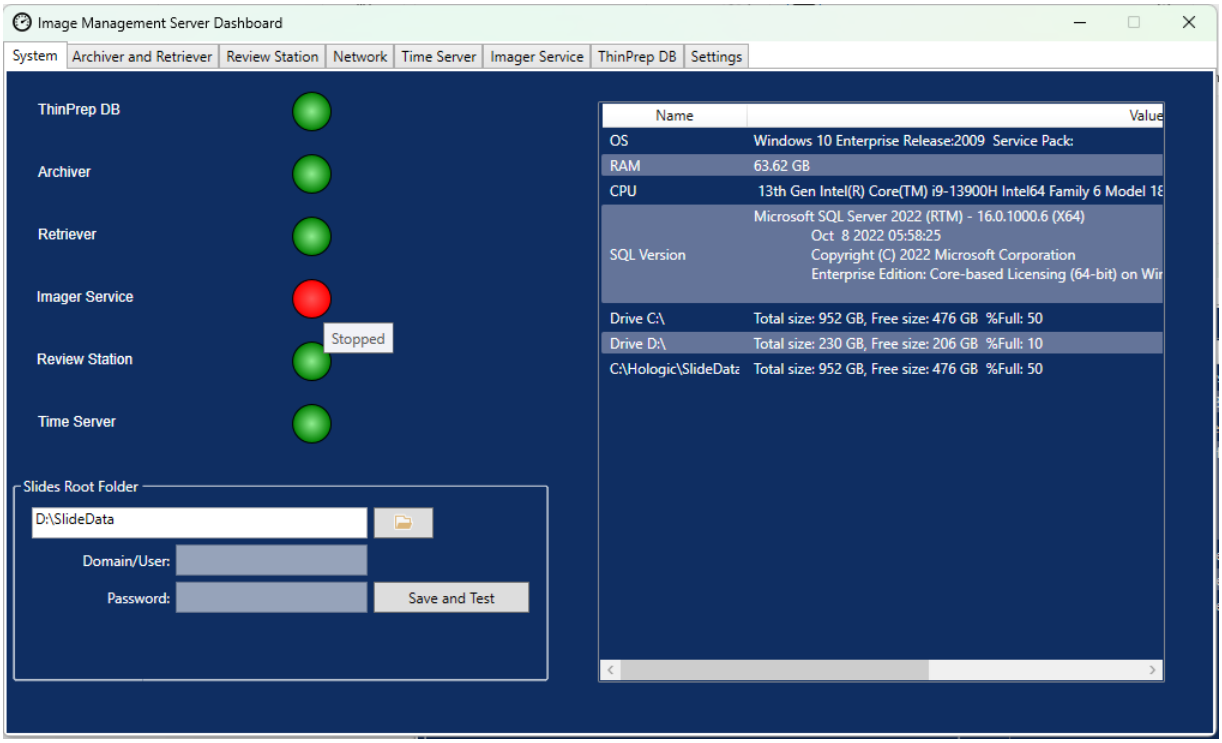


Figure 5-1 Hover mouse for more information, Imager service has stopped in this example

Unable to Archive or Approaching Full Capacity

When the storage capacity in the Slides Root Folder on the server approaches 90% full (10% free), the Image Management Server displays a red status indicator, with a warning message near the folder path information.

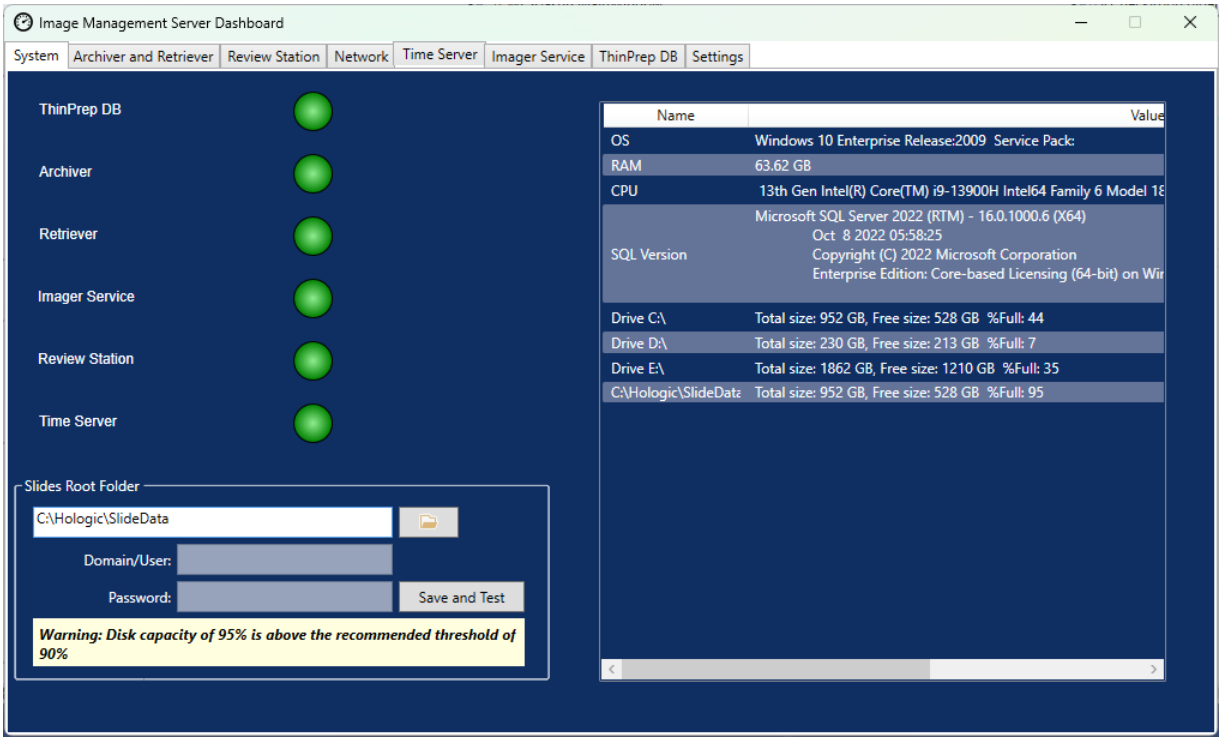


Figure 5-2 Slides Root Folder approaching capacity

Approaching capacity in the slides root folder may indicate that the Image Management Server is unable to transfer images from the slides root folder to the archive storage system. The slides root folder's storage capacity will fill up if the archive storage system is not properly installed and configured before slides are imaged.

If the Image Management Server fails to transfer any of the eligible images from the slides root folder to the archive storage system, the Review Station users with a manager role receive an alert at the Review Station. The alert instructs the manager to contact the site network administrator.

If the slides root folder approaches capacity and some of the eligible images are successfully archived each night, the Review Station users with a manager role do not receive an alert.

The issue may be in the Image Management Server's side of the transfer, or the issue may be in the archive storage system's side of the transfer. Hologic Technical Support can help troubleshoot, and IT network help at your site may be required, for example, if the laboratory's connection to the laboratory's archive storage system is down.

Hologic Technical Support may ask you to check the archive queue, test the archiver, or access Archive History to assist with troubleshooting. Refer to "Archive History" on page 3.11.

If the slides root folder is approaching full and the **Test Archiver** test is successful, the communication between the Image Management Server and the archive storage system is intact.

Communication may have been interrupted temporarily, at the moment the daily archive attempted to start. After a successful test of the archive, verify that the disruption was temporary and not a recurrent issue by checking the archive queue and Archive History the next day, after the scheduled daily archive.

Archiver Test Failed

To change any archive settings and to effectively troubleshoot archive issues, a user must have the proper credentials to access both the archive storage system and the Image Management Server. If a user has System Administrator rights in Windows for the Image Management Server and does not have the proper access to the archive storage system, the test of the archiver will fail. Follow your facility's policy for passwords and network security.

If a user attempts to test the archiver with a wrong or expired username and/or password for either the server or the archive storage system, the test will fail, without revealing any other cause of the failure to archive images.

If the test is not successful, there is an issue with the Image Management Server's communication with the archive storage system. If the **Test Archiver** fails, the Image Management Server will not be able to do the daily transfer of slide image files from the server to the archive storage system. Without the ability to archive, storage space on the server will fill up. The volume of slides imaged, the settings for archive criteria, and the server storage capacity influence how quickly storage space on the server is filled.

If the **Test Archiver** fails, contact Hologic Technical Support.

Username or password is incorrect

To change the start or duration of the daily archive, a user with System Administrator rights in Windows enters a username and password.

If the username or password is incorrect, the Image Management Server displays an error message.

If you have System Administrator rights, attempt the password and user name again.

If you do not have System Administrator rights, contact your site IT support.

Other Messages

There are several activities that should be performed by Field Service personnel trained by Hologic, such as setting up or changing an archive storage location or the storage location for the Slides Root Folder. For some of these activities, dialog boxes will pop up on the Genius IMS dashboard to alert the Field Service personnel of the success or failure of the activity.

6. Service Information

Chapter Six

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™ IMS 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.

6 SERVICE INFORMATION

This page intentionally left blank.

7. Ordering Information

7. Ordering Information

Chapter Seven

Ordering 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.

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™ IMS 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.

7 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.

Table 7.1 Orderable Items, Image Management Server Dashboard

Item	Description	Quantity	Part Number
Image Management Server Dashboard User's Manual	Additional user's manual	ea.	MAN-12120-001

Index

Index

A

C

D

INDEX

G

H

I

L

M

N

O

R

S

T

W

HOLOGIC®

Genius™ Image Management Server Dashboard

User's Manual

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
+1-508-263-2900

www.hologic.com

Patent Information
www.hologic.com/patent-information

MAN-12120-001 Rev. 001
Issue date: 5-2025