

HOLOGIC®



Genius™ Review Station

Operator's Manual

genius™
REVIEW STATION

Genius™ Review Station Operator's Manual

HOLOGIC®



Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
Tel: 1-800-442-9892
1-508-263-2900
Fax: 1-508-229-2795
Web: www.hologic.com

EC REP

Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium

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

The Genius™ Digital Diagnostics System is a PC-based automated imaging and review system for use with ThinPrep cervical cytology sample slides. The Genius Digital Diagnostics System is intended to help a cytotechnologist 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 cytotechnologists and pathologists trained by Hologic to evaluate ThinPrep-prepared slides.

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Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. Use of the Genius™ Review Station not in accordance with these instructions may void the warranty.

Document Number: AW-24825-001 Rev. 003

3-2023



Revision History

Revision	Date	Description
AW-24825-001 Rev. 001	8-2021	Clarify instruction use. Add instructions regarding reporting serious incidents.
AW-24825-001 Rev. 002	3-2022	Administrative change
AW-24825-001 Rev. 003	3-2023	Clarify intended purpose. Administrative changes.

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Genius™ Digital Diagnostics System



Instructions for Use

CE
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IVD

INTENDED USE/INTENDED PURPOSE

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

The Genius Digital Diagnostics System can also be used with ThinPrep® non-gynecological microscope slides and ThinPrep® UroCyte® microscope slides as an aid to the pathologist to review and interpret digital images.

The Genius Digital Diagnostics System includes the automated Genius™ Digital Imager, the Genius™ Image Management Server (IMS), and the Genius™ Review Station. The system is for the creation and viewing of digital images of scanned ThinPrep glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy. It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using this system.

Patient Population

The Genius™ Digital Diagnostics System uses gynecological specimens from women, collected during routine screening (including initial screening and referral population) and gynecological specimens collected from women with a previous cervical abnormality. Non-gynecological specimens for use on the Genius™ Digital Diagnostics System may be acquired from any patient population.

For professional use.

SUMMARY AND EXPLANATION OF THE SYSTEM

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

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

For ThinPrep® Pap test patient sample slides, the Genius Cervical AI algorithm identifies objects of interest found on the slide. The objects classified as most clinically relevant are presented in a gallery to a cytotechnologist (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. As slides are imaged by the Digital Imager and reviewed at the Review Station, the server stores, retrieves and transmits information based on the case ID.

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

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

The summary of safety and performance for this device may be found in the EUDAMED database at ec.europa.eu/tools/eudamed.

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

LIMITATIONS

- Only personnel who have been appropriately trained should operate the Genius Digital Imager or Review Station.
- The Genius Cervical AI algorithm is only indicated for use with the ThinPrep Pap test.
- The laboratory Technical Supervisor should establish individual workload limits for personnel using the Genius Digital Diagnostics System.
- ThinPrep microscope slides appropriate for the sample type must be used.
- Slides must be stained using the ThinPrep 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 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 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. They are required for proper performance of the system and cannot be substituted.

WARNINGS

- For *In Vitro* Diagnostic Use
- The Digital Imager generates, uses, and can radiate radio frequency energy and may cause interference to radio communications.
- Glass. The Digital Imager uses microscope slides, which have sharp edges. In addition, the slides may be broken in their storage packaging or on the instrument. Use caution when handling glass slides and when cleaning the instrument.
- Service Installation Only. The system must be installed by trained Hologic personnel only.

PRECAUTIONS

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

PERFORMANCE CHARACTERISTICS

OBJECTS OF INTEREST (OOI) STUDY

A laboratory study was conducted to demonstrate that the Genius Cervical AI algorithm accurately selects OOIs. An OOI is a cell or cluster of cells on a slide preparation that most likely contains clinically relevant information for diagnostic purposes. The study compared OOIs selected by the GeniusCervical AI algorithm to the same samples imaged and reviewed by CTs using the ThinPrep Imaging System (TIS-assisted review). The study evaluated the performance of the Genius Cervical AI algorithm to present images suitable for diagnosing abnormal cervical cases, for detecting the presence of common infectious organisms in a case, and for detecting the presence of endocervical component (ECC) in a normal case. The study also measured reproducibility of the Genius Digital Diagnostics System.

In the study, 260 ThinPrep slides were enrolled, made from individual residual ThinPrep Pap test specimens, covering the full range of abnormal diagnostic categories as defined in *The Bethesda System for Reporting Cervical Cytology*. The slides were imaged once on the ThinPrep Imaging System, and the same slides were imaged three times on three different Genius Digital Imagers.

Slides were reviewed by CTs using the ThinPrep Imaging System (TIS-assisted review), and, after a washout period, the same CT reviewed the nine runs of that same case on the Genius Digital Diagnostics System. In each review on the Genius Digital Diagnostics System, the CT recorded what the CT observed in every tile in the gallery for the case on the Review Station. The CT reviews were conducted per standard laboratory procedure, recording the diagnostic result, the presences or absence of endocervical component (ECC) and the presence of any infectious organisms, such as trichomonas, candida, coccobacillus, for the TIS-assisted review.

The accuracy and reproducibility of the algorithm were measured by comparison to the TIS-assisted diagnoses. The average and standard deviation across runs leading to the same diagnosis or higher was the metric used.

OOI Study: Specimen Enrollment

Table 1 shows the nominal enrollment diagnoses (base on donor lab results) for the slides in the study. In this study there was no independent truth standard, so the study did not measure absolute accuracy; the study compared TIS-assisted review with the OOs on the Genius Digital Diagnostics System.

Table 1. Slides Enrolled in the OOI Study

Category	# of slides
NILM	99
ASCUS	6
LSIL	60
ASC-H	8
AGUS	10
HSIL	60
CANCER	16

Study Results: Cervical Cytology Diagnostic Categories

The highest OOI category for any case across the nine runs of the case on the Genius Digital Diagnostics System was compared to the diagnostic category for the same slide in the TIS-assisted review. Table 2 shows the relationship between the Genius Digital Diagnostic System results and the TIS-assisted results.

Table 2. TIS-assisted Results vs. Genius Digital Diagnostic System OOs

		TIS							Total	
		UNSAT	NILM	ASCUS	LSIL	ASC-H	AGUS	HSIL		CANCER
OOI	NILM	2	83	4	0	0	2	0	0	91
	ASCUS	0	10	6	3	1	0	0	0	20
	LSIL	0	0	5	27	0	0	1	0	33
	ASC-H	0	1	5	11	2	0	7	0	26
	AGUS	0	2	0	0	0	5	1	1	9
	HSIL	0	0	2	2	2	1	49	5	61
	CANCER	0	0	0	0	1	1	6	9	17
		2	96	22	43	6	9	64	15	

The study showed an average of 6.8 OOs in tiles per case on the Genius Digital Diagnostic System matched the TIS-assisted diagnosis. The standard deviation was 1.3. These results demonstrate that the Genius Digital Diagnostic System accurately selects OOs of most interest for diagnosis. And, the results are repeatable across multiple instruments and multiple runs.

Study Results: ECC Detection on Normal Cases

Endocervical component (ECC) presence is noted during slide review to confirm adequate cellular sampling. ECC consists of either endocervical or squamous metaplastic cells. Because the Genius Digital Diagnostics cervical cancer algorithm prioritizes the presentation of abnormal cells when they are present, ECC detection was assessed in this study on the subset of slides deemed normal (NILM) by TIS-assisted review.

Table 3 shows the relationship of ECC presence on TIS-assisted versus OOI gallery review. In each case, the “+” or “-” corresponds to ECC present or absent, respectively. The count of slides in each category is shown in the table.

**Table 3. ECC Detection on Normal Cases:
Agreement between TIS-assisted Review and OOI Study Results**

ECC		TIS	
		-	+
OOI	-	4	2
	+	31	59
Agreement Rates	PPA	97%	(89%, 99%)
	NPA	11%	(5%, 26%)
Detection Rates	TIS	64%	(54%, 72%)
	OOI	94%	(89%, 99%)
	(Diff)	-30%	(-40%, -20%)

The positive and negative percent agreement (PPA and NPA) were calculated with reference to the TIS-assisted result. In addition, the detection rates and difference have also been provided. Confidence intervals for the proportions are calculated using the Newcombe score method and account for correlation between the matched pairs.

The ECC detection rate for OOI review was 94%, compared to 64% for TIS-assisted review. There were 31 NILM slides for which ECC was marked as present in the OOI gallery but not noted in TIS-assisted review. Upon further inspection of those cases, the ECC consisted of rare squamous metaplastic cells, which were not noted during the TIS-assisted review.

Infectious Organism Detection

The presence of infectious organisms is noted as part of slide review to help in the clinical assessment of the case. In this study, slides were enrolled that included three classes of organism: Trichomonas, Candida, and Coccobacilli. The tables below compare the detection of each organism on TIS-assisted review and review of OOI in the gallery of a Genius Digital Diagnostic Review Station. For each table, the positive and negative agreement rates with reference to the TIS-assisted result are provided. The overall detection rate for each organism and the difference in detection rates (TIS – OOI) are also included.

**Table 4. Trichomonas Detection:
Agreement between TIS-assisted Review and OOI Study Results**

		TRICH		TIS	
		-	+	-	+
OOI	-	246	1		
	+	2	8		
Agreement Rates	PPA	89%	(57%, 98%)		
	NPA	99%	(97%, 100%)		
Detection Rates	TIS	3.5%	(1.9%, 6.5%)		
	OOI	3.9%	(2.1%, 7.0%)		
	(Diff)	-0.4%	(-2.5%, 1.6%)		

The detection rate for Trichomonas for the Genius Digital Diagnostics System was 3.9%, compared to 3.5% for TIS-assisted review.

**Table 5. Candida Detection:
Agreement between TIS-assisted Review and OOI Study Results**

CAND		TIS	
		-	+
OOI	-	232	5
	+	3	17
Agreement Rates	PPA	77%	(57%, 90%)
	NPA	99%	(96%, 100%)
Detection Rates	TIS	8.6%	(5.7%, 12.6%)
	OOI	7.8%	(5.1%, 11.7%)
	(Diff)	0.8%	(-1.8%, 3.4%)

The detection rate for Candida for the Genius Digital Diagnostics System was 7.8%, compared to 8.6% for TIS-assisted review.

**Table 6. Coccobacilli Detection:
Agreement between TIS-assisted Review and OOI Study Results**

COCCO		TIS	
		-	+
OOI	-	203	5
	+	21	28
Agreement Rates	PPA	85%	(69%, 93%)
	NPA	91%	(86%, 94%)
Detection Rates	TIS	12.8%	(9.3%, 17.5%)
	OOI	19.1%	(14.7%, 24.3%)
	(Diff)	-6.2%	(-10.3%, -2.3%)

The detection rate for Coccobacilli for the Genius Digital Diagnostics System was 19.1%, compared to 12.8% for TIS-assisted review. Further inspection of these cases indicated that bacteria were indeed present in moderate quantities on some cells. In this study, the CTs were required to mark the type of each OOI presented, so Coccobacilli would be noted if any normal cells with bacteria overlaid were presented in the gallery. During a TIS-assisted review, and in clinical practice, bacterial infection is typically noted only when it is considered of possible clinical significance (so-called “clue” cells or a large number of infected cells). The difference in detection rates in the study is due to this difference in counting methodology and would not necessarily be reflected in clinical practice.

Overall, the presentation of infectious organisms by the algorithm is equivalent or higher than with TIS-assisted review.

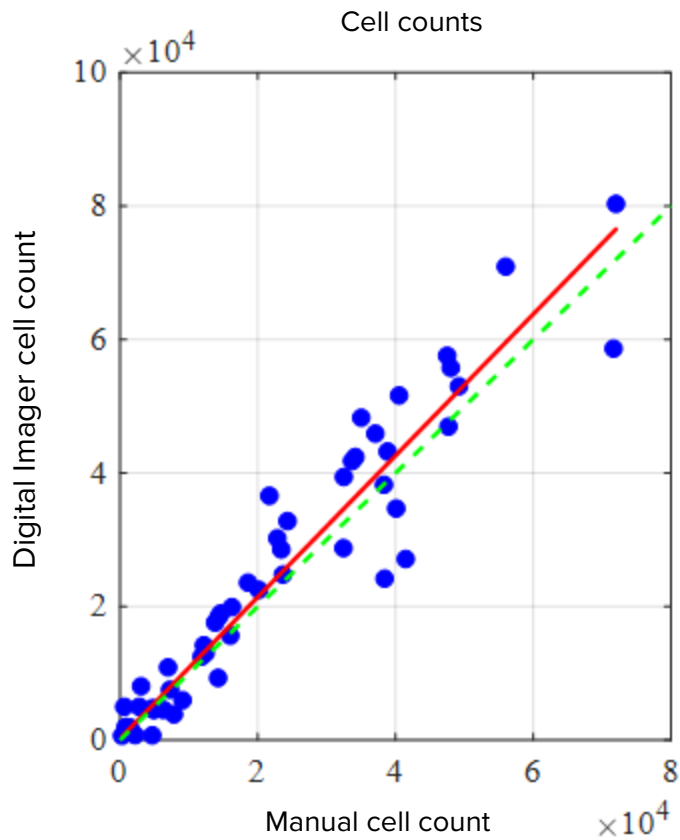
CELL COUNT STUDY

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 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 critical threshold of 5000 cells, were enrolled in the study. The slides covered a range of cellularity typical of a clinical environment. Figure 1 compares the cell counts between the Genius Cervical AI algorithm and a manual cell count method for each specimen.

Figure 1: Deming Regression
Cell Count: Digital Imager vs. Manual



The study calculated the average cell count generated by the Genius Cervical AI algorithm for each case across the three runs on each of the three Digital Imagers in the study. The intra-instrument %CV in the study was 0.6%. The inter-instrument %CV in the study was 2.7%.

The study also estimated the systematic bias of the cell count generated by the Genius Cervical AI algorithm as compared to the manual count, at a count of 5000 cells, the clinical threshold for diagnosis. In the Bethesda System¹, specimens with fewer than 5000 cells are considered unsatisfactory for screening. The count bias in the study was 528, with a 95% CI of -323 to 1379.

The results of the study demonstrate that the cell counts generated by the Genius Cervical AI algorithm are comparable to a manual cell count performed by a cytotechnologist.

GENIUS™ DIGITAL DIAGNOSTICS SYSTEM COMPARED TO MANUAL REVIEW (GENIUS CERVICAL AI CLINICAL STUDY)

A multi-center study was performed at four (4) sites within the United States. The objective of the study was to show that routine screening of ThinPrep Pap Test slides prepared on the ThinPrep® 2000 System, the ThinPrep® 5000 processor, or the ThinPrep® Genesis™ processor using the Genius Digital Diagnostics System with Genius Cervical AI is non-inferior at the ASCUS+ threshold for all categories used for cytologic diagnosis (specimen adequacy and descriptive diagnosis) as defined by the Bethesda System criteria.

The study approach allowed for a comparison of the cytologic interpretation (descriptive diagnosis and specimen adequacy) from a single ThinPrep-prepared slide (of known diagnosis), screened first using manual review and then screened with the assistance of the Genius Digital Diagnostics System. The adjudicated diagnosis for each case was used as a reference standard for truth to evaluate the results of the study.

Slides utilized in this study were processed on the ThinPrep® processors. All cases were reviewed independently. Each case in the study was screened using standard laboratory cervical cytology practices (manual review), the ThinPrep Imaging System (“TIS” review), pathologist adjudication consensus (“ADJ” review), and finally with the Genius Digital Diagnostics System. A minimum 14-day washout period occurred between each review phase. The slides were randomized prior to case review in each review phase. Cytological diagnoses and specimen adequacy were determined in accordance with the Bethesda System criteria.

Study slides prepared from a previous study were used, and additional slides were prepared specifically for this study.

Laboratory and Patient Characteristics

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

A total of 2020 cases, with 1 slide from each patient (505 cases at each site), were evaluated in this study. Each case was reviewed independently three (3) times at each site, by three (3) separate pairs of cytotechnologists and pathologists using normal laboratory and clinical procedures. Of the 2020 enrolled cases, 1995 (98.8%) cases met the requirements for inclusion in the evaluable population. Twenty-five (25) slides that were damaged, unreadable, excluded during a previous study, or processed outside the 6-week window from the collection date were excluded from all analyses. Forty-one (41) cases with UNSAT results from manual review, digital review, or adjudication were excluded from the performance analyses only. Table 7 describes the patient populations at each of the study sites.

Table 7. Clinical Study Characteristics

Site Number	Age (yrs) Median	# Hysterectomy (% of enrolled)	# Postmenopausal (% of enrolled)
1	33.0	20 (4.0)	40 (8.0)
2	36.5	6 (1.2)	25 (5.0)
3	35.0	22 (4.4)	44 (8.9)
4	37.0	7 (1.4)	42 (8.5)
Overall	35.0	55 (2.8)	151 (7.6)

Main Eligibility Criteria

Inclusion Criteria

Study slides were produced, reviewed, and adjudicated during the execution of the current study and two previous studies. The ThinPrep Pap Test slides from four sites included the following enrollment diagnoses:

- NILM: 266 cases
- ASC-US: 56 cases
- LSIL: 56 cases
- ASC-H: 56 cases
- AGUS: 5 cases
- HSIL: 56 cases
- Cancers: 5 cases
- UNSAT: 5 cases

Exclusion Criteria

Slides that were broken or rendered unreadable for the purposes of this study were excluded from the study.

Criteria for Evaluation

The primary objective of this study was to estimate the sensitivity and specificity when diagnosing cases imaged and reviewed on the Genius Digital Diagnostics System compared with manual review at the ASCUS+ threshold. The reference standard for the cases in this study was pathologist adjudication consensus diagnosis.

Descriptive Diagnosis Sensitivity and Specificity Estimates

Abbreviations for Diagnostic Thresholds:

Threshold	Category Partitions	
	Negative	Positive
ASCUS+	NILM	ASCUS, AGUS, LSIL, ASC-H, HSIL, Cancer
LSIL+	NILM, ASCUS, AGUS	LSIL, ASC-H, HSIL, Cancer
ASC-H+	NILM, ASCUS, AGUS, LSIL	ASC-H, HSIL, Cancer
HSIL+	NILM, ASCUS, AGUS, LSIL, ASC-H	HSIL, Cancer

The study results are presented in Table 8. In all abnormal categories, the sensitivity and specificity for the Genius Digital Diagnostics System were non-inferior to that of manual review. Superiority for the Genius Digital Diagnostics System as compared to manual review was also evident at the LSIL+, ASC-H+, and HSIL+ diagnostic thresholds for sensitivity.

Table 8. Adjudicated Review vs. Manual Review and Genius Digital Diagnostics System Review, Descriptive Diagnosis Summary (All Cases)

Diagnostic Threshold	Sensitivity %			Specificity %		
	Manual (95% CI)	Genius (95% CI)	Difference (95% CI)	Manual (95% CI)	Genius (95% CI)	Difference (95% CI)
ASCUS+	76.8 (75.8, 77.6%)	76.3 (75.1, 77.6)	0.50 (-0.87, 1.87)	93.0 (92.2, 93.7)	90.1 (89.1, 91.2)	2.83 (1.76, 3.89)
LSIL+	78.8 (77.8, 79.9)	80.9 (79.2, 82.6)	-2.04 (-3.39, -0.69)	95.3 (95.1, 95.5)	91.9 (91.2, 92.6)	3.38 (2.74, 4.03)
ASC-H+	79.1 (77.5, 80.6)	83.7 (82.6, 84.8)	-4.58 (-6.51, -2.65)	96.0 (95.7, 96.3)	92.3 (91.7, 92.8)	3.73 (3.06, 4.41)
HSIL+	72.7 (70.8, 74.5)	78.4 (76.2, 80.6)	-5.69 (-8.51, -2.88)	97.4 (97.1, 97.7)	94.7 (94.0, 95.4)	2.69 (2.04, 3.35)

There was a decrease in false negative HSIL+ diagnoses for the Genius Digital Diagnostic System as compared to manual review. The agreement of HSIL+ diagnoses for manual review with adjudicated review is 72.7%, or a false negative rate of 27.3%. The agreement of HSIL+ cases on the Genius Digital Diagnostics System with adjudicated review is 78.4%, or a false negative rate of 21.6%. This represents a 20.9% reduction in false negative diagnoses for HSIL+.

The study also compared the performance of the Genius Digital Diagnostic System with ThinPrep slides reviewed on the ThinPrep Imaging System (TIS). The results for the Genius Digital Diagnostics System versus TIS review are presented in Table 9.

**Table 9. Adjudicated Review vs.
TIS Review and Genius Digital Diagnostics System Review (Genius),
Descriptive Diagnosis Summary (All Cases)**

Diagnostic Threshold	Sensitivity %			Specificity %		
	TIS (95% CI)	Genius (95% CI)	Difference (95% CI)	TIS (95% CI)	Genius (95% CI)	Difference (95% CI)
ASCUS+	76.1 (75.0, 77.2%)	76.4 (75.1, 77.6)	-0.24 (-1.18, 0.69)	91.9 (91.2, 92.5)	90.1 (89.1, 91.2)	1.77 (0.83, 2.71)
LSIL+	80.9 (79.7, 82.0)	80.9 (79.2, 82.6)	-0.05 (-1.67, 1.57)	94.2 (93.7, 94.6)	91.9 (91.2, 92.6)	2.27 (1.74, 2.80)
ASC-H+	82.2 (80.8, 83.6)	83.8 (82.8, 84.9)	-1.63 (-3.46, 0.20)	95.0 (94.7, 95.4)	92.3 (91.7, 92.8)	2.75 (2.18, 3.32)
HSIL+	76.9 (74.9, 78.9)	78.5 (76.3, 80.7)	-1.62 (-4.57, 1.33)	96.9 (96.6, 97.1)	94.7 (94.0, 95.4)	2.17 (1.56, 2.79)

Table 10 through Table 17 show the performance of Genius Digital Diagnostics System review and manual review for the following major descriptive diagnosis classifications of the Bethesda System: NILM, ASCUS, LSIL, ASC-H, AGUS, HSIL, Cancer, and UNSAT, as determined by the adjudication panel.

**Table 10. “True Negative” (NILM) Contingency Table (for all Sites Combined)
Overall Adjudicated NILM
Genius Digital Diagnostics System vs. Manual Review**

		Manual							
		UNSAT	NILM	ASCUS	AGUS	LSIL	ASC-H	HSIL	Cancer
Genius	UNSAT	8	16	0	0	0	0	0	0
	NILM	7	2881	59	10	3	13	0	3
	ASCUS	0	94	24	1	1	1	2	0
	AGUS	0	18	2	0	0	0	1	0
	LSIL	0	16	17	0	15	1	0	0
	ASC-H	1	34	16	0	2	11	5	0
	HSIL	1	16	13	0	3	10	10	0
	Cancer	0	3	1	3	0	1	0	4

**Table 11. “True ASCUS” Contingency Table (for all Sites Combined)
Overall Adjudicated ASCUS
Genius Digital Diagnostics System vs. Manual Review**

		Manual							
		UNSAT	NILM	ASCUS	AGUS	LSIL	ASC-H	HSIL	Cancer
Genius	UNSAT	2	2	0	0	0	0	0	0
	NILM	1	346	62	1	8	9	2	0
	ASCUS	0	52	52	0	15	4	1	0
	AGUS	1	2	0	0	0	0	0	0
	LSIL	0	14	32	0	22	1	0	0
	ASC-H	0	8	12	1	6	7	0	0
	HSIL	0	6	8	0	7	3	7	0
	Cancer	0	0	1	0	0	0	1	0

**Table 12. “True AGUS” Contingency Table (for all Sites Combined)
Overall Adjudicated AGUS
Genius Digital Diagnostics System vs. Manual Review**

		Manual							
		UNSAT	NILM	ASCUS	AGUS	LSIL	ASC-H	HSIL	Cancer
Genius	UNSAT	1	2	0	0	0	0	0	0
	NILM	0	16	2	0	0	2	1	0
	ASCUS	0	1	1	0	0	0	1	0
	AGUS	0	0	0	0	0	1	0	3
	LSIL	0	0	2	0	0	0	0	0
	ASC-H	0	0	0	0	0	0	0	0
	HSIL	0	2	0	0	1	0	1	0
	Cancer	0	0	0	2	0	0	0	0

**Table 13. “True LSIL” Contingency Table (for all Sites Combined)
Overall Adjudicated LSIL
Genius Digital Diagnostics System vs. Manual Review**

		Manual							
		UNSAT	NILM	ASCUS	AGUS	LSIL	ASC-H	HSIL	Cancer
Genius	UNSAT	0	0	0	0	0	0	0	0
	NILM	0	31	31	0	15	0	1	0
	ASCUS	0	21	56	0	58	4	0	0
	AGUS	0	0	0	0	0	0	0	0
	LSIL	0	23	56	0	360	2	7	0
	ASC-H	0	2	10	0	21	10	4	0
	HSIL	0	1	12	0	49	11	45	1
	Cancer	0	0	0	0	1	0	1	1

**Table 14. “True ASC-H” Contingency Table (for all Sites Combined)
Overall Adjudicated ASC-H
Genius Digital Diagnostics System vs. Manual Review**

		Manual							
		UNSAT	NILM	ASCUS	AGUS	LSIL	ASC-H	HSIL	Cancer
Genius	UNSAT	0	0	1	0	0	0	0	0
	NILM	1	27	4	0	0	5	4	0
	ASCUS	0	1	1	0	1	3	2	0
	AGUS	0	1	1	0	0	1	0	0
	LSIL	0	1	1	0	3	0	0	0
	ASC-H	0	5	9	1	3	10	3	0
	HSIL	1	4	7	2	1	4	14	0
	Cancer	0	0	0	1	1	0	1	4

**Table 15. “True HSIL” Contingency Table (for all Sites Combined)
Overall Adjudicated HSIL
Genius Digital Diagnostics System vs. Manual Review**

		Manual							
		UNSAT	NILM	ASCUS	AGUS	LSIL	ASC-H	HSIL	Cancer
Genius	UNSAT	0	0	1	0	0	0	0	0
	NILM	0	8	1	2	0	7	14	1
	ASCUS	0	2	3	1	1	5	14	0
	AGUS	0	1	2	1	0	3	4	0
	LSIL	0	0	0	0	18	1	6	0
	ASC-H	0	2	8	0	10	17	37	4
	HSIL	0	11	19	7	25	66	396	25
	Cancer	0	1	3	0	0	1	17	8

**Table 16. “True Cancer” Contingency Table (for all Sites Combined)
Overall Adjudicated Cancer
Genius Digital Diagnostics System vs. Manual Review**

		Manual							
		UNSAT	NILM	ASCUS	AGUS	LSIL	ASC-H	HSIL	Cancer
Genius	UNSAT	0	0	0	0	0	0	0	0
	NILM	0	0	0	0	0	0	0	3
	ASCUS	0	0	0	0	0	0	0	0
	AGUS	0	1	0	1	0	0	1	4
	LSIL	0	0	0	0	0	0	0	0
	ASC-H	0	0	1	0	1	1	0	0
	HSIL	0	0	0	0	0	2	16	1
	Cancer	0	0	0	1	0	1	5	69

**Table 17. “True UNSAT” Contingency Table (for all Sites Combined)
Overall Adjudicated UNSAT
Genius Digital Diagnostics System vs. Manual Review**

		Manual							
		UNSAT	NILM	ASCUS	AGUS	LSIL	ASC-H	HSIL	Cancer
Genius	UNSAT	42	14	0	0	0	0	0	0
	NILM	7	25	1	0	0	0	0	0
	ASCUS	2	1	0	0	0	0	0	0
	AGUS	0	0	0	0	0	0	2	0
	LSIL	0	0	0	0	0	0	0	0
	ASC-H	1	0	1	0	0	1	0	0
	HSIL	0	0	0	0	0	0	1	0
	Cancer	0	1	0	0	0	0	0	0

Table 18 shows the performance of Genius Digital Diagnostics System review and manual review compared to adjudicated diagnostic threshold made by the adjudication panel for the following major descriptive diagnostic thresholds: ASCUS+, LSIL+, ASC-H+, and HSIL+.

**Table 18. Contingency Table (for all Sites Combined)
Overall Adjudicated vs. Manual Review and Genius Digital Diagnostics System**

Overall Adjudication		Manual Review		Genius Review	
Diagnostic Threshold		Positive	Negative	Positive	Negative
ASCUS+	Positive	1956	232	1943	325
	Negative	590	3062	603	2969
LSIL+	Positive	1435	189	1472	325
	Negative	385	3831	348	3695
ASC-H+	Positive	780	193	825	374
	Negative	206	4661	161	4480
HSIL+	Positive	625	130	674	264
	Negative	235	4850	186	4716

Table 19 shows the descriptive diagnosis marginal frequencies for benign cellular changes and other non-neoplastic findings for all sites combined. Each slide was read by a CT/pathologist pair three times. Each slide was read first by a cytotechnologist and then by a pathologist.

**Table 19. Unadjudicated Marginal Frequencies –
Summary of Descriptive Diagnosis for Benign Cellular Changes (for all Sites Combined)**

	Manual Review		Genius Review	
Number of Slides	5985		5985	
Descriptive Diagnosis	N	%	N	%
Benign Cellular Changes	721	12.0%	1035	17.3%
Organisms:				
<i>Trichomonas vaginalis</i>	71	1.2%	103	1.7%
Fungal organisms consistent with <i>Candida</i> spp.	261	4.4%	312	5.2%
Shift in flora s/o bacterial vaginosis	371	6.2%	562	9.4%
Bacteria consistent with <i>Actinomyces</i> spp.	16	0.3%	54	0.9%

Cellular changes consistent with Herpes virus	2	0.0%	3	0.1%
Other infection	0	0.0%	1	0.0%
Other Non-Neoplastic Findings	451	7.5%	522	8.7%
Reactive cellular changes associated with inflammation	229	3.8%	280	4.7%
Atrophy	199	3.3%	206	3.4%
Reactive cellular changes associated with radiation	1	0.0%	0	0.0%
Reactive cellular changes associated with IUD	0	0.0%	0	0.0%
Glandular cells status post hysterectomy	1	0.0%	2	0.0%
Endometrial cells in a woman ≥45 yrs of age	21	0.4%	34	0.6%

The Genius Digital Diagnostics System showed a slightly higher rate of detection of infectious organisms (17.3% vs 12.0%) and other non-neoplastic findings (8.7% vs 7.5%) than Manual review; the differences in the detection of infectious organisms and non-neoplastic findings were statistically significant (P-value <0.001).

Cytotechnologist Review Rates in the Clinical Study

As part of the clinical study, the amount of time each CT spent reviewing each case was recorded. The median amount of time per case as well as the minimum time and the maximum time are shown in Table 20. In the study, the review time started when the CT clicked on the accession ID until the CT clicked the Complete Review button.

Table 20. CT Review Rates, Time per Case Genius Cervical AI Clinical Study

Site	Reviewer	Median Review Time per Case (minutes:seconds)	Minimum Review Time per Case (minutes:seconds)	Maximum Review Time per Case (hours:minutes:seconds)*
Site 1	CT-1	01:59	00:37	10:27
	CT-2	01:03	00:12	42:57
	CT-3	00:46	00:06	27:18
Site 2	CT-1	01:14	00:15	1:10:36
	CT-2	01:46	00:18	29:28
	CT-3	01:39	00:06	32:15
Site 3	CT-1	00:28	00:07	26:25
	CT-2	01:28	00:22	14:55
	CT-3	01:32	00:24	13:31
Site 4	CT-1	01:25	00:20	16:09
	CT-2	01:58	00:29	10:41
	CT-3	01:15	00:32	26:38
Combined		01:20	00:06	1:10:36

*CT activity was not specifically monitored in the clinical setting. Review times are case-open through case-close time stamps and may include time away from the Review Station.

Conclusion

The sensitivity and specificity of the Genius Digital Diagnostics System for review of slides processed on ThinPrep systems are non-inferior to the sensitivity and specificity of the manual review of the same slides. The sensitivity of the Genius Digital Diagnostics System is superior to the sensitivity of the manual review for the detection of abnormal cells at the LSIL+, ASC-H+, and HSIL+ diagnostic thresholds.

CYTOTECHNOLOGIST SCREENING TIME STUDY (INTERNAL STUDY)

Hologic conducted an internal study to characterize screening volumes for cytotechnologists (CTs) on the Genius Digital Diagnostics System when presented with gynecological clinical specimens of varying diagnoses. The study also intended to characterize the accuracy of screening for these cytotechnologists based on the adjudicated result of manual review of these slides.

Seventeen-hundred, forty-four (1744) slides produced from clinical specimens were available for review by CTs using the Genius Review Station in this study. Slides were imaged using two Genius Digital Imagers. Ten cytotechnologists each reviewed the resulting case images over the course of five days, working up to 8 hours per day. Case images were introduced to the cytotechnologists in a pre-randomized order throughout the 5-day work schedule. All ten cytotechnologists shared the same case randomization order. Diagnostic results were recorded into an electronic Case Report Form (CRF), and CT review times were captured by the Genius Digital Diagnostics System software for use in assessing screening volume.

This study demonstrated that CT review rates of approximately 1 minute per case are achieved when screening with the Genius Digital Diagnostics System and that screening rates did not have any effect on diagnostic accuracy.

Results of this study are presented in Table 21 through Table 23.

Table 21 shows the time spent by each of the CTs in the internal study reviewing each of the cases in the study. The median amount of time per case as well as the minimum and maximum CT review times are shown. The listed CT review times reflect the time between opening and closing of the case as recorded on the Genius Review Stations. Per the instructions of the study, this includes the time to record the diagnosis in an electronic Case Report Form.

**Table 21. CT Review Rates, Time Per Case
Internal Study**

Reviewer	Median Review Time per Case (minutes:seconds)	Minimum Review Time per Case (minutes:seconds)	Maximum Review Time per Case (minutes:seconds)
CT-1	01:03	00:17	07:04
CT-2	01:03	00:16	06:44
CT-3	01:02	00:19	05:41
CT-4	00:56	00:18	07:27
CT-5	00:51	00:28	04:42
CT-6	00:56	00:11	10:29
CT-7	01:02	00:18	05:16
CT-8	00:47	00:06	13:32
CT-9	00:51	00:09	14:14
CT-10	00:44	00:13	07:21
Combined	00:55	00:06	14:14

Diagnostic results were collected from each cytotechnologist’s completed CT Review Record. Diagnostic results were applied to three clinically relevant thresholds of ASCUS+/-, LSIL+/-, or ASC-H+/-, according to the Bethesda System. Table 22 presents the sensitivity and specificity results for each CT compared to adjudicated “truth” with respect to each of the thresholds. Diagnostic “truth” is defined according to the adjudicated results obtained in the Genius Cervical AI Clinical Study.

**Table 22. Sensitivity and Specificity Summary for all CTs vs. Clinical Thresholds
(internal study)**

CT	Median Review Time per Case (minutes:seconds)	Sensitivity			Specificity		
		ASCUS +/-	LSIL +/-	ASC-H +/-	ASCUS +/-	LSIL +/-	ASC-H +/-
CT-1	01:03	77.0%	81.0%	80.1%	92.5%	92.6%	93.2%
CT-2	01:03	79.0%	86.0%	85.1%	89.9%	87.6%	90.8%
CT-3	01:02	83.5%	84.2%	88.1%	88.4%	89.9%	91.2%
CT-4	00:56	78.8%	85.8%	92.3%	90.1%	88.6%	87.2%
CT-5	00:51	52.2%	49.7%	33.8%	97.6%	97.7%	98.9%
CT-6	00:56	80.1%	85.7%	88.1%	88.7%	88.1%	87.7%
CT-7	01:02	67.4%	75.1%	77.9%	94.1%	93.8%	94.7%
CT-8	00:47	80.4%	86.4%	86.4%	88.9%	89.9%	91.1%
CT-9	00:51	78.2%	82.1%	83.5%	88.2%	87.2%	89.7%
CT-10	00:44	64.0%	72.3%	71.5%	94.7%	93.6%	95.0%

Note: Slides which were deemed unsatisfactory for review by either the CT or the adjudication results were not included in the sensitivity and specificity results in this table.

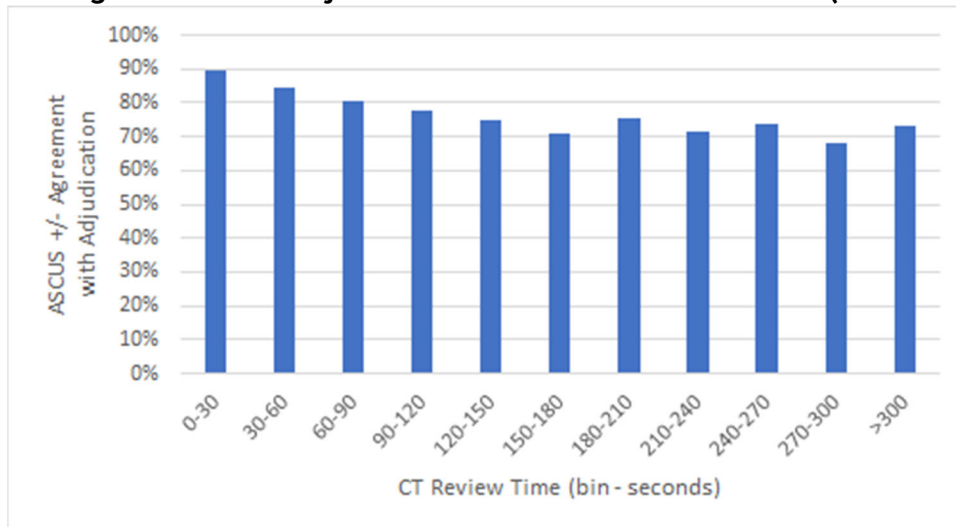
Figure 2 shows a graphical representation of the relationship between median case review time and diagnostic performance at the ASCUS +/- threshold.

Figure 2. CT Case Review Time vs. Sensitivity / Specificity (internal study)



Figure 3 shows the diagnostic agreement with adjudicated truth at the ASCUS +/- threshold as a function of individual CT case review times across all CTs in this study.

Figure 3. Agreement with Adjudicated “Truth” vs. CT Review Time (internal study)



The adequacy results for the cases in the study for all ten CTs were compared to the adjudicated adequacy results. Table 23 presents the results of the comparison.

Table 23. Case Adequacy Contingency Table – Results from all 10 CTs Combined (internal study)

		Adjudicated Result	
		Satisfactory	Unsatisfactory
Genius Digital Diagnostics System Result	Satisfactory	15772	113
	Unsatisfactory	105	81

The results show a 98.6% agreement across all results between the Genius Digital Diagnostics System adequacy reviews versus adjudicated adequacy results, and unsatisfactory rates of 1.2% for both the Genius Digital Diagnostics System and adjudicated results.

This study showed that the CT review rates for Genius Digital Diagnostics System case image review are higher than rates achieved with other review methods, such as manual review or review using the ThinPrep Imaging System (TIS).

CTs showed median case review rates of approximately 1 minute per case (minimum of 44 seconds and maximum of 63 seconds per case).

The study rates are expected to be an underestimation of real-world review rates, as the clinical population in this study was highly challenging (approximately 50% abnormal rate). Analysis of per-case review times showed that reviews were longer for abnormal (ASCUS+) compared to normal (ASCUS-) cases with 1:09 (one minute, nine seconds) and 0:46 (forty-six seconds) median review times, respectively.

Specimen adequacy results showed a high agreement rate between the adjudicated adequacy results and the Genius Digital Diagnostics System adequacy results for each CT and all CTs combined (98.6% agreement). Unsatisfactory rates were also at expected levels (approximately 1.2% overall) between adjudicated and Genius Digital Diagnostics System review results.

CYTOTECHNOLOGIST SCREENING RATES: WORKLOAD GUIDANCE

Workload is defined by CLIA as a maximum of 100 cases in no less than an 8-hour workday. This refers to a full manual review of 100 cases. In the Genius Cervical AI clinical study and in the internal CT screening time study, CTs accurately diagnosed cases using digital images presented by the system more efficiently than with a full manual review of a case.

Figure 4 compares the median CT review rates from both the clinical study and the internal study to the sensitivity of diagnostic agreement with adjudicated truth at the ASCUS+/- threshold.

Figure 4. CT Case Review Time vs. Sensitivity (Clinical Study and Internal Study)

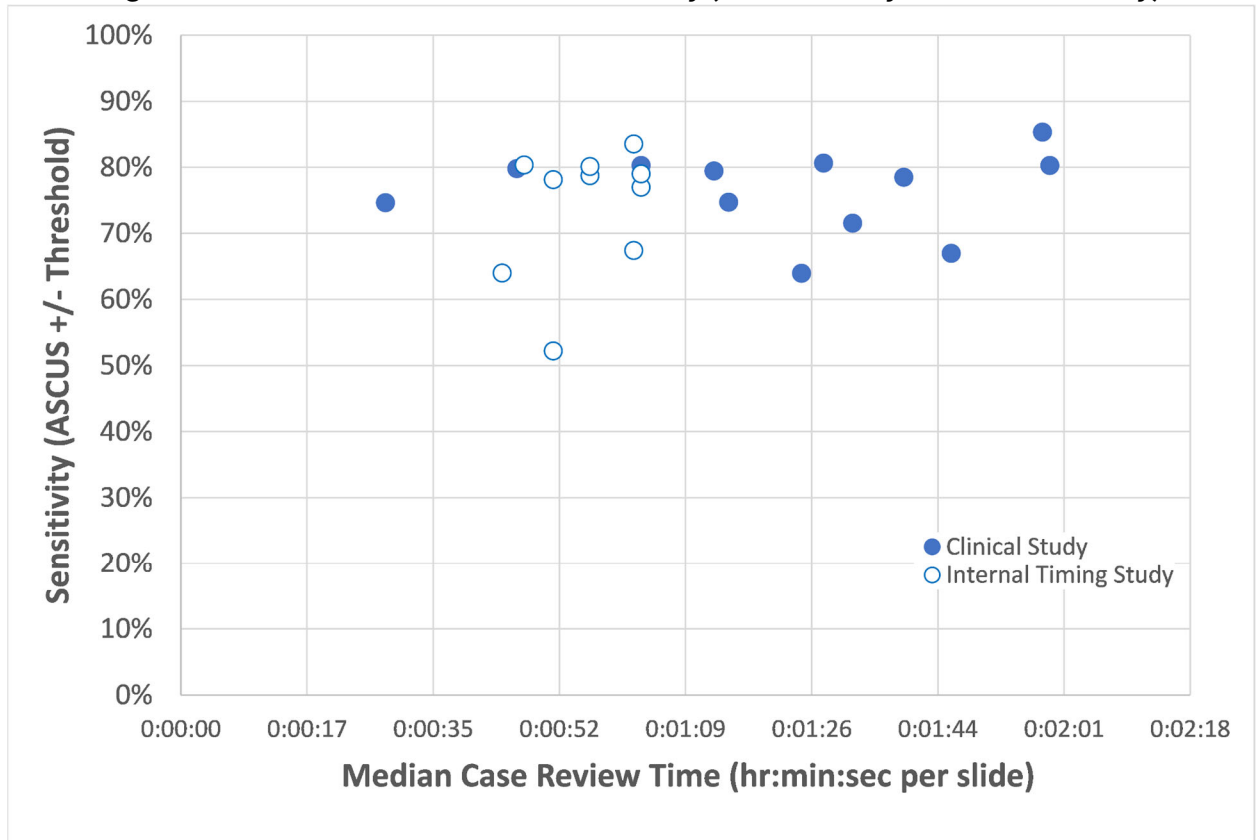
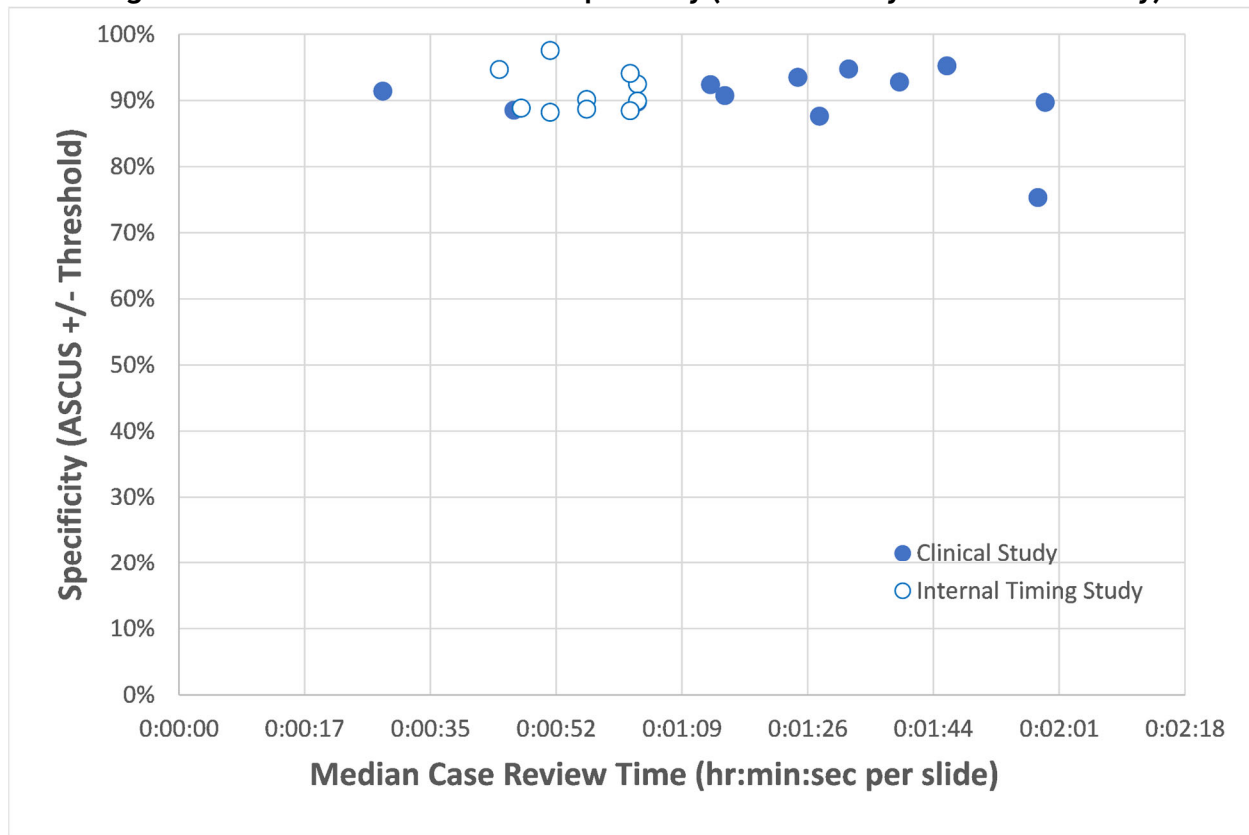


Figure 5 compares the median CT review rates from both the clinical study and the internal study to the specificity of diagnostic agreement with adjudicated truth at the ASCUS+/- threshold.

Figure 5. CT Case Review Time vs. Specificity (Clinical Study and Internal Study)



In both studies, the amount of time spent by the CT to review a case on the Genius Digital Diagnostics System did not change the rate of agreement with the adjudicated diagnostic result at the ASCUS +/- threshold.

A “slide equivalent” factor was calculated from the review rates by CTs in the clinical study (Table 20) and in the internal CT screening time study (Table 22).

The CLIA limit of 100 cases per day with Full Manual Review (FMR) is equivalent to 4.8 minutes/slide in an 8-hour day.

In the case review data collected from the studies with the Genius Digital Diagnostics System, the median rate of review for each CT ranged from 28 seconds (0.5 minute) to 1 minute, 59 seconds (2 minutes). Based on the case review data collected in the studies, the observed median rate of review was 1 minute, 20 seconds (1.33 minutes) per slide in the clinical study and 55 seconds (0.92 minutes) per slide in the internal study.

Taken together, the CT review rate can be assumed to be approximately 1.2 minutes per slide, or one-quarter of the time required for full manual review (FMR) using a microscope. A resulting “slide equivalent” recommendation for case review with the Genius Digital Diagnostics System is therefore:

1 Genius Digital Diagnostics System Case = 0.25 CLIA Slide Equivalent

An example of the workload for reviewing ThinPrep Pap tests with the Genius Digital Diagnostic System:

200 Genius Digital Case Reviews = 50 slides
(200 x 0.25 = 50)

Total number of slides screened: 50

Note: ALL laboratories should have a clear standard operating procedure for documentation of their method of workload counting and for establishing workload limits.

It is the responsibility of the Technical Supervisor to evaluate and set workload limits for individual cytotechnologists based on laboratory clinical performance. According to CLIA '88, these workload limits should be reassessed every six months.

NON-GYNECOLOGICAL SPECIMEN STUDY

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

Four hundred (400) ThinPrep slides, including a range of non-gynecological specimen types, were enrolled in the study. The study included the following types of specimens: anal Pap, fluids, FNA, respiratory/mucoid, and urine. The specimens were a mix of normal, abnormal, and non-diagnostic cases, according to their donor lab results. The slides were evaluated using a manual microscope as a control. The slides were imaged on a Genius Digital Imager. After a two-week washout period to minimize recognition bias, the case images were evaluated using the Genius Review Station.

Non-gynecological Study Results

Table 24 provides the overall results of the diagnostic screening of the specimens.

Table 24. Matched-Pair Diagnostic Categories, Non-Gynecological Specimens

		Manual		
		Abnormal	Normal	Non-Diagnostic
Genius	Abnormal	147	23	0
	Normal	11	196	8
	Non-Diagnostic	0	0	14

Further analysis of the study data was performed to compare the diagnoses from the Genius case review versus the manual review of the glass slides for slides where a diagnosis was possible. The results are presented in Table 25.

Table 25. Proportions of Diagnoses of Abnormal Cases, Non-Gynecological Specimens

	Proportion	95% confidence interval
Manual Review	0.419	[0.370 , 0.470]
Genius Digital Review	0.451	[0.401 , 0.501]
Difference, Genius - Manual	0.032	[-0.004 , 0.062]

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

CONCLUSIONS

The data from the studies conducted on the Genius Digital Diagnostics System demonstrate that the Genius Digital Diagnostics System, when used with the Genius Cervical AI algorithm, is 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, including adenocarcinoma, as defined by *The Bethesda System for Reporting Cervical Cytology*¹.

The data from the studies conducted on the Genius Digital Diagnostics System showed greater sensitivity with the Genius Digital Diagnostics System with the Genius Cervical AI algorithm than with manual review in cases with a diagnosis of HSIL+ and more severe lesions. The increase in sensitivity for HSIL+ cases is 5.7% for all sites combined. The data showed a reduction of 20% in false negatives in cases with a diagnosis of HSIL+ and more severe lesions.

The data from the studies conducted on the Genius Digital Diagnostics System showed that screening time is reduced without adversely affecting diagnostic accuracy, contributing to a workload limit recommendation of 400 cases in no less than an 8-hour workday.

The data from internal studies demonstrate that the Genius Digital Diagnostics System provides images that may be reliably reviewed for diagnostic evaluation of non-gynecological cytology specimens.

MATERIALS REQUIRED

MATERIALS PROVIDED

- Genius Digital Imager
 - Digital Imager
 - Digital Imager computer
 - Slide carriers
- Genius Review Station
 - Monitor
 - Review Station computer*
- Genius Image Management Server
 - Server*
 - Network switch

*In some configurations of the system, the laboratory may supply the Review Station computer into which Hologic installs a Hologic-supplied graphics card. In some configurations of the system, a laboratory may supply the server hardware.

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, contact Hologic:

Telephone: 1-800-442-9892

Fax: 1-508-229-2795

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

Email: info@hologic.com

REVISION HISTORY

Revision	Date	Description
AW-24823-001 Rev. 001	8-2021	Replace CE mark. Add clinical study data. Add instructions regarding reporting serious incidents.
AW-24823-001 Rev. 002	3-2023	Clarify intended purpose.



Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
1-800-442-9892
www.hologic.com



Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium

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Table of Contents

Table of Contents

Table of Contents

Chapter One

Introduction

SECTION A: Overview	1.1
SECTION B: The Genius Digital Diagnostics System Process for Cervical Cancer Screening	1.4
SECTION C: The Genius Digital Diagnostics System Process for Non-Gyn and UroCyte Specimens	1.6
SECTION D: Specimen Preparation.....	1.8
SECTION E: Review Station Technical Specifications	1.9
SECTION F: Internal Quality Control.....	1.13
SECTION G: Genius Review Station Hazards	1.14
SECTION H: Disposal	1.19

Chapter Two

Installation

SECTION A: General.....	2.1
SECTION B: Action Upon Delivery	2.1
SECTION C: Preparation Prior to Installation	2.2
SECTION D: Moving the Review Station	2.4
SECTION E: Connecting Review Station Components.....	2.5
SECTION F: Power On the Review Station	2.6
SECTION G: Storage and Handling - Post Installation.....	2.12
SECTION H: System Shutdown	2.13

Chapter Three

User Interface

SECTION A: Overview	3.1
----------------------------------	-----

SECTION B: Log In.....	3.3
SECTION C: Display Overview	3.7
SECTION D: Settings.....	3.12
SECTION E: Customize the view	3.26
SECTION F: Bookmarks	3.42
SECTION G: Reports.....	3.43

Chapter Four

Operation

SECTION A: Overview	4.1
SECTION B: Materials Required Prior to Operation	4.4
SECTION C: Review a Case.....	4.5

Chapter Five

Maintenance

SECTION A: General Cleaning.....	5.1
---	-----

Chapter Six

Troubleshooting

SECTION A: No connection to Image Management Server...	6.1
SECTION B: Digital Imager Information Viewed from the Review Station.....	6.2

Chapter Seven

Service Information	7.1
----------------------------------	-----

Chapter Eight

Ordering Information	8.1
-----------------------------------	-----

Index

Chapter One

Introduction

SECTION A

OVERVIEW

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

The Review Station is to be used by a cytotechnologist (CT) and a pathologist to screen ThinPrep™ microscope slides that have been imaged on a Genius™ Digital Imager. Digital images of a slide's cell spot area are available for a CT or pathologist to review on the Review Station monitor, rather than using a microscope to review a glass slide. The Genius Digital Diagnostics System is a version of ThinPrep™ Imaging System.

For gynecological samples:

- For cervical cancer screening of gynecological samples prepared on ThinPrep Imaging System slides, an artificial intelligence image analysis algorithm within the product identifies Objects of Interest (OOIs) and presents a gallery of these images to aid a CT or pathologist in quickly and accurately reviewing the slide.
- The CT or pathologist views the gallery by selecting the case ID from a list. A set of high-resolution images from the slide's cells spot is presented in the gallery. The image of the entire cell spot is also available.

For non-gynecological (Non-gyn) samples and UroCyte samples

- The CT or pathologist views an image of a ThinPrep slide by selecting the case ID from a list. A high-resolution image of the slide's cell spot is presented.

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

The Review Station consists of:

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

1

INTRODUCTION

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



Figure 1-1 Genius Review Station

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

Intended Use/Intended Purpose

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

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

The Genius Digital Diagnostics System can also be used with ThinPrep™ non-gynecological microscope slides and ThinPrep™ UroCyt™ microscope slides as an aid to the pathologist to review and interpret digital images.

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

Patient population

The Genius Digital Diagnostics System uses gynecological specimens from women, collected during routine screening (including initial screening and referral population) and gynecological specimens collected from women with a previous cervical abnormality. Non-gynecological specimens for use on the Genius Digital Diagnostics System may be acquired from any patient population.

For professional use.

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

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

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

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

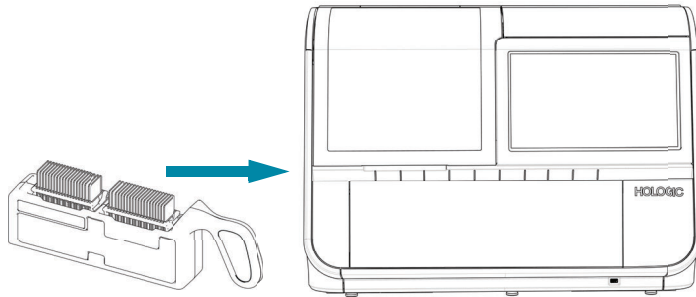
For ThinPrep™ Pap test patient sample slides, the system identifies objects of interest found on the slide. The objects classified as most clinically relevant are presented in a gallery to a cytotechnologist (CT) or pathologist for review in a gallery of images. The slide image data, the slide ID and 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. As slides are imaged by the Digital Imager and reviewed at the Review Station, the server stores, retrieves and transmits information based on the case ID.

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

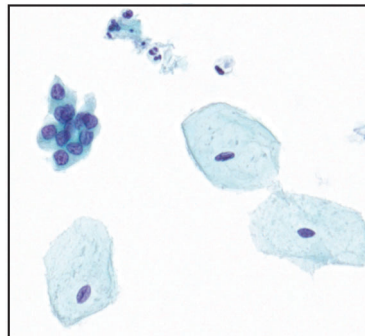
When any image is being reviewed, the CT or pathologist has the option to electronically mark objects of interest and include the marks in the slide review. The reviewer always has the option to move and zoom through a view of the whole slide image, which provides complete freedom to move any portion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

Genius Digital Diagnostics System Process, Gyn Cases



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

The cell spot is imaged.



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

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

Case review by the cytotechnologist or pathologist



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

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

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



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

Figure 1-2 Genius Digital Diagnostics System Process, Gyn Cases

**SECTION
C****THE GENIUS DIGITAL DIAGNOSTICS SYSTEM PROCESS FOR NON-GYN
AND UROCYTE SPECIMENS**

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

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

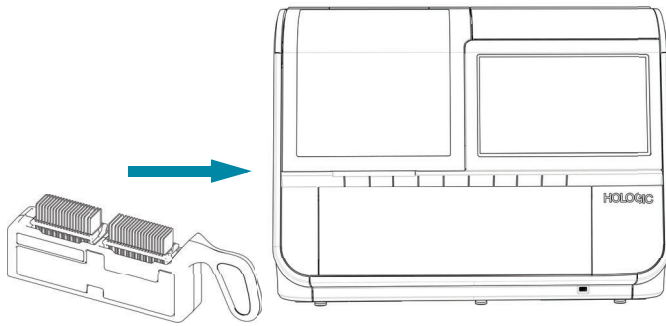
The slide image data, the slide ID and its associated data record are transmitted to the Image Management Server, and the slide is returned to its slide carrier.

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

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

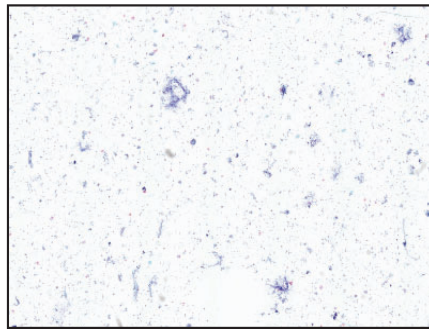
The CT or pathologist has the option to electronically mark objects of interest and include the marks in the case review. The reviewer always has the option to move and zoom through a view of the whole slide image, which provides complete freedom to move any portion of the cell spot into the field of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

**Genius Digital Diagnostics System Process,
Non-Gyn Cases or UroCyte Cases**



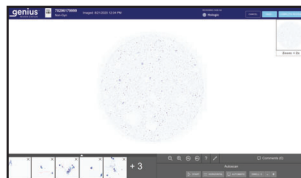
Prepared ThinPrep slides are loaded into a slide carrier, which is loaded into the Digital Imager.

The cell spot is imaged.



The Digital Imager scans the entire cell spot.
Case data and images are stored on the Image Management Server.

Case review by the cytotechnologist or pathologist



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

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

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



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

Figure 1-3 Genius Digital Diagnostics System Process, Non-Gyn Cases or UroCyte Cases

1

INTRODUCTION

SECTION D

SPECIMEN PREPARATION

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

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

**SECTION
E**

REVIEW STATION TECHNICAL SPECIFICATIONS

Overview of Components

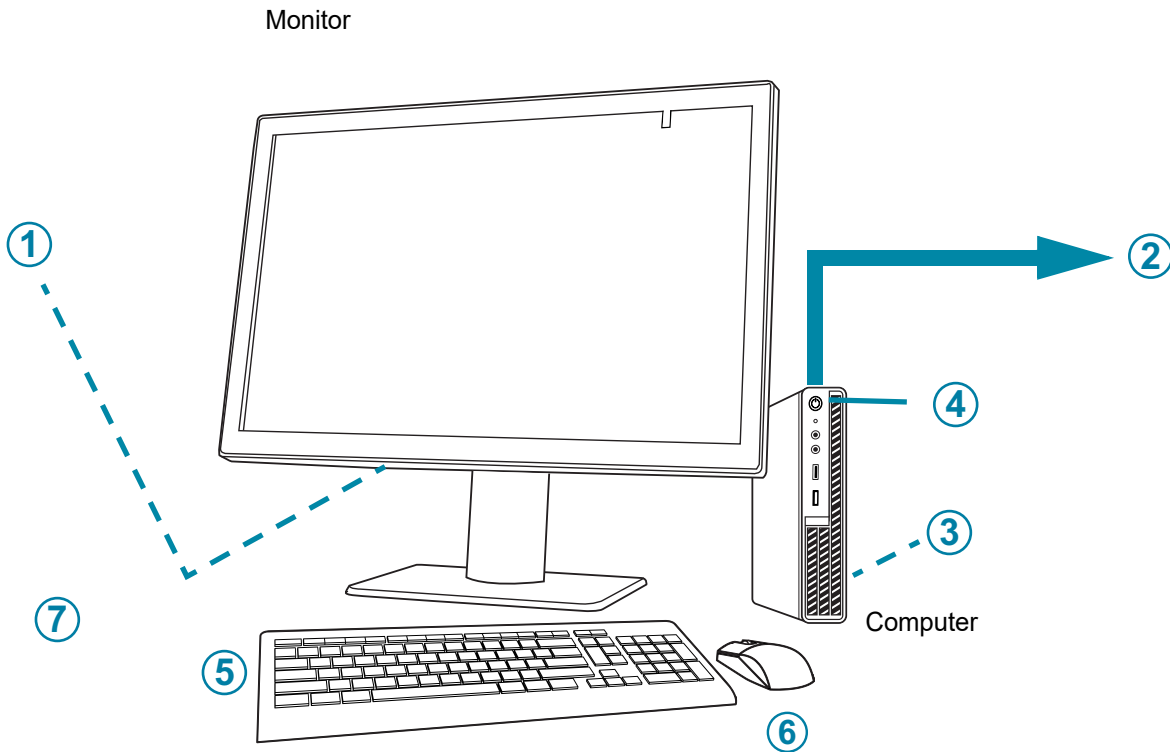


Figure 1-4 Review Station Components

Key to Figure 1-4	
①	Monitor power button, under the connector compartment cover
②	Connection to the Image Management Server (depicted in concept in Figure 1-4)
③	Computer processor card, installed in the computer

1

INTRODUCTION

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

Review Station Monitor Dimensions

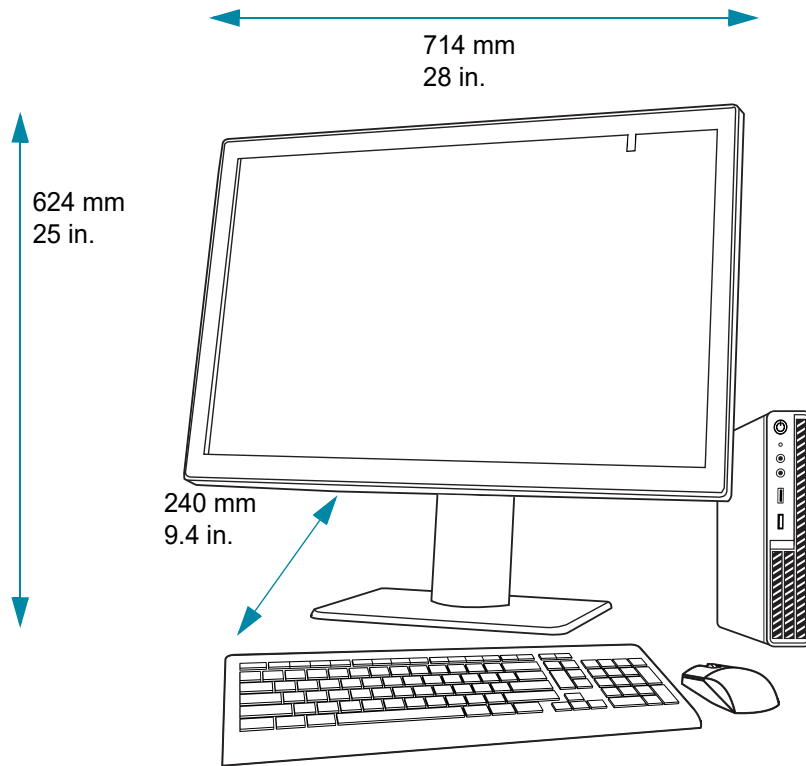


Figure 1-5 Review Station Monitor Dimensions

Weight

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

Review Station Computer Specifications

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

Hardware:

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

1

INTRODUCTION

- Keyboard and Mouse

Operating System:

- Window 10 – 64Bit

Operating temperature range

Refer to the documentation provided with the monitor and computer.

Non-operating temperature range

Refer to the documentation provided with the monitor and computer.

Operating humidity range

Refer to the documentation provided with the monitor and computer.

Non-operating humidity range

Refer to the documentation provided with the monitor and computer.

Pollution Degree: Refer to the documentation provided with the monitor and computer.

Altitude

Refer to the documentation provided with the monitor and computer.

Atmospheric pressure

Refer to the documentation provided with the monitor and computer.

Sound levels

Refer to the documentation provided with the monitor and computer.

Power

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

Fuses

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

Safety, EMI and EMC Standards

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

**SECTION
F****INTERNAL QUALITY CONTROL**

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

1

INTRODUCTION

SECTION G

GENIUS REVIEW STATION HAZARDS

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

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

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

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




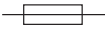





Warnings, Cautions and Notes

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

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











Symbols Used on the Instrument

The following symbols may appear on this instrument.

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

1

INTRODUCTION

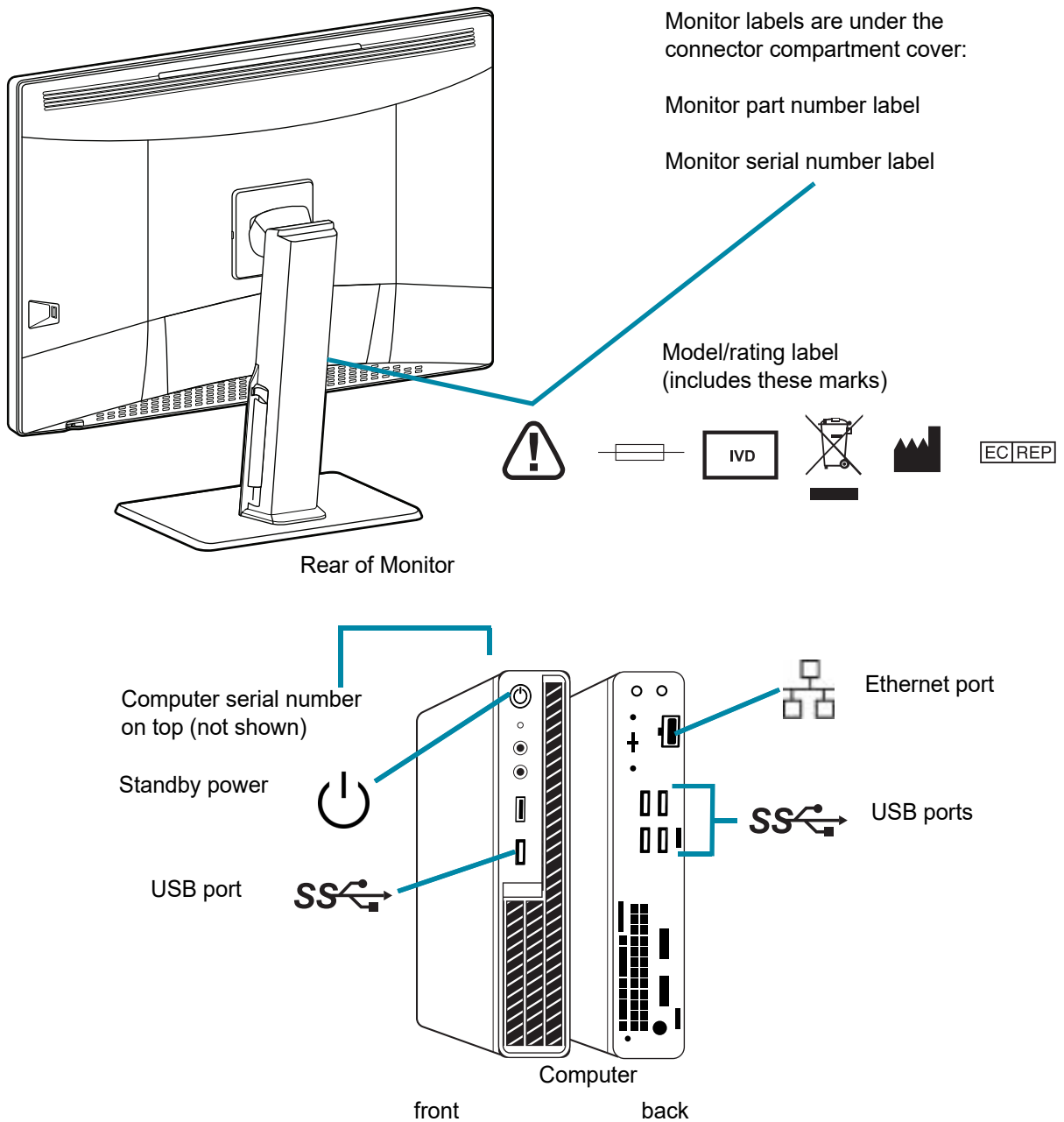
	Catalogue number
	On (Power switch)
	Off (Power switch)
	On/Off, Standby mode
	USB 3 port (computer)
	Ethernet port (computer)
	Made in USA
	Information is applicable only in the USA and Canada
	Product meets the requirements for CE marking in accordance with EU-IVD Regulation 2017/746
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician, or any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device and are trained and experienced in the use of the product.

	UK Conformity Assessed (Great Britain)
---	--

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

Figure 1-6 Symbols used on the monitor and computer

Location of Labels



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

Figure 1-7 Location of Labels on the Instrument

Warnings

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

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

Limitations

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



DISPOSAL

Disposal of the device

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

Do not dispose in municipal waste.



EC|REP

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

Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium

1

INTRODUCTION

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Chapter Two

Installation

WARNING: Service Installation Only

SECTION A

GENERAL

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

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

SECTION B

ACTION UPON DELIVERY

Inspect the packing cartons for damage. Report any damage immediately to the shipper and/or Hologic Technical Support as soon as possible. (Refer to Chapter 7, Service Information.)

Leave the instrument in the packing cartons for Hologic service installation.

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

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

SECTION
C

PREPARATION PRIOR TO INSTALLATION

Pre-Installation Site Assessment

A pre-installation site assessment is performed by qualified Hologic service personnel. 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 Hologic service personnel.

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

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

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

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

Computer preparation

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

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

Location

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

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

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

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



Figure 2-1 A Typical Review Station Configuration

Security

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

Cybersecurity safeguards

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

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

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

2

INSTALLATION

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

Operating system patching

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

Cybersecurity updates

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

SECTION D

MOVING THE REVIEW STATION

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

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

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

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



Figure 2-2 Moving the Review Station

SECTION
E

CONNECTING REVIEW STATION COMPONENTS

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

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

Monitor - a customized, medical-grade, high-resolution, large-format computer display screen

2

INSTALLATION

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

Computer - hosts the browser for the system application.

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

CAUTION: Only use Hologic-supplied monitor and GPU.

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

The computer may be supplied by Hologic. Computers supplied by Hologic arrive at the laboratory with the computer graphics card installed. For laboratory-supplied computers, Hologic field service personnel install the computer graphics card as part of the Review Station installation. Laboratory-supplied computers must meet or exceed minimum specifications for the Review Station. (Refer to “Review Station Computer Specifications” on page 1.11).

A network connection using a minimum of cat 6 cabling connects the Review Station to a networking device. (See Figure 1-7.) The networking device enables communication to the Genius Image Management Server.

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

Adjusting Monitor Height and Tilt

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

SECTION F

POWER ON THE REVIEW STATION

WARNING: Grounded Outlet

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

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

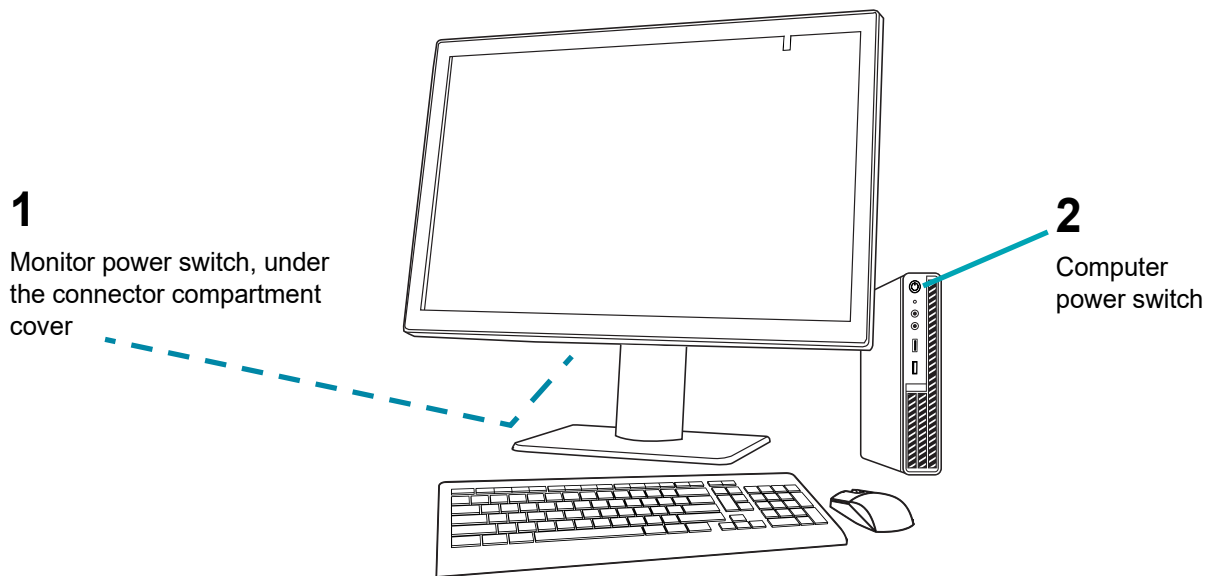


Figure 2-3 Power Switches

1. Press the power button on the computer. Allow the computer and monitor to initialize.
2. Double-click “Genius Review Station” icon on the computer desktop to launch the Review Station software.

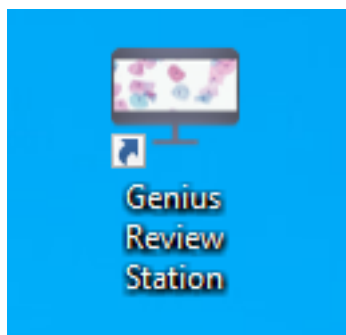


Figure 2-4 Launch the application

2

INSTALLATION

3. The application launches.

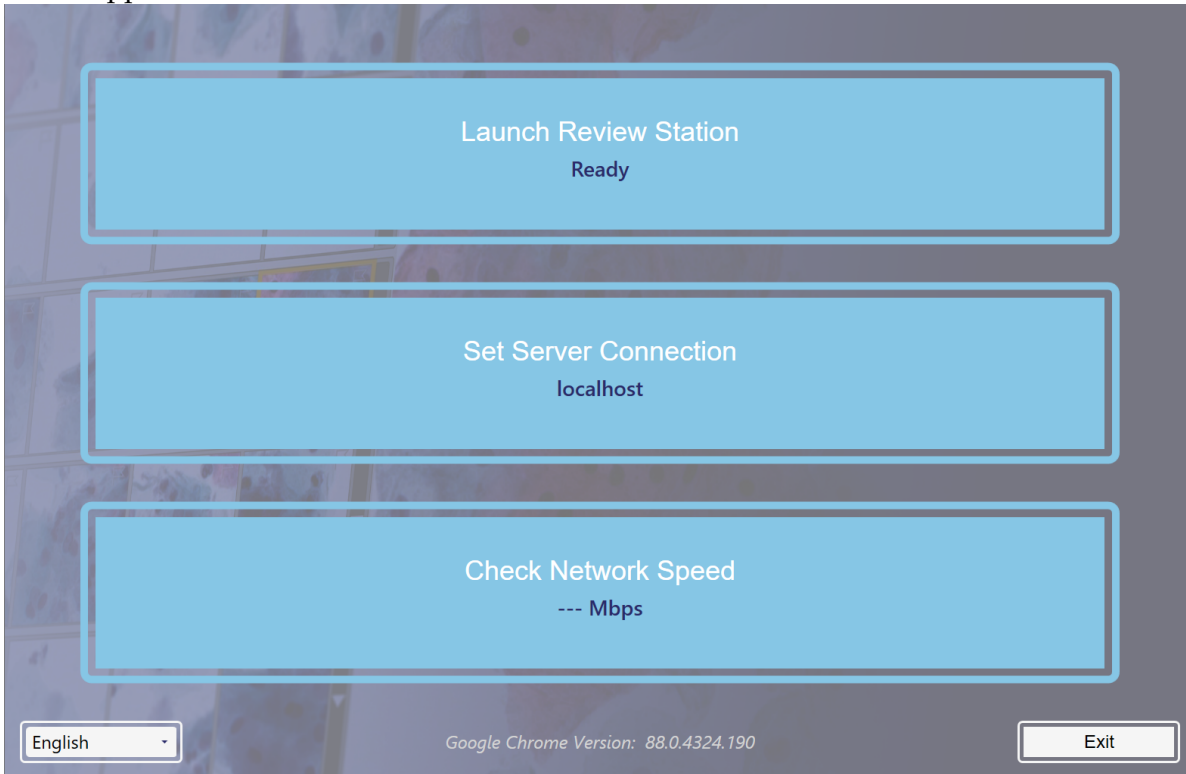


Figure 2-5 Launch the Review Station Software

There are two specifications that need to be set or confirmed the first time the Review Station is set up. These do not need to be used every time the Review Station is launched. The IP address and network speed information are helpful in troubleshooting communication issues.

IP Address

1. Select **Set Server Connection**.

2. If the IP address field is empty, enter the IP address for the Image Management Server. If the Review Station has previously connected with the Image Management Server, the IP address used the last time is shown.

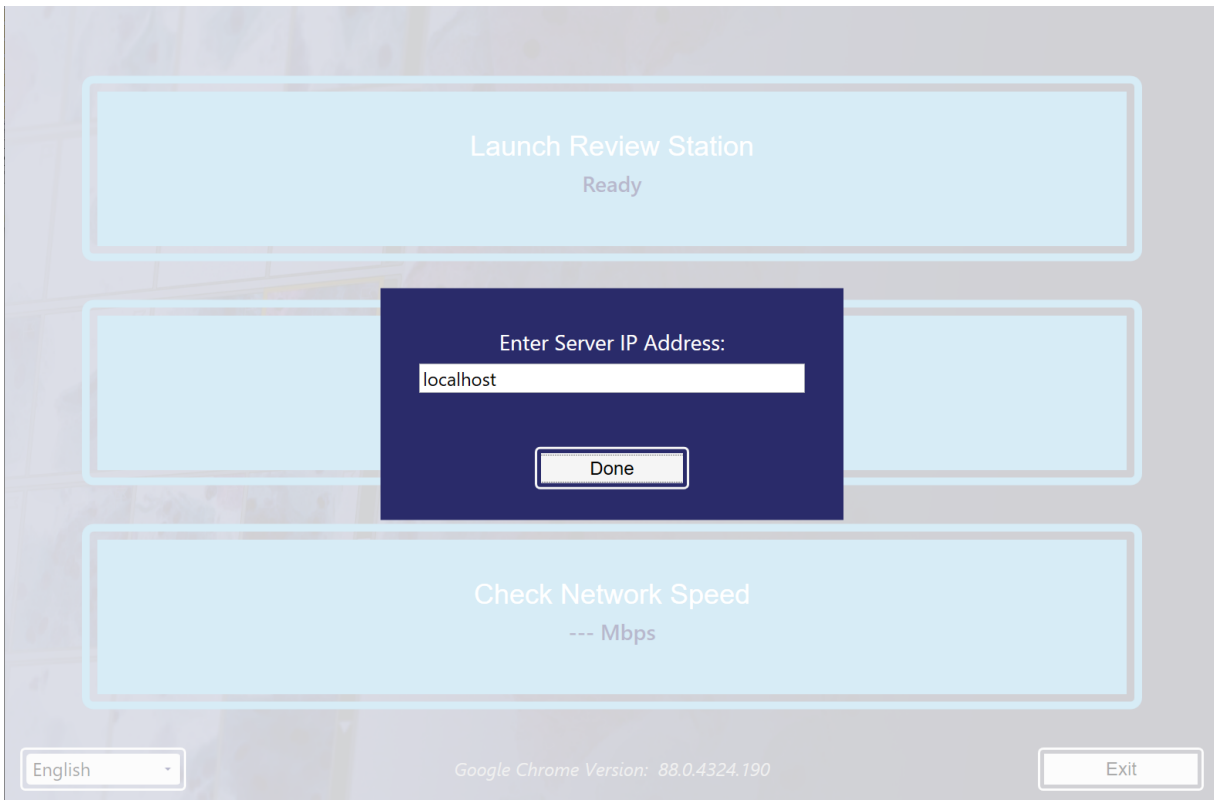


Figure 2-6 Enter Server IP Address

Network Speed

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

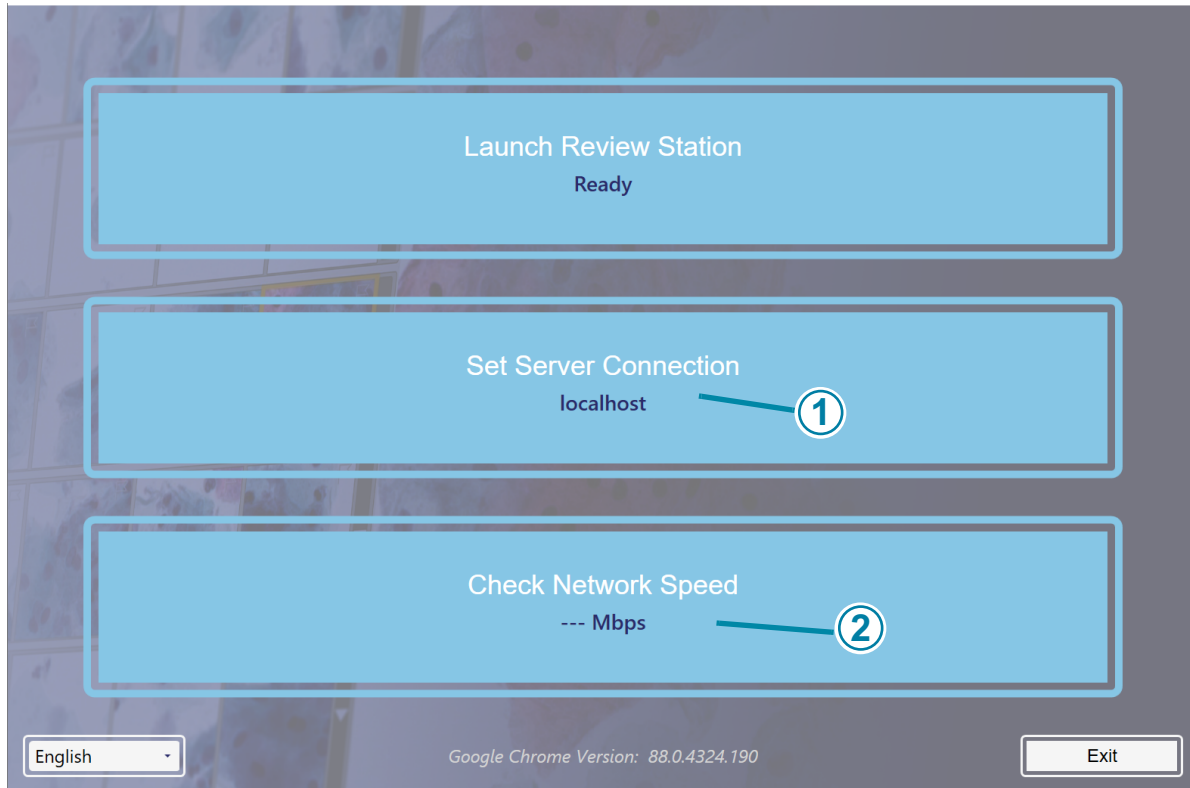


Figure 2-7 Review Station Startup Screen, Example

Key to Figure 2-7	
①	IP address
②	Network speed

When the Review Station is connected to a network, select **Launch Review Station** to launch the Review Station application.

Next, log into the application with a username and password. (Refer to “Login Screen” on page 3.6.)



Figure 2-8 Login Screen

The Review Station is ready for use when the Dashboard is displayed (Figure 2-9).

2

INSTALLATION



Figure 2-9 Review Station Dashboard

SECTION G

STORAGE AND HANDLING - POST INSTALLATION

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

SECTION H SYSTEM SHUTDOWN

Normal Shutdown

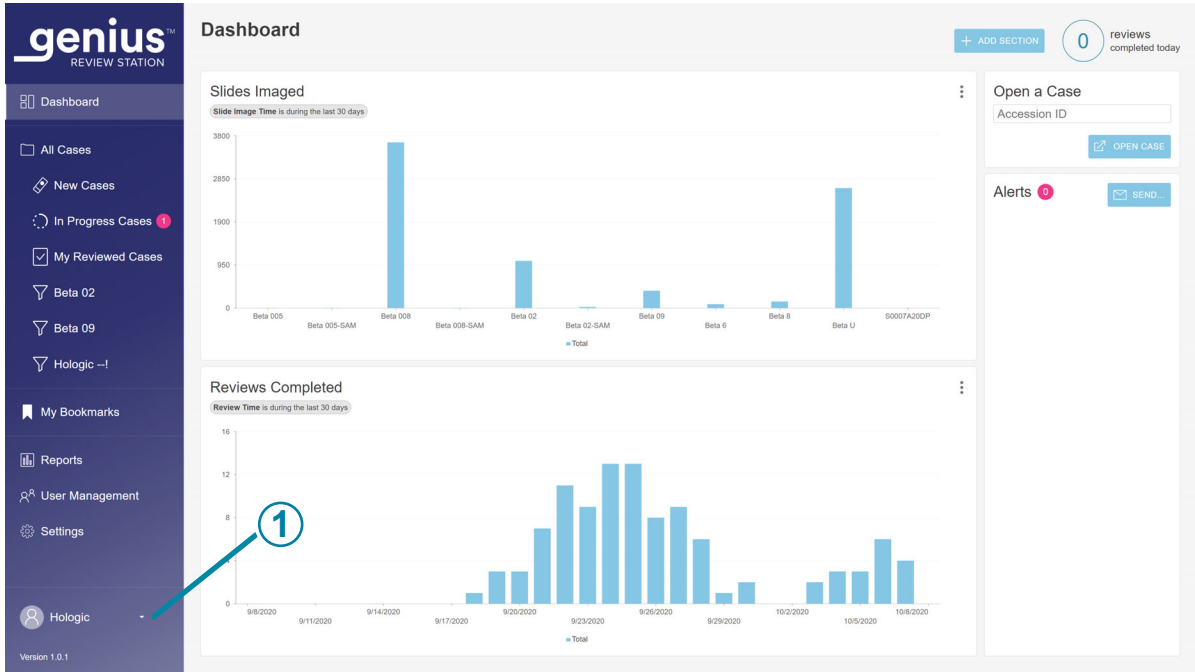


Figure 2-10 Exit the application

Key to Figure 2-10	
1	Exit. Click the arrow next to your name to see the Exit command.

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

To shut down the Review Station:

1. Click on your name in the lower left of the menu bar on the left to exit the Review Station application.
 - Note:** To exit the Review Station application from the Login screen, click the “x” in the upper right of the screen.
2. Next, select **Exit** in the window.

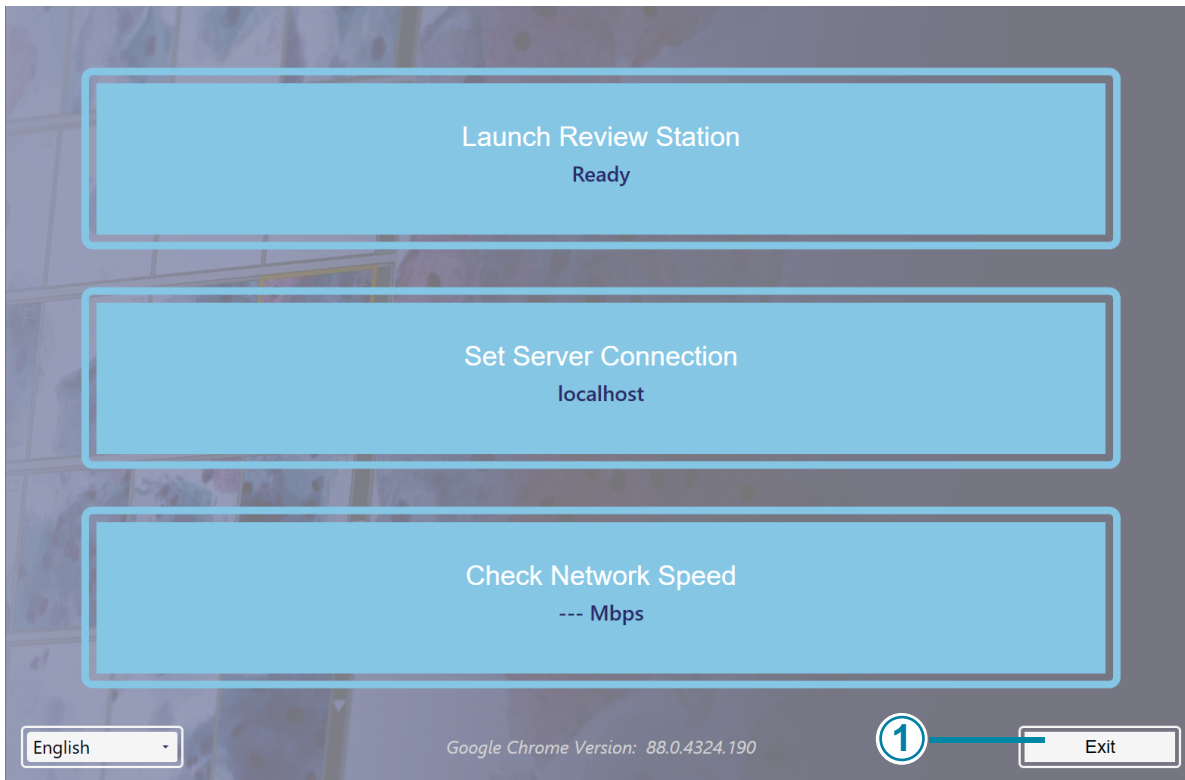


Figure 2-11 Exit the launch application

Key to Figure 2-11	
①	Exit button

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

Extended Shutdown

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

Chapter Three

User Interface

SECTION A

OVERVIEW

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

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

There are two user roles for the Review Station, a reviewer role and a manager role. The manager role can do all of the same functions as the reviewer role, and the manager can perform additional activities. These instructions describe all of the Review Station features.

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

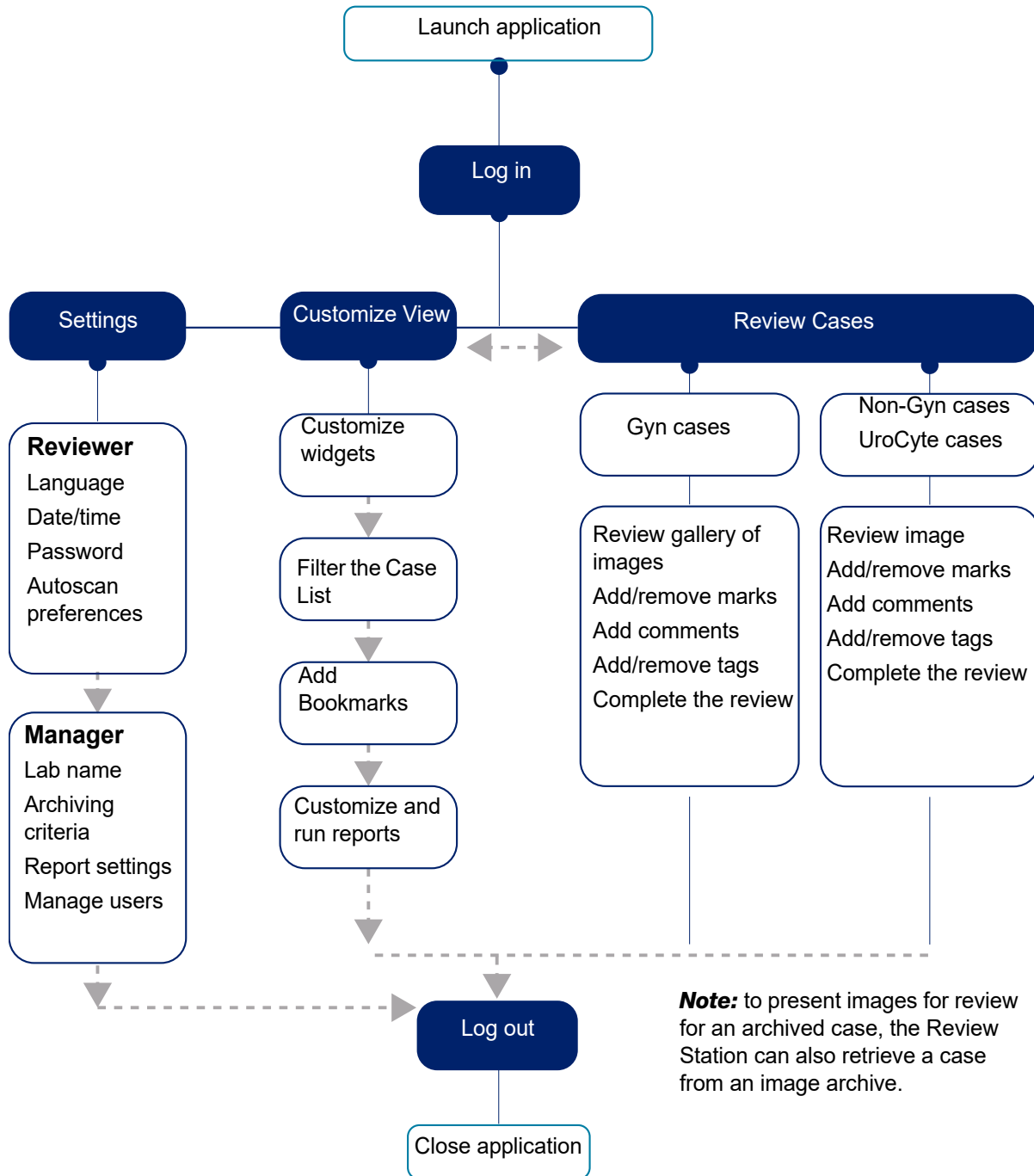


Figure 3-1 Overview of Review Station Functions

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

The content found in this chapter:

Log In	3.3
• Normal Login	3.3
• Forgotten username or password	3.6
Display Overview	3.7
• Menu Bar and Case Lists	3.8
Settings	3.12
• User Management	3.22
Customize the view	3.26
• Customize the Dashboard widgets	3.26
• Case Lists	3.33
• Data Filters	3.37
• Log out	3.41
• Alerts	3.41
Bookmarks	3.42
• Setting up Bookmarks	3.42
• Using Bookmarks	3.42
Reports	3.43
• Standard reports	3.43

SECTION
B

LOG IN

Normal Login

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

3

USER INTERFACE

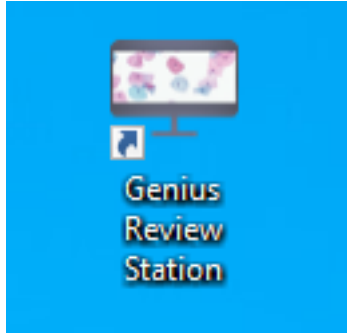


Figure 3-2 Launch the application from the computer desktop

2. The application launches.

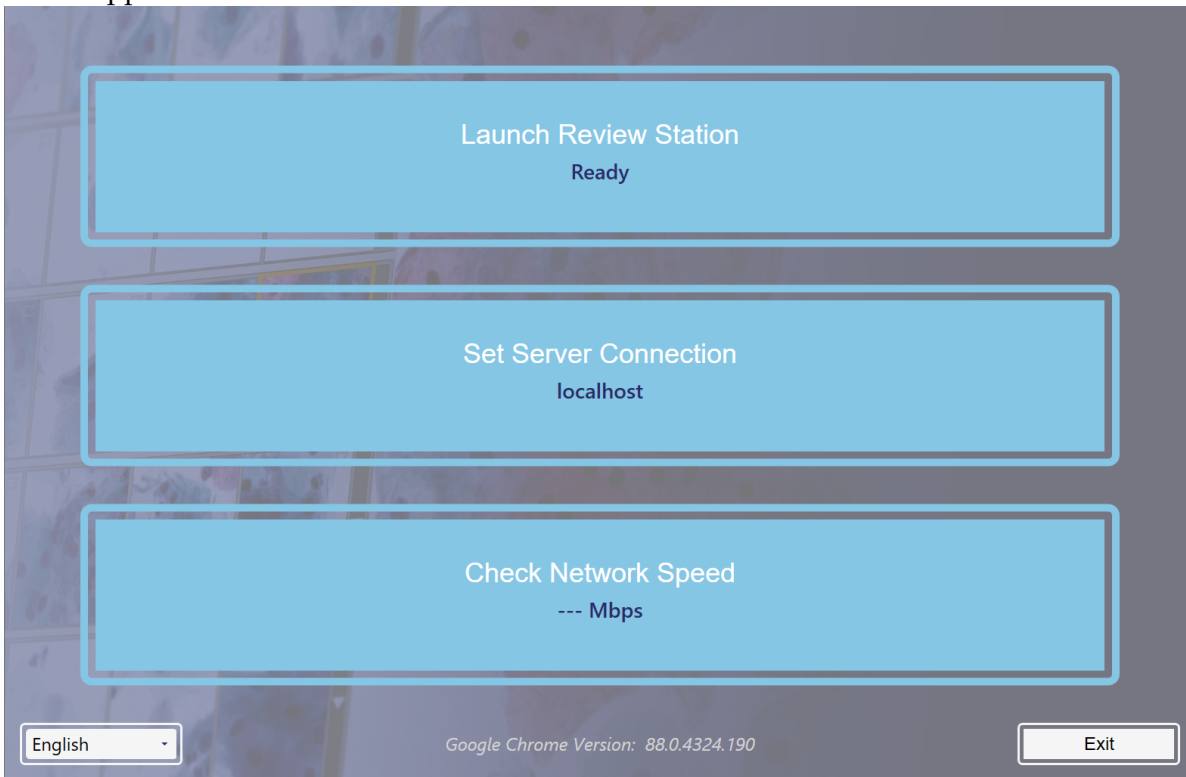


Figure 3-3 Launch the Review Station Software

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

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

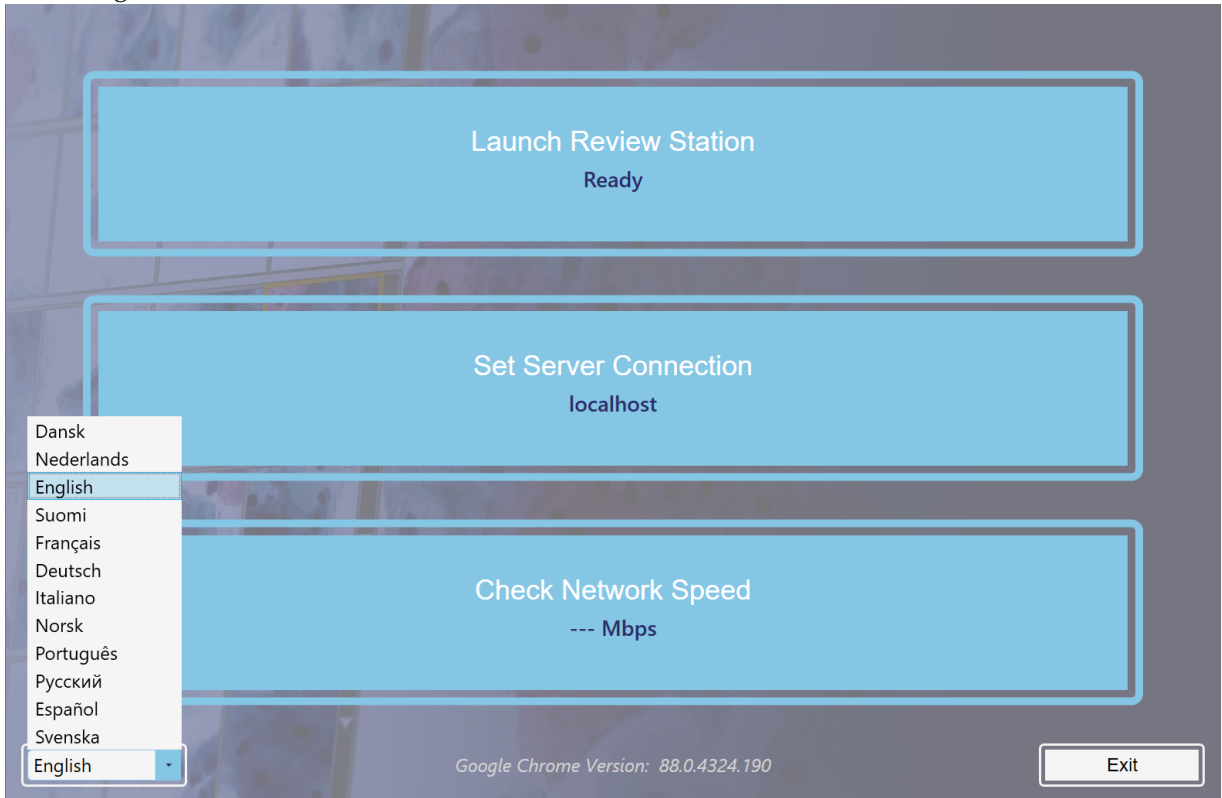


Figure 3-4 Select language when launch application (optional)

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

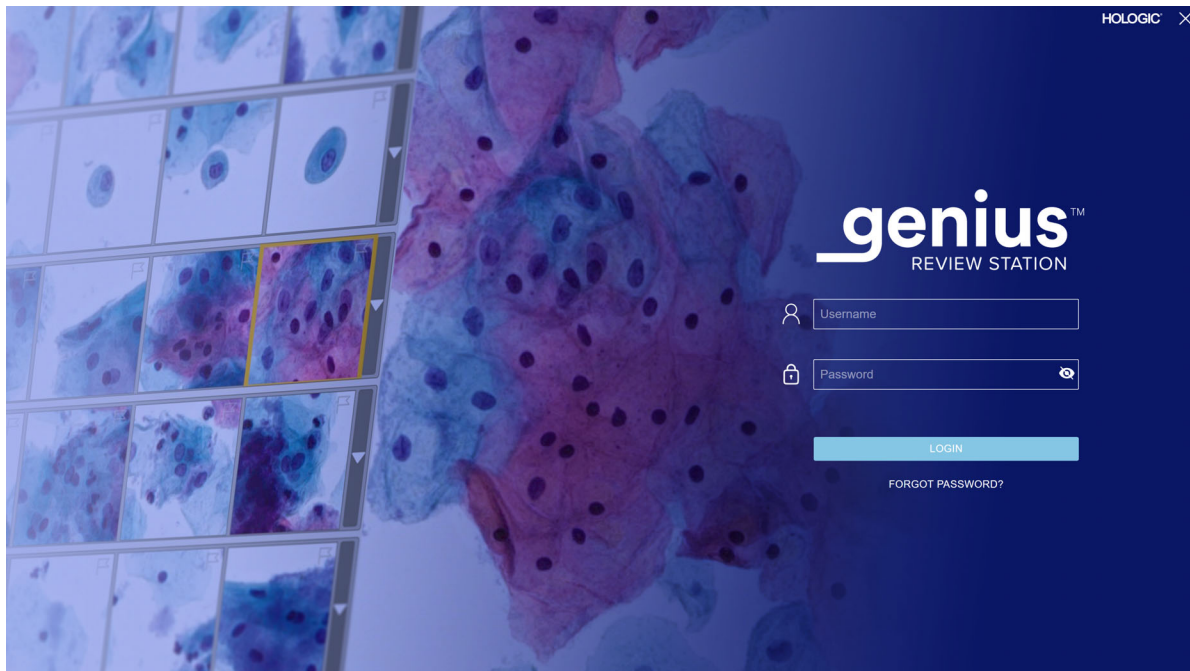


Figure 3-5 Login Screen

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

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

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

Refer to “Password” on page 3.14 for information on setting up usernames and passwords.

Forgotten username or password

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

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

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

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

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

3. Log in using the temporary password and then reset your password. The new password must meet the requirements for passwords. Refer to “Password” on page 3.14 for the requirements for the new password.

SECTION C **DISPLAY OVERVIEW**

The Review Station has some elements that are always displayed and some that can be customized for each user. The features for customizing your view on the Review Station are described in “Customize the view” on page 3.26.

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

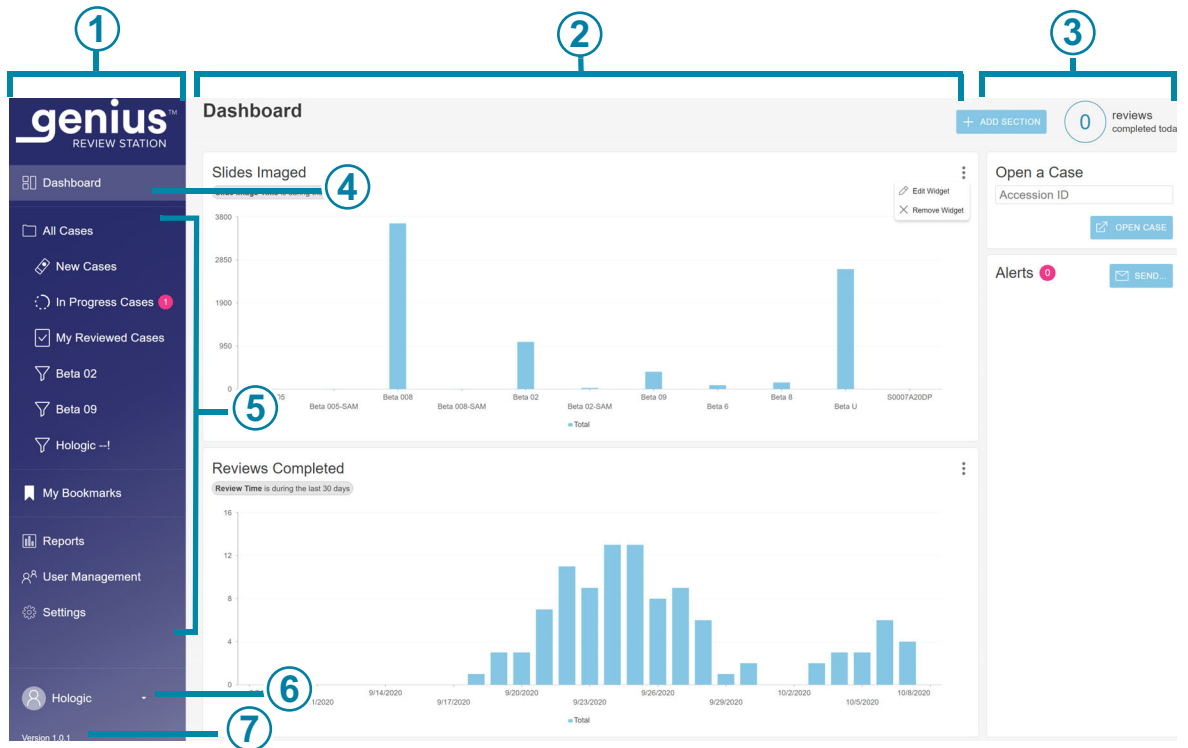


Figure 3-6 Review Station Dashboard

Key to Figure 3-6	
①	Menu bar on the left. Click on an item in the menu bar to select it.

Key to Figure 3-6	
②	Center pane of the Review Station display
③	Information section on the right. This section provides details on the content selected in the center section, for some of the menu items.
④	The lighter color in the menu bar indicates that the Dashboard view is the current view. The Dashboard provides a quick view of case data, in a way that the user can customize.
⑤	This section of the menu bar provides navigation among: Case Lists, displayed in standard groups and available to customize. Refer to page 3.33. My Bookmarks, which can be customized for each user. Refer to page 3.42. Reports. Refer to page 3.43. User Management settings (available only to users with a manager role). Refer to page 3.22. Settings, which can be customized for each user. Refer to page 3.13.
⑥	The user's first and last name. Use the down arrow to access the log out screen.
⑦	The version number for the Review Station software.

Menu Bar and Case Lists

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

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

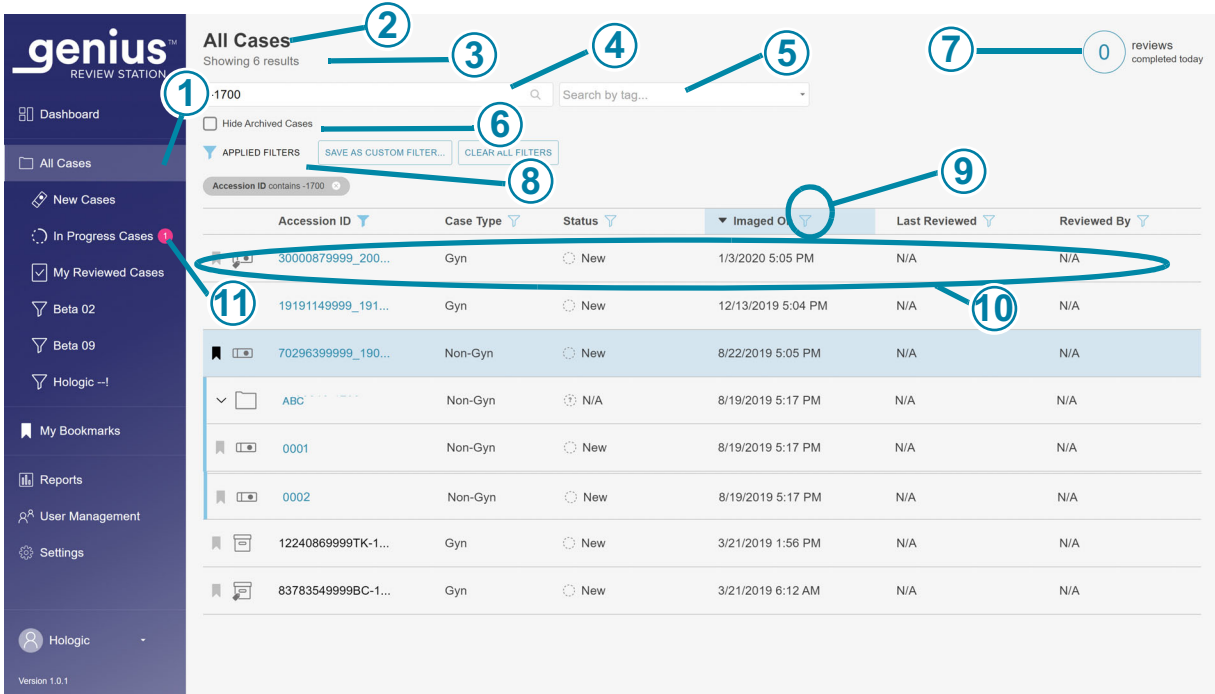


Figure 3-7 Typical Case List (All Cases selected in this example)

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

3

USER INTERFACE

Key to Figure 3-7	
⑥	A check box to hide archived cases in the list of cases. When this box is checked, archived cases will not be displayed in the list.
⑦	The number of cases that this reviewer has completed today
⑧	Applied filters describe how the data shown in the center section has been filtered
⑨	The filter icon (Refer to “Data Filters” on page 3.37)
⑩	Case data - the data in each row describes one case
⑪	Pink bubble - this indicates the number of cases whose review is in progress for this reviewer

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

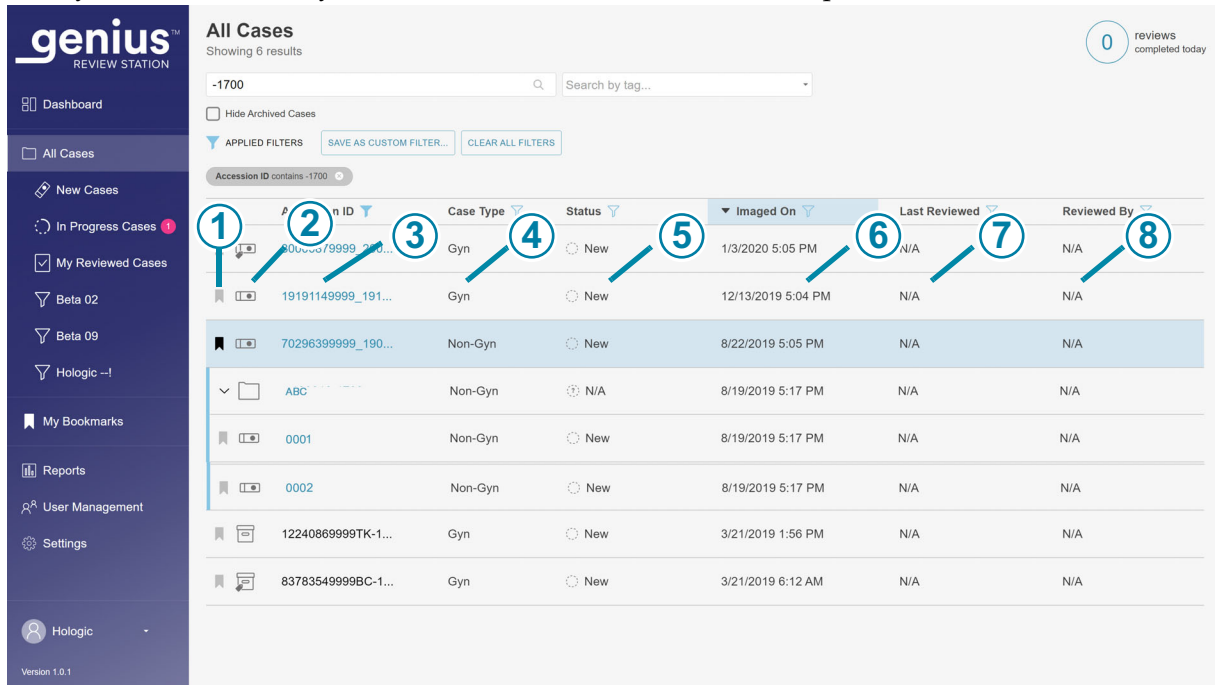


Figure 3-8 Typical Case List (All Cases selected in this example)

Key to Figure 3-8	
	<p>Bookmark icon (Refer to “Bookmarks” on page 3.42)</p> <p>Clear bookmark indicates a case is not bookmarked.</p> <p> Solid bookmark icon indicates a case is bookmarked.</p>
	<p> Slide icon - A case with the slide icon consists of one slide and has not been archived.</p> <p> Tag icon - A reviewer has applied a tag to this case.</p> <p> Folder icon - A Non-Gyn case comprised of multiple slides, grouped together with a primary ID</p> <p> Archived icon - A case with the archived icon has been archived. (Refer to “Archive” on page 3.21.) When retrieval of an archived case is in progress, blue arrows display on the archived icon.</p>

3

USER INTERFACE

Key to Figure 3-8	
③	Accession ID for a case - clicking on the accession ID for a case displays the images for that case
④	Sample type for the case: Gyn, Non-Gyn, or UroCyte
⑤	Status - The status is New, In Progress, or Reviewed
⑥	The date that the slide(s) for the case were imaged on the Genius Digital Imager
⑦	The most recent date that the case was reviewed on the Review Station
⑧	The name of the reviewer who completed the most recent review of the case on that Review Station

SECTION D

SETTINGS

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

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

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

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

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

Locale

(Reviewer and Manager)

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

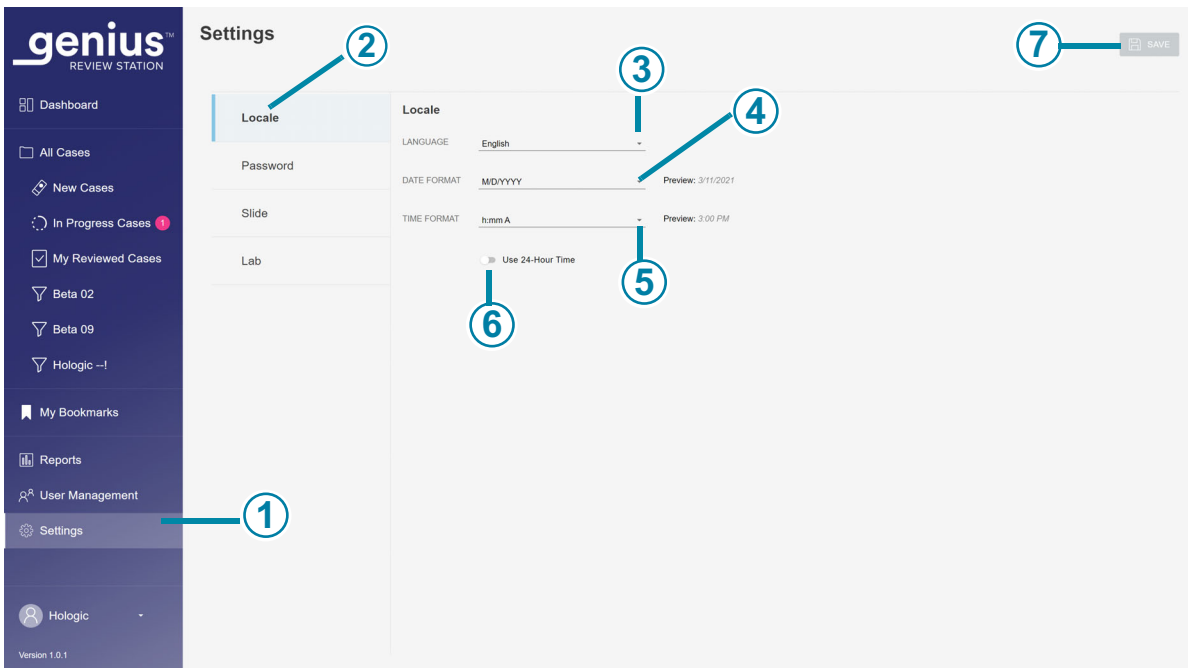


Figure 3-9 Set the language, date format, time format

Key to Figure 3-9	
①	The lighter color in the menu bar indicates that Settings is selected.
②	The blue color in the list of settings indicates that the Locale settings are selected.

3

USER INTERFACE

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

Password

(Reviewer and Manager)

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

temporary password to a different password. The password can be changed at any time from the Settings screen by the user.

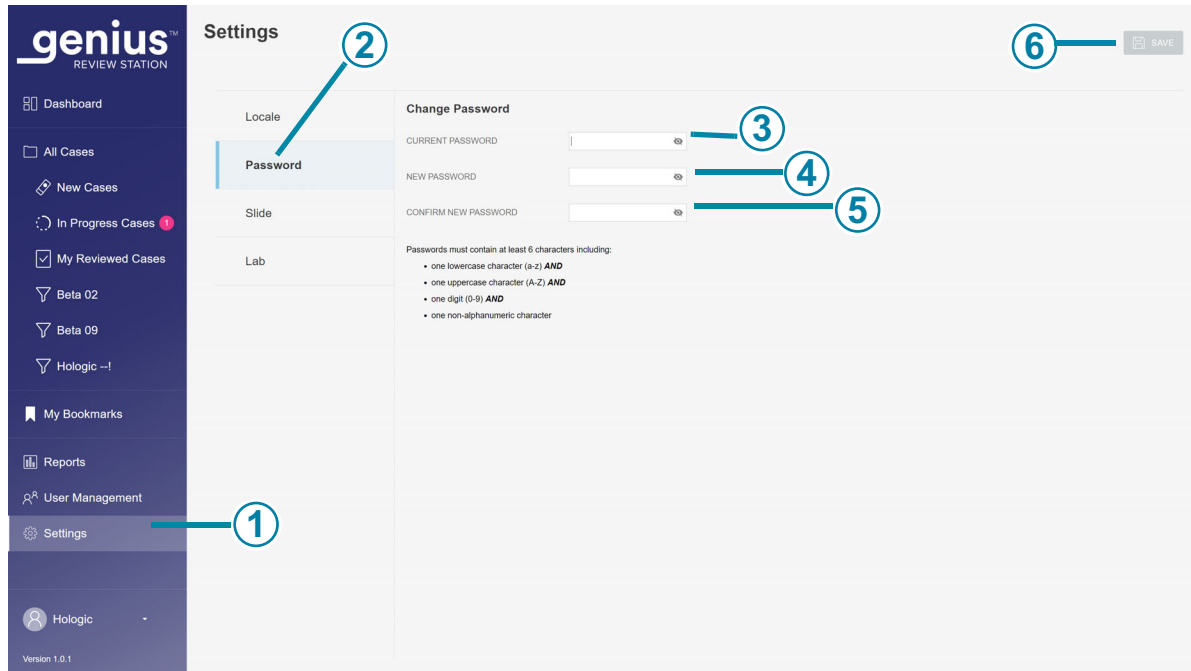


Figure 3-10 Change Password

Key to Figure 3-10	
①	The lighter color in the menu bar indicates that Settings is selected.
②	The blue color in the list of settings indicates that the Password settings are selected.
③	Enter the current password.
④	Enter the new password.

3

USER INTERFACE

Key to Figure 3-10	
⑤	Confirm the new password by entering it again. If the new password does not meet the format requirements, or if the new and confirmed passwords do not match, an error message appears. Try to set the password again. And an error will also display if the current password is incorrect.
⑥	To save the new password, click the Save button.

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

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

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

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

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

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

Slide (Reviewer and Manager)

The Slide setting sets the preferences for the Autoscan feature.

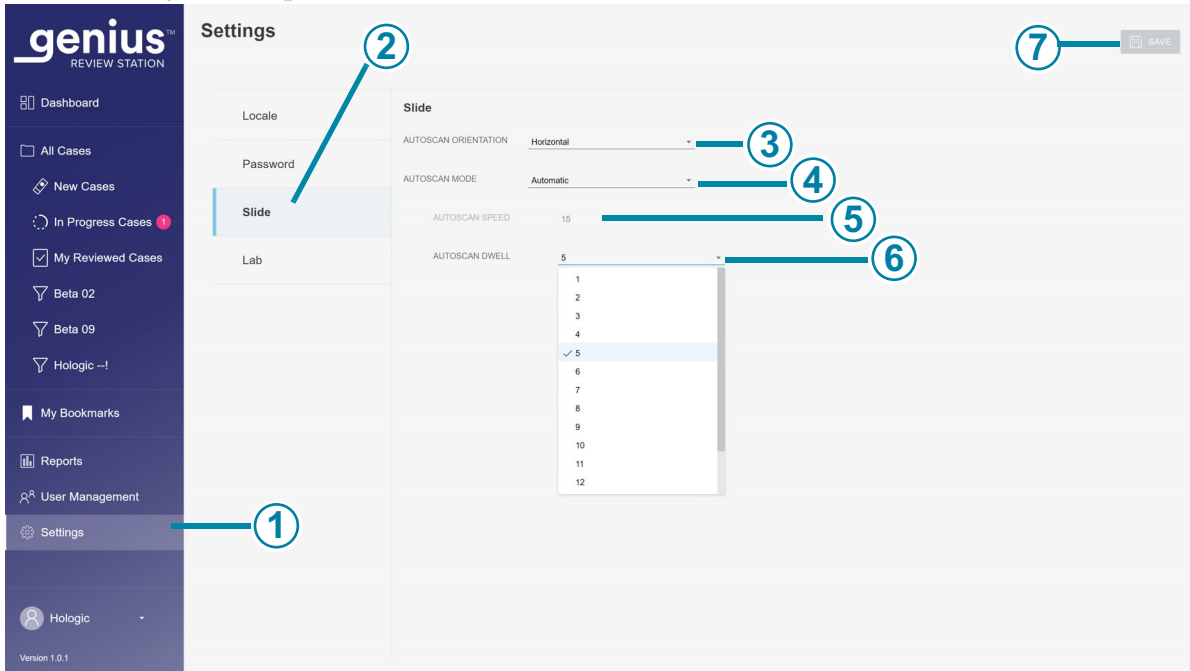


Figure 3-11 Slide settings for Autoscan (automatic mode in this example)

Key to Figure 3-11	
①	The lighter color in the menu bar indicates that Settings is selected.
②	The blue color in the list of settings indicates that the Slide settings are selected.
③	<p>Autoscan orientation</p> <p>The Autoscan orientation is the direction in which the scan pattern travels through the whole slide image. To change the pattern for the field of view to travel during Autoscan, click on the arrow to the right of the current setting to select horizontal or vertical. Click on an orientation select it.</p>
④	<p>Autoscan mode</p> <p>Autoscan can be set up to automatically advance and pause the view through the whole slide image, or it can be set up to continuously advance through the whole slide image without pausing.</p> <p>To change the mode for Autoscan of slide images, click on the arrow to the right of the current setting to see the available options of Continuous or Automatic.</p>
⑤	<p>Autoscan speed</p> <p>In Continuous mode, the view moves continuously, without pausing.</p> <p>The Autoscan speed setting controls how fast the view moves on the screen during Autoscan. Click on the arrow to the right of the current setting to see the available options.</p> <p>Click on a speed to select it.</p> <p>Note: During case review, the Autoscan speed for the case under review can be adjusted using the -/+ tools.</p>
⑥	<p>Autoscan dwell</p> <p>In Automatic mode, the view moves one frame at a time, with a brief pause between movements. The duration of that pause is the dwell time, which can be set from 1 to 15. A lower number for the dwell time has a faster Autoscan than a higher number for the dwell time. A higher number has a longer pause.</p> <p>In Automatic mode, click on a dwell time to select it.</p> <p>Note: During case review, the Autoscan speed for the case under review can be adjusted using the -/+ tools.</p>

Key to Figure 3-11	
7	To save the Autoscan settings, click the Save button.

Lab

(Manager)

A user with a manager role can establish settings that apply to all cases reviewed in Review Station network. Unlike the other settings, these lab settings are not customizable for each user account. Refer to Figure 3-12 on page 3.19.

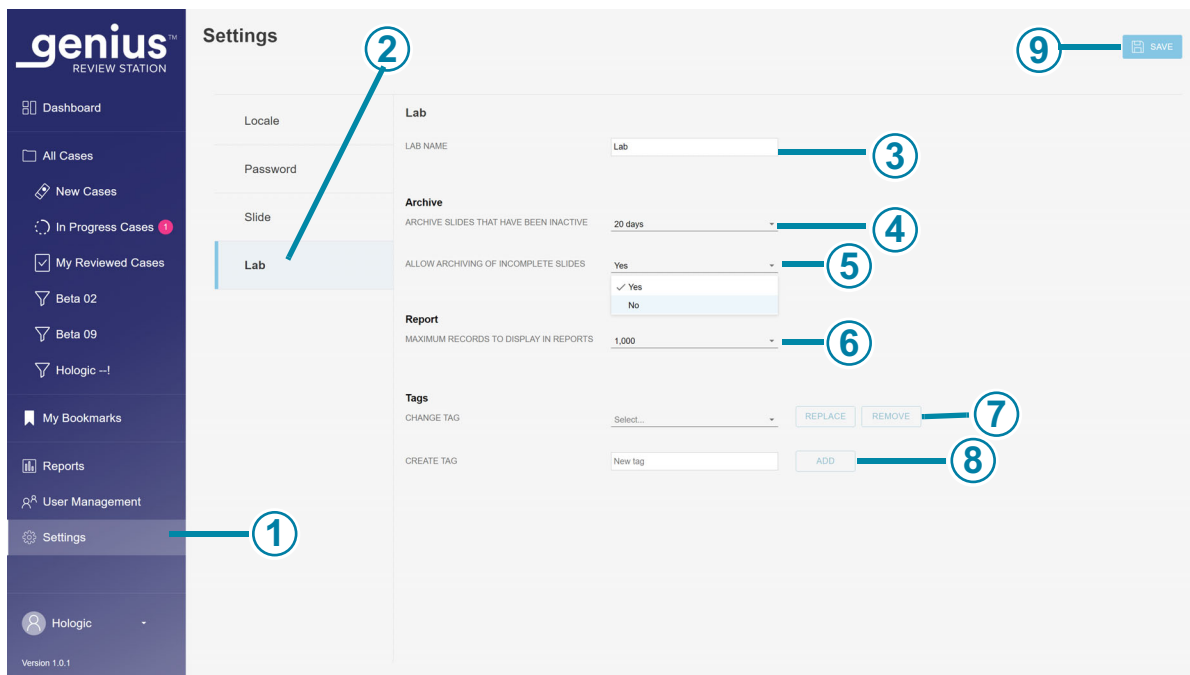


Figure 3-12 Lab settings

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

Key to Figure 3-12	
②	The blue color in the list of settings indicates that the Lab settings are selected.
③	<p>Lab name (Manager only)</p> <p>To have a lab name appear on Reports, type in the name of your lab.</p>
④	<p>Archive slides that have been inactive</p> <p>After a period of time, data for inactive cases is transferred to a long-term archive storage system from the Image Management Server. The default setting is 20 days.</p> <p>The storage capacity of the server and a lab's archive system may vary from lab to lab. A lab manager can change the archive frequency to a shorter or longer time period. To change that time period, click on the arrow to the right of the current setting to see the available options.</p> <p>Click on a time period to select it. Select a time period from the available options that are 5 days apart, from a minimum of 5 days to a maximum of 45 days.</p>
⑤	<p>Allow archiving of incomplete slides</p> <p>This setting either includes or excludes cases where a review has not been completed as archived slides.</p> <p>To change the current setting, click on the arrow to the right of the current setting to choose between the available options of yes or no. Click yes or no.</p> <p>A "yes" setting will archive inactive new cases and completed cases at the set time or disk capacity.</p> <p>A "no" setting will archive completed cases at the set time or disk capacity, and keep new cases on the Image Management Server.</p> <p>Note: A case with the "In Progress" status cannot be archived.</p>
⑥	<p>Maximum records to display in reports</p> <p>To change the maximum number of records to display in reports, click on the arrow to the right of the current setting to see the available options.</p> <p>Click on a number to select it.</p> <p>Select from the available options of 100, 500, and 1000 results.</p>

Key to Figure 3-12	
<p>⑦</p>	<p>Change tag</p> <p>To rename or remove an existing tag for all users in the Review Station network, click on the arrow to the right of the Select box to see the list of current tags. Select the tag from the list.</p> <p>To rename the selected tag, click the Replace button. Type the new name for the tag in the box where the existing name is displayed. A confirmation message appears. Click Continue to change the name and return to the Lab settings screen, or click Cancel to leave the tag unchanged.</p> <p>To remove the selected tag from all cases in the Review Station network, click the Remove button. A confirmation message appears. Click Continue to return to the Lab settings screen, or click Cancel to leave the tag as it is.</p>
<p>⑧</p>	<p>Create tag</p> <p>To create a new tag, type the name for the new tag in the New tag box. Click Add.</p> <p>A manager can also create a new tag during case review. The creation and use of tags is optional.</p>
<p>⑨</p>	<p>To save the Lab settings, click the Save button.</p>

Archive

(Manager only)

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

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

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

Report

(Manager only)

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

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

To change the maximum number of records to display in reports, click on the arrow to the right of the current setting to see the available options. Click on a number to select it. Select from the available options of 100, 500, and 1000 results.

Tags

(Manager only)

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

The name of a tag is limited to 50 characters.

After a tag is set up by a manager, any reviewer in the lab can apply or remove a tag from a case.

After a tag is set up by a manager, any reviewer can search for cases using that tag.

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

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

Note: If a manager removes a tag from the Review Station, consider deleting any custom filters for that tag, since the filter will yield no results (0 cases). Refer to “Delete a custom filter” on page 3.41.

Refer to “Add a tag” on page 4.18 for instructions for adding tags during case review.

User Management

(Manager only)

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

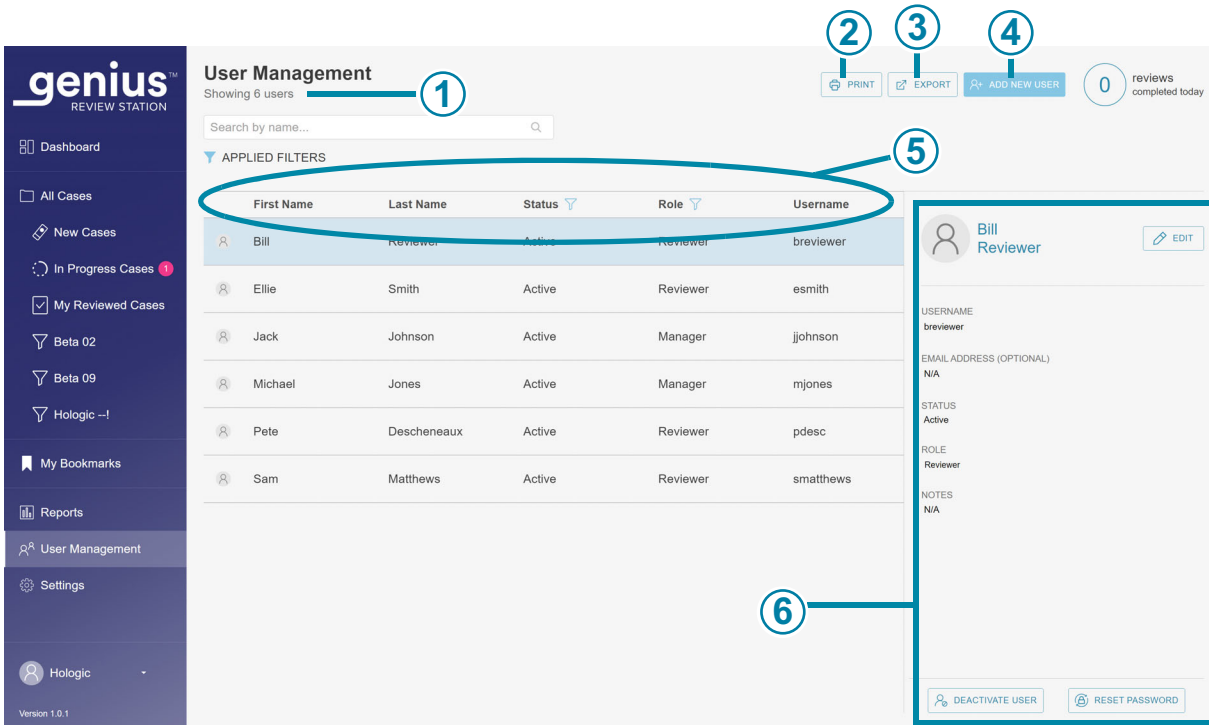


Figure 3-13 User Management: List of Users

Key to Figure 3-13	
①	In the upper left, the number of users is shown. The number displayed in the upper left may change if the list is filtered by status or filtered by role.
②	The Print button generates a PDF view on the screen, and opens the print dialog window from the web browser. To print out the PDF, use the web browser’s print dialog.
③	The Export button saves the list of users either as a .csv file (comma-separated variable file) or a PDF file in the downloads folder of the Review Station computer. After clicking the Export button, choose CSV or PDF .
④	The Add New User button opens a screen for entering data about a new user. Refer to “Add a New User” on page 3.24.
⑤	The list of users shows the first name, last name, status, role and username for users in the Review Station network.

Key to Figure 3-13	
⑥	<p>User details</p> <p>Click on any user in the list to display details describing the user whose name is highlighted in the list.</p>

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

- The list of users can be filtered by status, to display all the active users, all the inactive users and all users.
- The list of users can be filtered by role to display all of the users, all of the users with a reviewer role, and all of the users with a manager role

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

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

- The username field
- The email address field is optional. If an email address is part of the user details, a reviewer can enter the email address in place of a username in the Login screen. This field is also a convenient place to store the user's email address. The Review Station cannot send or receive emails.
- The status is either active or inactive. An inactive user cannot log in nor use the Review Station.
- The role for a user is either reviewer or manager.
- The notes field is an area where the manager can type in any additional information appropriate for your lab. The notes field is visible to all managers on the Review Station network.

Refer to "Edit a user account" on page 3.25 for instructions on editing a user profile.

Add a New User

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

1. Click on the **Add New User** button.
2. Enter the new user's first name and last name.
3. Enter a username for the new user.
4. Enter a password. This is a temporary password. The temporary password can be as short as one character. The first time a user logs in, a user must change from that temporary password to a different password.
5. Enter the user's e-mail address. (Optional)
6. For a new user, the status field is set to **Active**.

7. Select a role for the new user.
A user with the reviewer role can search for and review cases. A reviewer can run reports, but a reviewer's view is typically limited to the workload for that reviewer.
A user with the manager role can also perform other activities:
 - A user with the manager role can search for and review cases. A manager can run reports that can include data from all of the Review Station users.
 - A manager can delete a slide record from the Genius Image Management Server. Refer to "Delete a Slide" on page 3.37.
 - A manager can "reclaim" an In-progress case from a reviewer. Refer to "Reclaim a case" on page 3.35.
 - A manager can send Alerts to other users in the Review Station network. Refer to "Send an alert" on page 3.41.
 - A manager can establish settings that apply to all users, reset passwords for other users, and activate or deactivate user accounts.
8. Enter notes about the user account. (Optional)
9. Click the **Save** button to save the new user information, or click **Cancel** to close the new user pane without adding the new user.

Edit a user account

A user with the manager role can edit existing user accounts.

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

When the user appears in the list, click anywhere in that user's information to select that user from the list.
2. To edit the user's username, first name, last name, email address, role or the notes in the user's account, click the edit button next to the user's first and last name.
 - Type any changes into the fields for username, first name, last name, email address, or the notes in the user's account.
 - Click the **Save** button.
3. To edit the users' status, click the button at the bottom of the panel on the right.
 - To activate an inactive user, click the **Activate User** button.
 - To deactivate an active user, click the **Deactivate User** button.

3

USER INTERFACE

- On the confirmation screen, click **Yes** to continue with the change, or click **No** to cancel the change.
4. To reset a user's password, click the Reset password button at the bottom of the panel on the right.
- Type a temporary password in the box that says, "Enter a new password."
 - Click the **Continue** button to continue with the change, or click **Cancel** to cancel the resetting of the password.
 - Communicate the new password to the user. When the user logs in with this temporary password, the system prompts the user to reset the password.

SECTION E

CUSTOMIZE THE VIEW

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

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

Customize the Dashboard widgets

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

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

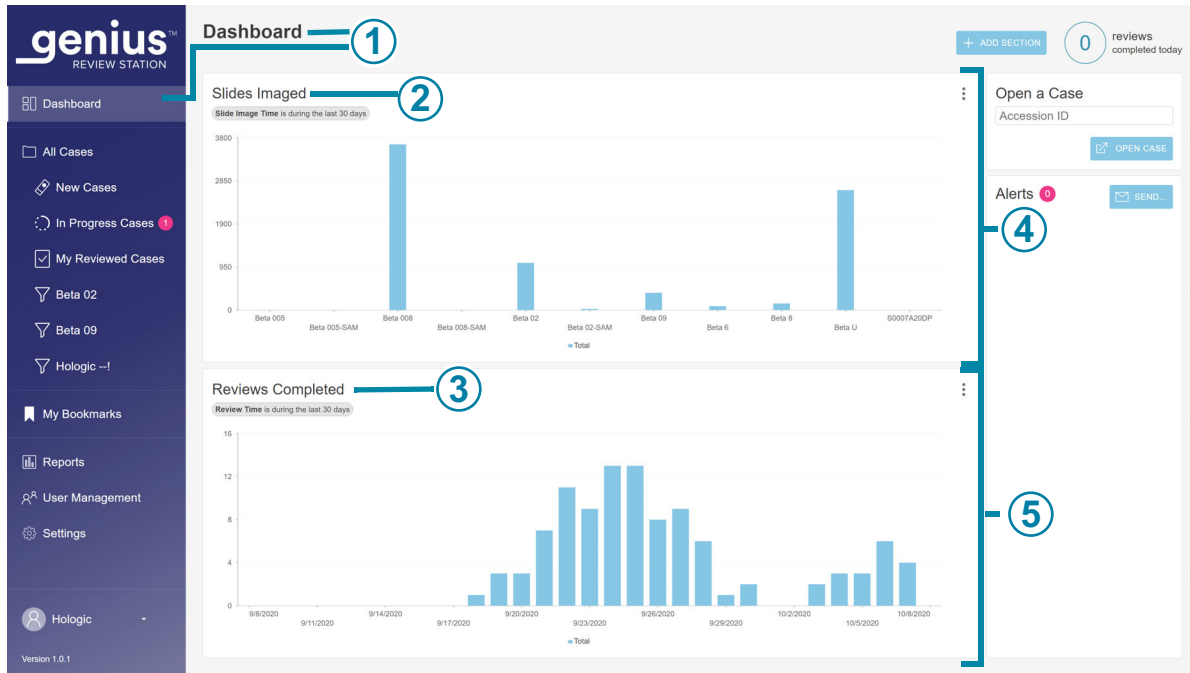


Figure 3-14 Review Station Dashboard, Default Widgets of Slides Imaged and Reviews Completed

Key to Figure 3-14	
①	The lighter color in the menu bar indicates that the Dashboard view is the current view. The name Dashboard also appears at the top of the center window. After login, the Review Station opens to the Dashboard, and a reviewer can navigate to the Dashboard at any time.
②	The name of widget in the first widget section. Slides Imaged is one of the two default widgets and is shown in this example. The default format for the Slides Imaged widget is a column graph of slides imaged over time.
③	The name of widget in the second widget section. Reviews Completed is one of the two default widgets and is shown in this example. The default format for the Reviews Completed widget is a column graph of case reviews completed over time.
④	A section (horizontal row) for widgets. Each section can be divided into one, two, or three columns. One column is shown in this example.
⑤	A section (horizontal row) for widgets, shown with one column in this example.

There are four options for widgets:

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

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

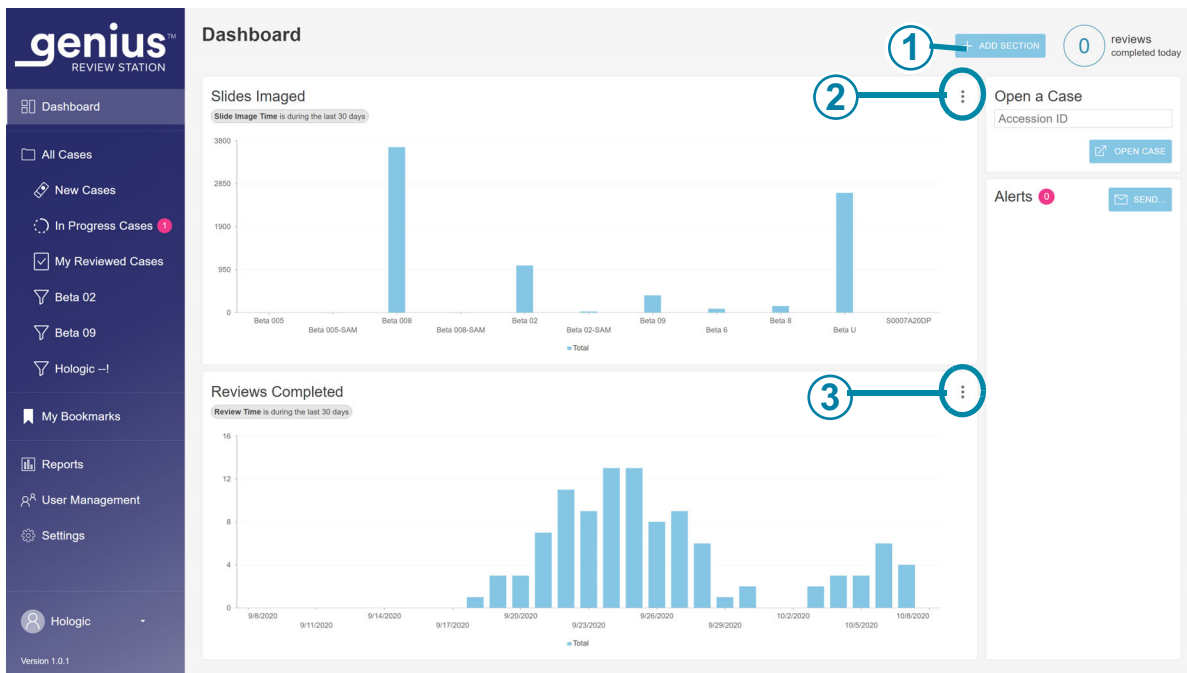


Figure 3-15 Review Station Dashboard, widget options button

Key to Figure 3-15	
①	Use the +Add Section button on the Dashboard. See “Add a widget to the Dashboard” on page 3.32.
②	The options button looks like three dots. Use the options to remove or edit the existing widgets on the Dashboard. In this example, this button allows the user to edit or remove the Slides Imaged widget.
③	The options button looks like three dots. Use the options to remove or edit the existing widgets on the Dashboard. In this example, this button allows the user to edit or remove the Reviews Completed widget.

Remove a widget from the Dashboard

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

3

USER INTERFACE

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

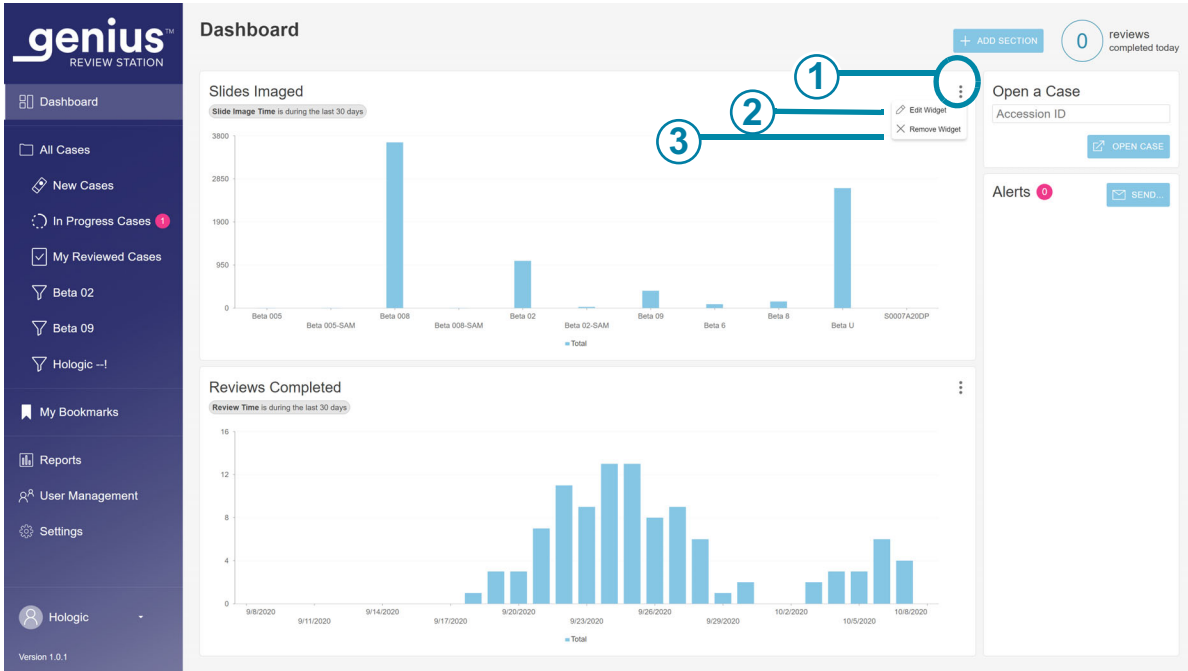


Figure 3-16 Review Station Dashboard, add widget section, remove or edit widget

Key to Figure 3-16	
①	The options button looks like three dots. Click here to see the Edit Widget and Remove Widget options.
②	Edit Widget Refer to “Edit a widget” on page 3.31.
③	Remove Widget Click here to remove this widget from the Dashboard.

Edit a widget

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



Figure 3-17 Review Station Dashboard, edit a widget

Key to Figure 3-17	
①	<p>Widget Name Type in a name for the widget.</p>
②	<p>Graph Type Click on the icon representing the kind of graph for the widget (graphed area, horizontal bar chart, circle, or vertical columns).</p>

Key to Figure 3-17	
③	<p>Filters</p> <p>Use the drop-down menus to set the criteria for a filter.</p> <p>In this example, the data displayed in the widget can be filtered by sample type, by Digital Imager, and/or by slide image time because this example is a Slides Imaged widget. The filter criteria differ for the different widgets.</p> <p>Caution: There are limits on how much data can be displayed in a graph. If the filter will generate too much data, an error message will appear, recommending that the selections for the filter be changed.</p> <p>Note: Choose the interval that is one unit smaller than the desired time period. For example, for a graph of slides imaged in a one-year period, try selecting a time interval of month; for a graph of slides imaged in a month, try selecting a time interval of a week.</p>
④	<p>Category or segmentation category</p> <p>Depending on the graph type, the edit widget screen may have a category section for choosing x- and y-axes for the graph, and it may have a segmentation category.</p> <p>When segmentation is used, when the user hovers the mouse over a portion of the graph, the values for each segment in that section of the graph are displayed.</p> <p>Use the drop-down menu to set the criteria for the graph axes or the segmentation. Using segmentation in one of the widget graphs shows more detail, showing which data contributed to the section of the graph.</p>
⑤	<p>Segment</p> <p>When some segmentation categories are used, such as time, a segment can also be specified.</p> <p>For example, a user can set up a widget with a segmentation category of slide image time and a segment of "day" to see how many slides per Digital Imager were imaged in a day.</p>

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

Add a widget to the Dashboard

1. To add a section and a widget, select "+Add Section".
2. Choose the layout for the section. The Dashboard can show the widgets in one, two or three columns. Select the number of columns that you prefer.
3. Select "continue". An empty space for graphs appears on the screen.
4. Select "+" in the center of the empty space for graphs. The screen shows the four options for widgets.
5. Select one of the options and the widget is added to the Dashboard. To edit the widget, select the three dots. The options for editing a new widget are the same for editing an existing widget. Refer to "Review Station Dashboard, edit a widget" on page 3.31.

Case Lists

Hide Archived Cases

The reviewer can specify whether the list of cases should show or hide cases that have been archived or not.

Data for archived cases is stored in the Genius Digital Diagnostics System database. The images for an archived cases are not immediately available for viewing on the Review Station. An archived case must be retrieved from storage before its images can be viewed. For more information on archived cases, refer to “Archive” on page 3.21.

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

Search by accession ID

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

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

The list of cases changes to the search results.

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

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

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

Search by tag

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

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

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

The list of cases changes to the search results. The search criteria for this tag can be saved as a custom filter. When the search results are displayed in the Case List, click **Save as Custom Filter...** For information on saving custom filters, refer to “Save a custom filter” on page 3.40.

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

All Cases

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

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

The data in the list of cases can be filtered by different criteria. The lists of cases can include or exclude archived cases by un-checking or checking the “Hide Archived Cases” button.

New Cases

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

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

In Progress Cases

“In Progress” cases are the cases that the current reviewer has saved as “in Progress”.

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

My Reviewed Cases

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

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

Case Details

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

The screenshot displays the 'All Cases' section of the Genius Review Station. The interface includes a sidebar with navigation options like 'Dashboard', 'All Cases', 'New Cases', 'In Progress Cases', 'My Reviewed Cases', 'Beta 02', 'Beta 09', 'Hologic', 'My Bookmarks', 'Reports', 'User Management', and 'Settings'. The main area shows a table of cases with columns for Accession ID, Case Type, Status, and Imaged On. A detailed view for case '77701529999_A' is shown on the right, featuring a photo of the slide, a status indicator, and a 'Reclaim Case' button.

Accession ID	Case Type	Status	Imaged On
201904090908358...	Gyn	New	9/10/2020 8:00 AM
201904090904582...	Gyn	New	9/2/2020 2:03 PM
201904090905481...	Gyn	New	9/2/2020 2:03 PM
70296179999	Non-Gyn	New	8/21/2020 12:04 PM
77701529999_A	Gyn	New	6/5/2020 10:22 AM
70310019999	Gyn	New	1/9/2020 8:58 AM
70310029999	Gyn	New	1/8/2020 5:35 PM
70310039999	Gyn	New	1/8/2020 5:33 PM
70310049999	Gyn	New	1/8/2020 5:30 PM
70310059999	Gyn	New	1/8/2020 5:28 PM

Figure 3-18 Case Detail - Gyn example, manager role

The Case Details section shows the case type, a photo of the entire slide including its label, a status indicator describing if the case has been reviewed or not, the date the slide was imaged, and the Imager where the slide was imaged. A Case History summarizes the review status, review date and reviewer.

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

In the Case Details section, a manager has two options that are not available to a reviewer: "Reclaim a case" and "Delete a case".

Reclaim a case

(Manager only, in-progress cases only)

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

Find the case to reclaim. Use the "Search by Accession ID" search bar, or consider filtering "In Progress Cases" by a reviewer's name.

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

3

USER INTERFACE

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

The status remains “In progress”, and that manager is now assigned as the reviewer for the case. The existing comments and marks are included with the case. The manager can now complete the review for the case.

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

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

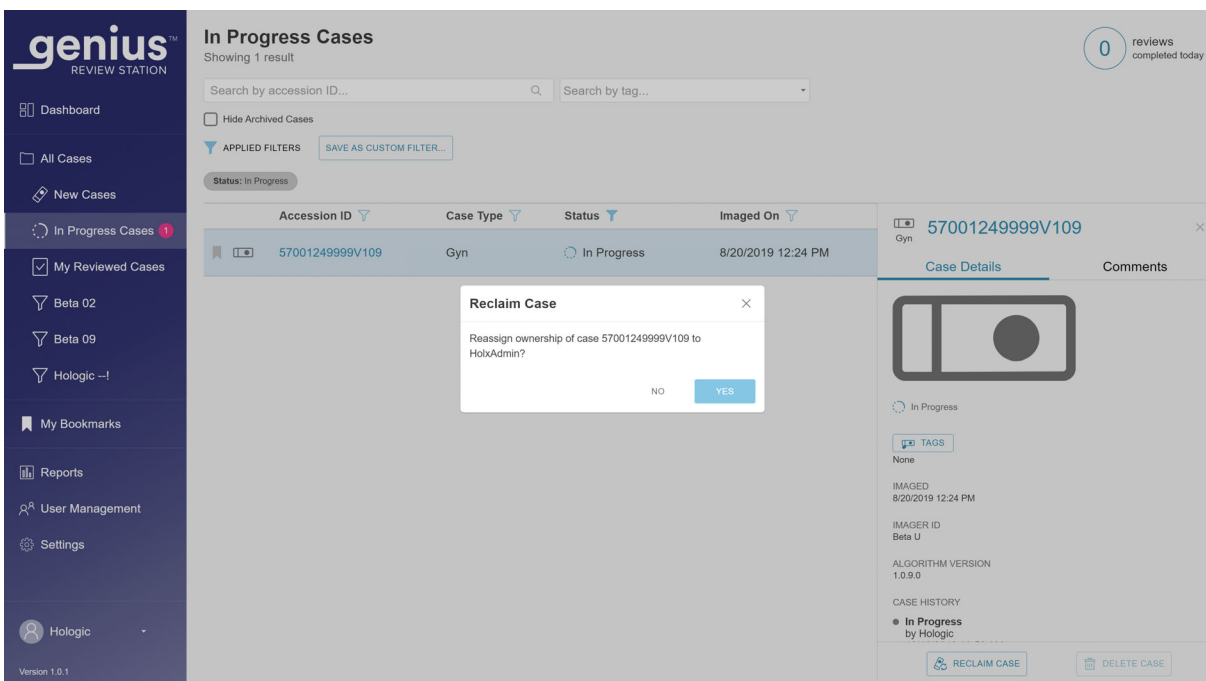


Figure 3-19 Reclaim an in-progress case by a manager

Delete a Slide

(Manager only, new cases only)

A manager has a **Delete Slide** button available in the Case Details section of new cases. This feature may be helpful in cases where there is a need to re-image the slide. Cases that are in progress or already reviewed cannot be deleted.

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

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

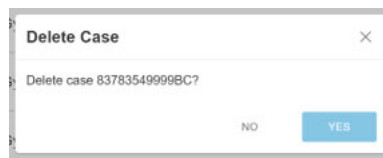


Figure 3-20 Confirm deletion (manager only, new cases only)

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

Data Filters

Using Data Filters

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

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

3

USER INTERFACE

Accession ID Filter – the Accession ID Filter can be used to search for all cases that contain specific number or letters. Or, the Accession ID Filter can be used to search for all cases between a specific numeric range.

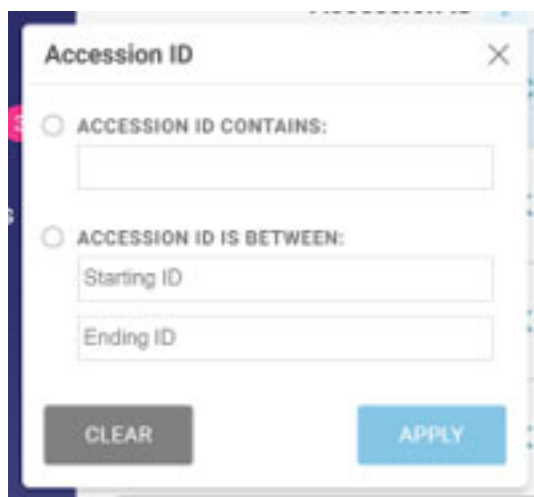
The screenshot shows a dialog box titled "Accession ID" with a close button (X) in the top right corner. It contains two radio button options. The first option is "ACCESSION ID CONTAINS:" followed by a text input field. The second option is "ACCESSION ID IS BETWEEN:" followed by two text input fields labeled "Starting ID" and "Ending ID". At the bottom of the dialog, there are two buttons: "CLEAR" (grey) and "APPLY" (blue).

Figure 3-21 Accession ID Filter

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

- Set the filter to Gyn to display only Gyn cases.
- Set the filter to Non-Gyn to display only Non-Gyn cases.
- Set the filter to UroCyte to display only UroCyte cases.

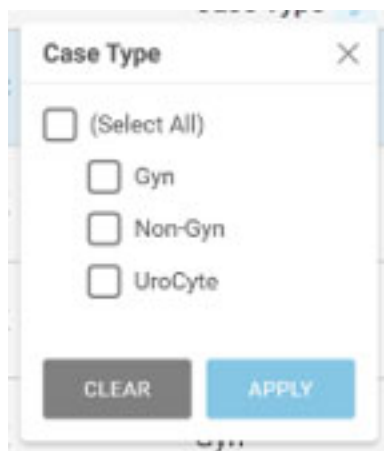
The screenshot shows a dialog box titled "Case Type" with a close button (X) in the top right corner. It contains three checkbox options: "(Select All)", "Gyn", "Non-Gyn", and "UroCyte". At the bottom of the dialog, there are two buttons: "CLEAR" (grey) and "APPLY" (blue).

Figure 3-22 Case Type Filter

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

- Set the filter to "New" to display cases where no review of the slide image has started.

- Set the filter to “In Progress” to display cases where a review of the slide image has started but has not been completed.
- Set the filter to “Reviewed” to display cases where the review of the slide image has been marked as reviewed in the Review Station.

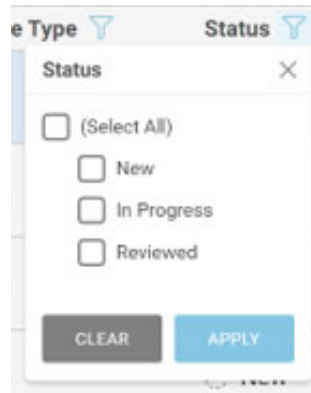


Figure 3-23 Status Filter

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

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

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

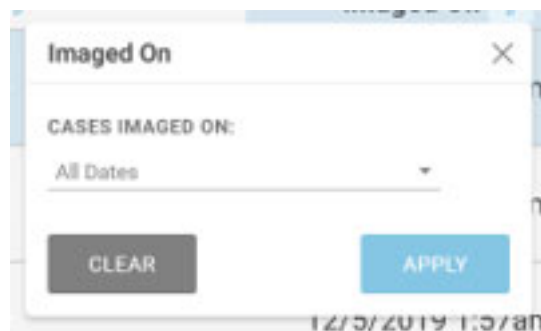


Figure 3-24 Imaged On Filter

Last Reviewed Filter – to display results for cases that were reviewed on a certain date or a certain period of time, use the Last Reviewed filter. The “Last Reviewed” date is the latest date that review

data for a case was saved from any Review Station connected to the Image Management Server, reviewed by any reviewer.

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

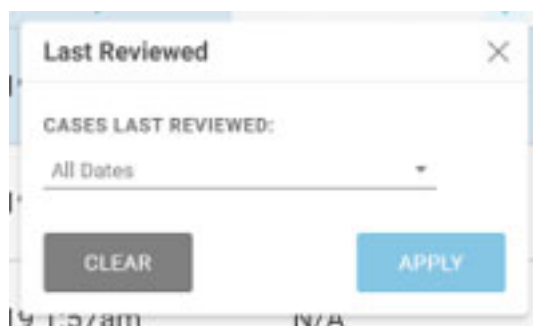


Figure 3-25 Last Reviewed Filter

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

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

Save a custom filter

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

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

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

Edit a custom filter’s filter criteria

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

Edit the name of a custom filter

1. To change the name of a custom filter or its filter criteria, select the custom filter in the menu bar on the left.
2. Select the **Edit name** button in the upper right.

3. Type the new name where the existing custom name is shown.
4. Select **Continue** to change the name, or select **Cancel** to leave the name unchanged.

Delete a custom filter

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

Log out

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

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

Alerts

The Alerts feature provides a way for a manager to send a message to the Dashboard of one or more reviewers.

Send an alert

(Manager and automatic only)

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

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

1. Click in the Alerts area on the right side of the Dashboard screen.
2. Type in the text for the alert with the keyboard.
3. Click **Send** and select from the available options to send an alert to all reviewers, all managers, or one individual user.

Receive and read an alert

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

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

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

SECTION
F

BOOKMARKS

Use the Bookmarks feature to save an individual case or groups of cases for future reference. The Bookmarks feature is intended to make individual cases and individual categories of cases readily available. The use of bookmarks is optional.

Setting up Bookmarks

Categories

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

Uncategorized

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

Create a Bookmark

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

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

Using Bookmarks

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

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

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

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

SECTION
G

REPORTS

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

Standard reports

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

1. To view reports, select Reports in the menu bar on the left.
2. Select a report from the list. A description and criteria for filtering and sorting appear on a pane on the right.
3. For each report, select the filter criteria and select the sorting criteria.
4. Either select **Run Report** to run the report

or

Select **Save as Custom**. Saving a custom report saves a report with the specified filter criteria and sorting criteria. When the “Save as New Report” screen appears, type in a name for the custom report. To add an optional description for the report, type a description into the “Description” box.

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

To save the name and description, press “Continue.”

Once it is saved, the custom report is available in the list of reports for the reviewer who created the custom report. Select the report name to run the report.

3

USER INTERFACE

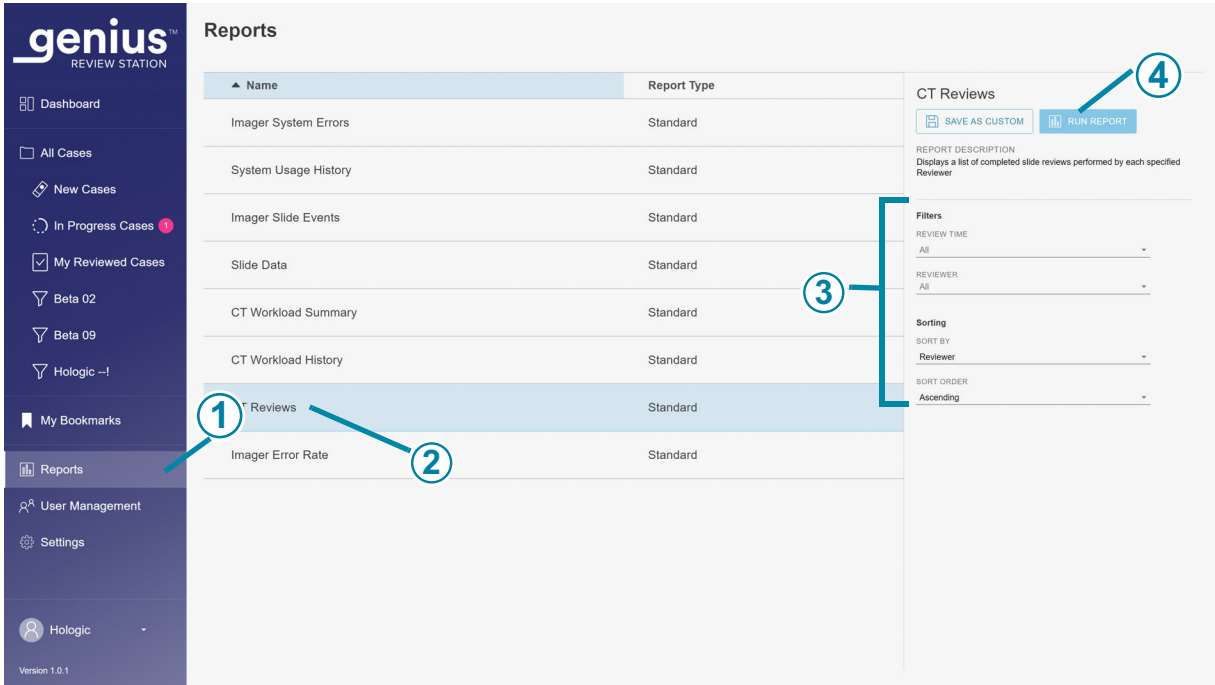


Figure 3-26 List of Reports, CT Reviews selected

Key to Figure 3-26	
①	Click on Reports .
②	Select the name of an existing report.
③	Select the criteria for filtering and sorting the data in the report.
④	Select Run Report , or save the report as a custom report and then run the report.

- When a report is run, the report results appear in a new window on the screen. The heading shows the name of the report, the number of entries in the report, the date the report was generated, and the lab name.

Use the buttons on the upper right to print the report as a PDF or to export the report as a CSV file. Reports saved as CSV will open in Microsoft Excel or Notepad depending on what applications are installed on the Review Station computer. A PDF or CSV file can be saved on the Review Station computer.

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

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

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

Custom Time Period for Reports

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

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

CT Reviews

The CT Reviews Report lists individual accession IDs reviewed during a period of time. A manager can select more than one reviewer to include in the report. When a reviewer runs the report, the data only includes that one reviewer.

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

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

3

USER INTERFACE

Note: Each review of a case, whether an initial review by a CT, a subsequent review for quality control or a review by a pathologist, is considered a review by the Review Station.

3. Choose the category that will be used to sort the data in the report. The CT Reviews report is preset to sort by the name of the reviewer, and it is the only available option.
4. Choose the order in which the data will appear:
 - Sort the results in ascending or descending order.

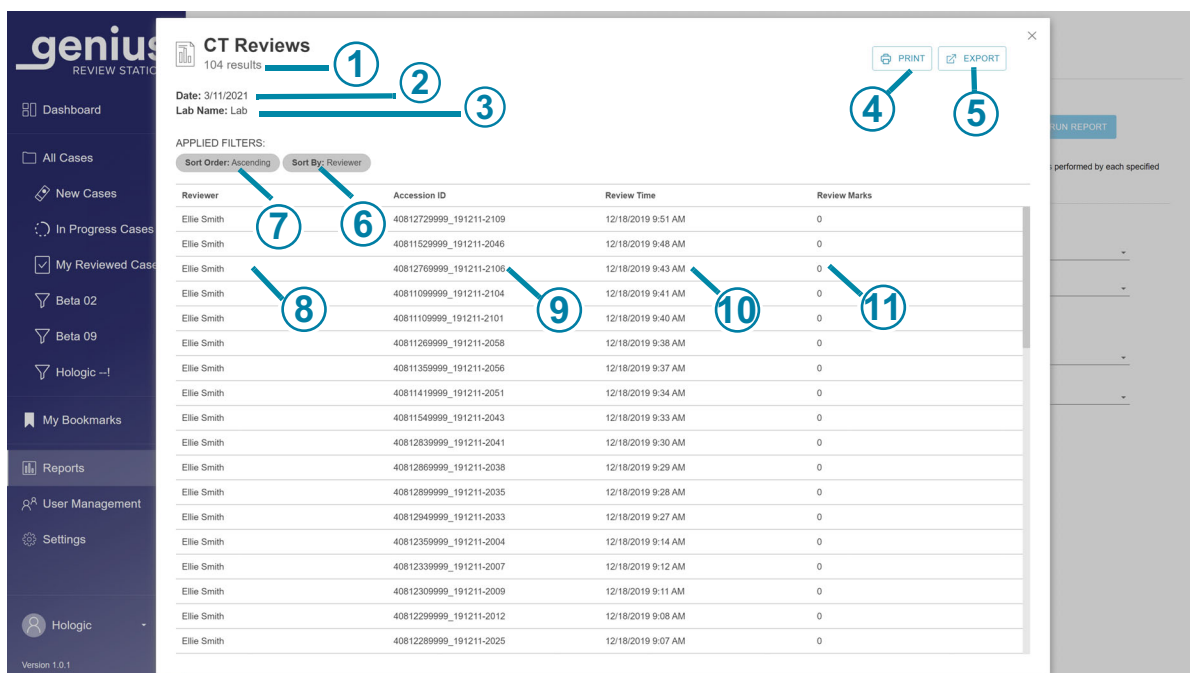


Figure 3-27 CT Reviews Report, example

Key to Figure 3-27	
①	Total number of reviews during the time period for the report Note: For any report, if there is no data that meets the report criteria, the report will list “0 results” in the header.
②	Date the report is run (today’s date)

Key to Figure 3-27	
③	Lab name
④	Print to PDF
⑤	Export the data as a CSV file
⑥	The sorting criteria for the data in the report. For the CT Reviews Report, the “Sort by” criteria is by Reviewer.
⑦	The sorting order for the data in the report.
⑧	The name of this CT
⑨	The date and time that the case review was completed
⑩	The Accession ID for each case reviewed by this CT during this time period
⑪	The number of marks saved on that case

CT Workload History

The CT Workload History Report lists the total number of reviews completed by a Review Station user (reviews per person) during a period of time. A manager can select more than one reviewer to include in the report. When a reviewer runs the report, the data only includes that one reviewer.

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

1. Choose the time period for the report data.

3

USER INTERFACE

Select a review time from the available options of:

- All (up to one year of data on the server, starting at the current date)
 - Today
 - Yesterday
 - Last 7 Days
 - Last 30 Days
 - Custom
2. A manager must also choose which reviewers to include in the report data.
- Select one or more reviewers by clicking on name(s) of the reviewer in the list, or
 - All (all of the reviewers in the server's database)

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

3. Choose a time interval. This determines the level of detail for the data in the report. Select from the available options of:
- All (this selects the largest interval, which is by the calendar year)
 - Hour
 - Day
 - Week (the start of each reviewer's week in the report is the day of the week that the first review by that reviewer was completed. In the report, the week may or may not start on a Sunday or a Monday.)
 - Month
 - Year
4. Choose the category that will be used to sort the data in the report. Choose from:
- Review Time
 - Reviewer
5. Choose the order in which the data will appear:
- Sort the results by the reviewers' names.
 - Sort the results by time period.

CT Workload History
4 results

Date: 3/11/2021
Lab Name: Lab

APPLIED FILTERS:
Sort Order: Ascending Sort By: Reviewer

Reviewer	Time Interval	Review Count
Ellie Smith	2019	79
Hologic	2019	1
Jack Johnson	2019	1
James Jones	2019	19
	2020	4

Figure 3-28 CT Workload History Report, example

CT Workload Summary

The CT Workload Summary lists how many reviews were done by each reviewer over a specific time period. When a manager runs the CT Workload Summary Report, the report includes all reviewers in the database. When a reviewer runs the report, the data only includes that one reviewer.

Note: The CT Workload Summary does not separate out the workload by a time interval over a period of time. The CT Workload Summary lists the workload over a period of time. For example, the CT Workload Summary Report can show the number of reviews in a month.

1. Choose the time period for the report data.
Select a review time from the available options of:
 - All (all of the data in the server’s database)
 - Today
 - Yesterday
 - Last 7 Days
 - Last 30 Days
 - Custom
2. Choose the category that will be used to sort the data in the report. Choose from:
 - Review Time
 - Reviewer

3

USER INTERFACE

3. Choose the order in which the data will appear:
 - Sort the results by the reviewers' names.
 - Sort the results by the number of completed reviews.

The screenshot displays the 'CT Workload Summary' report in the Genius Review Station interface. The report is for the date 3/11/2021 and Lab Name: Lab. It shows 4 results. The data is sorted by Reviewer. The table below represents the data shown in the report.

Reviewer	Review Count
Ellie Smith	79
Hologic	1
Jack Johnson	1
James Jones	23

Figure 3-29 CT Workload Summary Report, example

Review Station Reports for Errors

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

Imager slide events on the Digital Imager are errors related to slide processing. The Imager slide events codes are described in "Slide Event Messages" on page 6.3.

Imager System errors are errors related to instrument performance. The Imager System error codes are described in "Imager Error Codes" on page 6.5.

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

Imager Error Rate

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

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

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

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

1. Choose the time period for the report data.
Select a review time from the available options of:
 - All (all of the data in the server's database)
 - Today
 - Yesterday
 - Last 7 Days
 - Last 30 Days
 - Custom
2. Choose which Digital Imager(s) to include in the report.
Select the name of one or more Digital Imagers from the list, or select **All**.
3. Choose the category that will be used to sort the data in the report. Choose from:
 - The name of the Digital Imager
 - The percentage of errors
4. Choose the order in which the data will appear:
 - Sort the results in ascending or descending order.

Imager Error Rate
11 results

Date: 3/11/2021
Lab Name: Lab

APPLIED FILTERS:
Sort Order: Ascending Sort By: Imager ID

Imager ID	Slide Image Count	Error Count	Error Rate
Beta 005	142	6	4.2%
Beta 005-SAM	4	0	0%
Beta 008	5,736	84	1.5%
Beta 008-SAM	4	0	0%
Beta 02	1,357	37	2.7%
Beta 02-SAM	26	0	0%
Beta 05	234	3	1.3%
Beta 09	444	5	1.1%
Beta 6	101	4	4%
Beta 8	218	4	1.8%
Beta U	2,752	96	3.5%

Figure 3-30 Imager Error Rate Report, example

Imager Slide Events

The Imager Slide Events Report lists detailed information about errors from one or more Digital Imager over a specific time period. The Imager Slide Events Report lists the Accession ID, the date and time that the error occurred, the error number, the sample type, the name of the Digital Imager and the version of software running on the Digital Imager at the time.

1. Choose the time period for the report data. The time in this report is the time the slide was processed on the Digital Imager.
Select the time period from the available options of:
 - All (all of the data in the server's database)
 - Today
 - Yesterday
 - Last 7 Days
 - Last 30 Days
 - Custom
2. Choose which Sample Type(s) to include in the report. Select from the available options:
 - Gyn
 - Non-Gyn

- UroCyte
- All

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

3. Choose which Digital Imager(s) to include in the report.
Select the name of one or more Digital Imagers from the list, or select **All**.
4. Choose the category that will be used to sort the data in the report. Choose from:
 - The name of the Digital Imager
 - The Accession ID
 - The Slide Image Time
 - The error number
 - The sample type
 - The software version
5. Choose the order in which the data will appear. Sort the results in ascending or descending order.

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

Imager Slide Events
1000 results

Date: 3/11/2021
Lab Name: Lab
Too many results match these criteria. Showing a portion of the results. Specify additional filter criteria to reduce results.

APPLIED FILTERS:
Sort Order: Ascending Sort By: Imager ID

Accession ID	Slide Image Time	Error Number	Sample Type	Imager ID	Software Version
19190809999_191121-1344	11/21/2019 1:53 PM	E0007	Gyn	Beta 005	0.0.0.0
19190799999_191121-1342	11/21/2019 1:47 PM	E0007	Gyn	Beta 005	0.0.0.0
19190789999_191121-1336	11/21/2019 1:42 PM	E0018	Gyn	Beta 005	0.0.0.0
19190779999_191121-1331	11/21/2019 1:39 PM	E0007	Gyn	Beta 005	0.0.0.0
19190769999_191121-1326	11/21/2019 1:34 PM	E0007	Gyn	Beta 005	0.0.0.0
19190759999_191121-1320	11/21/2019 1:29 PM	E0007	Gyn	Beta 005	0.0.0.0
19190749999_191121-1315	11/21/2019 1:23 PM	E0007	Gyn	Beta 005	0.0.0.0
19190739999_191121-1309	11/21/2019 1:18 PM	E0007	Gyn	Beta 005	0.0.0.0
19190729999_191121-1304	11/21/2019 1:13 PM	E0007	Gyn	Beta 005	0.0.0.0
19190719999_191121-1299	11/21/2019 1:07 PM	E0007	Gyn	Beta 005	0.0.0.0
19190699999_191121-1253	11/21/2019 1:02 PM	E0007	Gyn	Beta 005	0.0.0.0
19190689999_191121-1248	11/21/2019 12:56 PM	E0007	Gyn	Beta 005	0.0.0.0
19190739999_191121-1242	11/21/2019 12:51 PM	E0007	Gyn	Beta 005	0.0.0.0
19190619999_191121-1237	11/21/2019 12:46 PM	E0007	Gyn	Beta 005	0.0.0.0
19190629999_191121-1232	11/21/2019 12:40 PM	E0007	Gyn	Beta 005	0.0.0.0
19190639999_191121-1227	11/21/2019 12:35 PM	E0007	Gyn	Beta 005	0.0.0.0
19190649999_191121-1221	11/21/2019 12:30 PM	E0007	Gyn	Beta 005	0.0.0.0
19190659999_191121-1216	11/21/2019 12:24 PM	E0007	Gyn	Beta 005	0.0.0.0

Figure 3-31 Imager Slide Events Report, example

Imager System Errors

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

- Choose the time period for the report data. The time in this report is the time the slide was processed on the Digital Imager.
Select the time period from the available options of:
 - All (all of the data in the server's database)
 - Today
 - Yesterday
 - Last 7 Days
 - Last 30 Days
 - Custom
- Choose which Digital Imager(s) to include in the report.
Select the name of one or more Digital Imagers from the list, or select **All**.
- Choose the category that will be used to sort the data in the report. Choose from:
 - The name of the Digital Imager
 - The time the error occurred

- The error number
 - The software version
4. Choose the order in which the data will appear. Sort the results in ascending or descending order.

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

Imager ID	Error Number	Error Time	Software Version
Beta 8	E1004	7/11/2019 7:33 PM	0.0.0.0
Beta 8	E4027	7/11/2019 7:33 PM	0.0.0.0
Beta 8	E5003	7/11/2019 7:33 PM	0.0.0.0
Beta 8	E1004	7/11/2019 7:25 PM	0.0.0.0
Beta 8	E4027	7/11/2019 7:25 PM	0.0.0.0
Beta 8	E5003	7/11/2019 7:25 PM	0.0.0.0
Beta 8	E0502	7/11/2019 7:19 PM	0.0.0.0
Beta 8	E1000	7/11/2019 7:17 PM	0.0.0.0
Beta 8	E1019	7/11/2019 7:17 PM	0.0.0.0
Beta 8	E0502	7/11/2019 7:22 PM	0.0.0.0
Beta 8	E0502	6/19/2019 1:12 PM	0.0.0.0
Beta 8	E1000	6/19/2019 1:10 PM	0.0.0.0
Beta 8	E0502	6/19/2019 10:13 AM	0.0.0.0
Beta 8	E1000	6/18/2019 3:45 PM	0.0.0.0
Beta 8	E1000	6/18/2019 3:06 PM	0.0.0.0
Beta 8	E1002	6/18/2019 3:04 PM	0.0.0.0
Beta 8	E1000	6/18/2019 3:04 PM	0.0.0.0
Beta 8	E2501	6/18/2019 3:04 PM	0.0.0.0

Figure 3-32 Imager System Errors Report, example

Slide Data

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

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

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

Select the imaging criteria for the Slide Data Report

The screenshot displays the Genius Review Station interface. On the left is a dark blue sidebar with navigation icons and labels: Dashboard, All Cases, New Cases, In Progress Cases (with a red notification dot), My Reviewed Cases, Beta 02, Beta 09, Hologic, My Bookmarks, Reports (highlighted), User Management, Settings, and Hologic (with a user profile icon and 'Version 1.0.1' at the bottom). The main area is titled 'Reports' and contains a table with two columns: 'Name' and 'Report Type'. The table lists several reports, with 'Slide Data' highlighted in blue. To the right of the table is the 'Slide Data' configuration panel. It features a 'SAVE AS CUSTOM' button and a 'RUN REPORT' button. Below these is a 'REPORT DESCRIPTION' section stating 'Displays basic imaging and review information for slide data sets'. The 'Filters' section includes dropdown menus for 'SLIDE IMAGE TIME' (set to 'All'), 'ACCESSION ID' (with an input field), 'SAMPLE TYPE' (set to 'All'), 'SLIDE IMAGE STATUS' (set to 'All'), and 'REVIEW TIME' (set to 'All'). A 'Slide Image Time' dropdown is expanded, showing options: 'Accession ID' (checked), 'Sample Type', 'Imager ID', 'Slide Image Status', 'Review Station ID', 'Reviewer', and 'Review Time'. At the bottom, there is an 'Accession ID' input field and a 'SORT ORDER' dropdown set to 'Ascending'.

Figure 3-33 Select criteria for Slide Data Report

1. Choose the slide image time period for the report data. This is the time the slide was processed on the Digital Imager.
2. Select the time period from the available options of:
 - All (all of the data in the server’s database)
 - Today
 - Yesterday
 - Last 7 Days
 - Last 30 Days
 - Custom

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

3. Choose which Accession IDs to include in the report.
Enter several characters that appear in Accession IDs, the entire Accession ID, or leave the field blank to include all Accession IDs.
4. Choose which Digital Imagers to include in the report.
Select the name of one or more Digital Imagers from the list, or select **All**.
5. Choose which Sample Type(s) to include in the report. Select from the available options:
 - Gyn

- Non-Gyn
- UroCyte
- All

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

6. Choose which Slide Image Status criteria to include in the report. This includes or excludes slides with slide imaging events. Select from the available options:
 - All
 - Success
 - Error
7. Choose the category that will be used to sort the data in the report. Choose from:
 - The name of the Digital Imager
 - The Accession ID
 - The Slide Image Time
 - The error number
 - The sample type
 - The software version

Select the case review criteria for the Slide Data Report

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

Note: When a case has been reviewed more than once, if any of the reviews is in the date range specified for the report, the case is included in the report.

2. Choose which Review Stations to include in the report.
Select the name of one or more Review Station IDs from the list, or select **All**.
3. A manager can also choose which reviewers to include in the report data.
 - Select one or more reviewers by clicking on the name of the reviewer(s) in the list, or
 - All (all of the reviewers in the server's database)

3

USER INTERFACE

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

4. Choose whether to include or exclude archived cases in the report. Select a "Slide Archived" status from the available options of:
 - All - The report will include data for active cases and for inactive cases that have not been archived yet.
 - Yes - The report will only include archived cases.
 - No - Archived cases will be excluded from the report.

Note: Depending on the range of data selected for the report, reporting out archived data could generate a very high number of results.

5. Choose the category that will be used to sort the data in the report. Choose from:
 - Accession ID
 - Imager ID
 - Slide Image Time
 - Slide Image Status
 - Sample Type
 - Review Time
 - Reviewer
6. Choose the order in which the data will appear. Sort the results in ascending or descending order.

Slide Data
1 result

Date: 3/11/2021
Lab Name: Lab

APPLIED FILTERS:
Sort Order: Ascending Sort By: Accession ID Accession ID: 660C

Accession ID	Imager ID	Slide Image Time	Slide Image Status	Sample Type	Review Station ID	Review Time	Reviewer
00010991660C	Beta U	4/19/2019 2:03 PM	OK	Gyn	DEV	12/5/2019 10:38 AM 5/16/2019 12:00 PM	Hologic James Jones

Figure 3-34 Slide Data Report, example

System Usage History

The System Usage History Report lists instrument activity over a specific time period.

1. Choose the time period for the report data.
Select an imaged time from the available options of:
 - All (all of the data in the server's database)
 - Today
 - Yesterday
 - Last 7 Days
 - Last 30 Days
 - Custom
2. Choose which systems to include in the report.
Select the name of one or more Review Station IDs from the list, one or more Digital Imagers on the list, or select **All**.
3. Choose the category that will be used to sort the data in the report. Choose from:
 - System ID
 - System Type
 - Success

3

USER INTERFACE

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

System Usage History
14 results

Date: 3/11/2021
Lab Name: Lab

APPLIED FILTERS:
Sort Order: Ascending Sort By: System ID

System ID	System Type	Success	Total
	Review Station	138	138
Beta 005	Imager	1,248	1,384
Beta 005-SAM	Imager	4	4
Beta 008	Imager	15,050	18,155
Beta 008-SAM	Imager	4	4
Beta 02	Imager	1,669	1,911
Beta 02-SAM	Imager	90	90
Beta 05	Imager	451	689
Beta 09	Imager	1,002	1,066
Beta 1-UA	Imager	2,642	2,728
Beta 2-UA	Imager	14	24
Beta 6	Imager	87	101
Beta 8	Imager	146	218
DEV	Review Station	18	18

Figure 3-35 System Usage History Report, example

Chapter Four

Operation

SECTION A

OVERVIEW

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

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

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

For all sample types (Gyn, Non-Gyn, and UroCyte), the Review Station presents an image of the whole cell spot. A reviewer can adjust the zoom of the whole slide image.

Case Review

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

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

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

Case Data Record

The case data record is the accumulation of all imaging and review activity the case encounters. The reports are generated from data that is in the case data record. A case data record is generated when

4

OPERATION

a valid slide ID is accepted into the Image Management Server's database. Items that are associated with the case data record include:

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

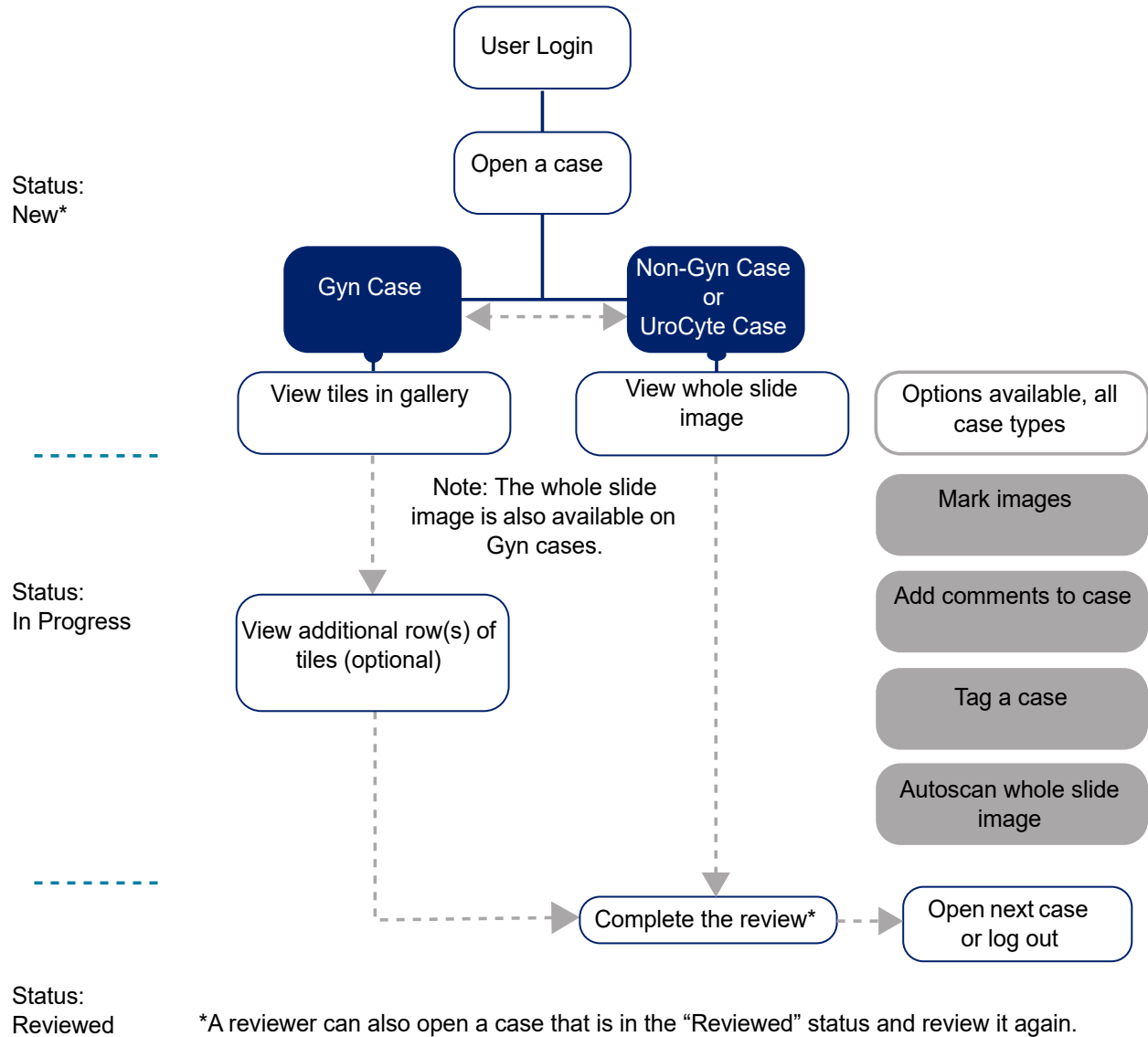


Figure 4-1 Typical Case Review Processes

4

OPERATION

SECTION B

MATERIALS REQUIRED PRIOR TO OPERATION

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

Important Operational Notes:

- For Gyn samples, examine the gallery of tiles
- Marking images - the case images are digitally marked by the CT or pathologist. Follow your laboratory's guidelines for marking objects of interest in case images.

SECTION
C

REVIEW A CASE

For Gyn cases, a gallery of images is presented to the reviewer. Additional images of the case are also available for viewing. A reviewer can mark the images and comment on the case.

For Non-Gyn and UroCyte cases, one image of the whole slide cell spot is presented to the reviewer. A reviewer can add marks and comments.

Open a case

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

From a Case List:

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

From the Dashboard, in the **Open a Case** section, type in the accession ID using the keyboard or, with the cursor in the Accession ID field, scan the accession ID from your laboratory records with the optional barcode scanner. Select **Open Case**, and the review screen displays. See Figure 3-6 on page 3.7.

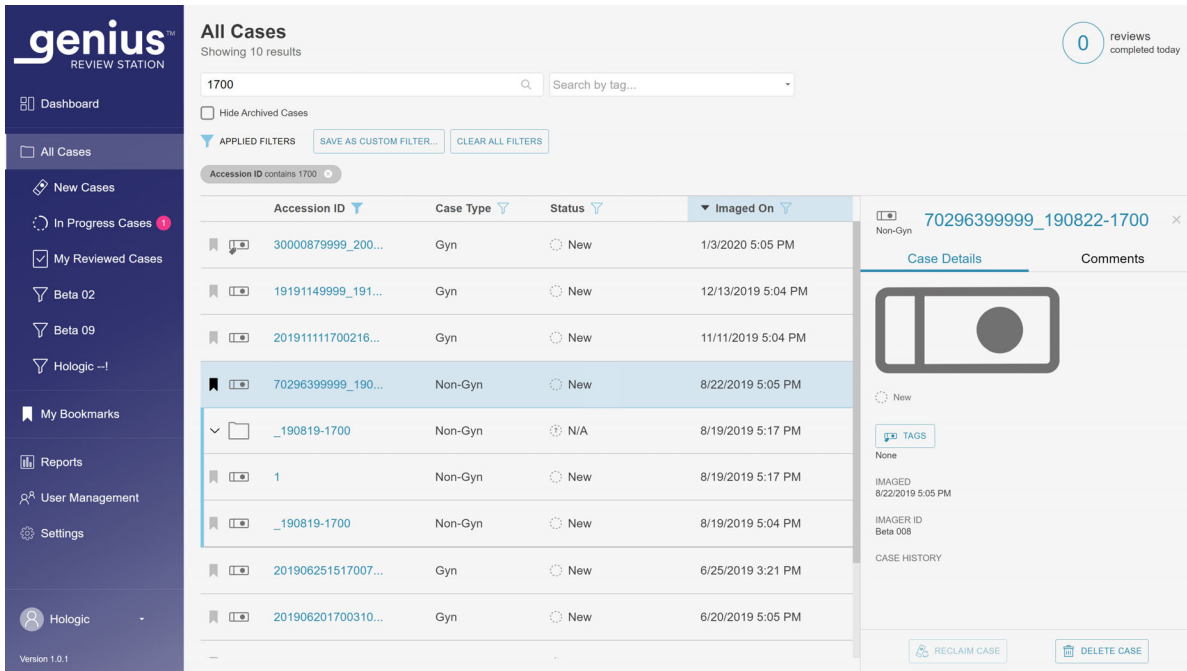


Figure 4-2 Case List - Click Accession ID to Open Case

Note: For Non-Gyn cases comprised of multiple slides grouped together with a primary ID, the accession ID in the Case List represents the group of slides. Click the arrow to the left of the primary ID or click anywhere in the blue shaded line to see the accession ID for each of the slides in that case. If the Digital Imager was not configured to group several Non-Gyn slides from the same case together, then each slide for a case is listed as a separate case.

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

The review screen for Gyn cases differs from the review screen for Non-Gyn and UroCyte cases.

Review Images for a Gyn Case

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

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

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

The heading of the review screen shows:

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

4

OPERATION

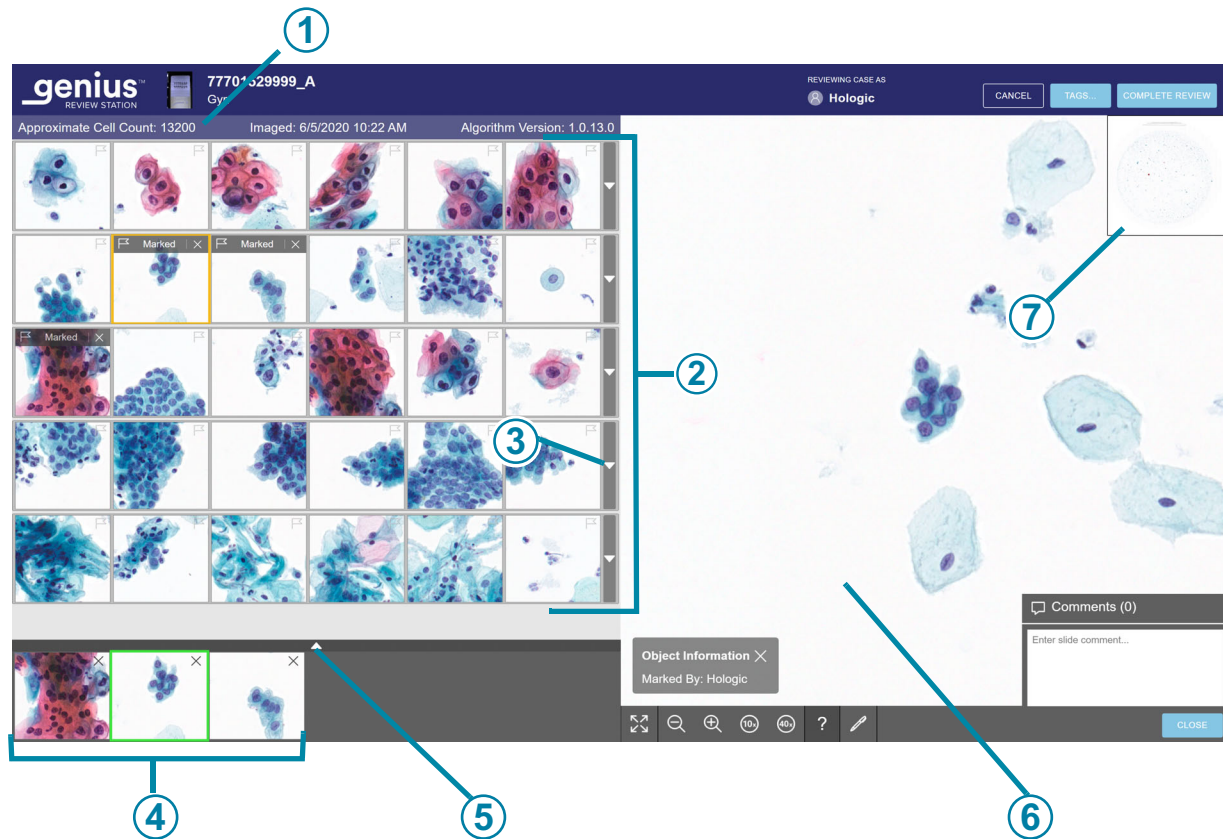


Figure 4-3 Gyn case - new case opened for review, example

Key to Figure 4-3	
①	Above the gallery, the approximate cell count, date the slide was imaged, and algorithm version display. Refer to “Cell count, date and algorithm version” on page 4.9 for more details.
②	The gallery of 30 tiles: five rows of six tiles. For Gyn cases only. Refer to “Review the Gallery of Objects of Interest (OOIs), Gyn Case” on page 4.9 for more details.
③	Arrow to show or hide additional rows in the gallery. Refer to “The Gallery, Gyn Case” on page 4.9 for more details.

Key to Figure 4-3	
④	“Shortlist” of marked cells. Refer to “About Shortlists of marked objects” on page 4.23 for more details.
⑤	Arrow to show or hide additional rows in the Shortlist. Refer to “About Shortlists of marked objects” on page 4.23 for more details.
⑥	Whole Slide Image and tools for navigating the whole slide image. Refer to “The Whole Slide Image, all Sample Types” on page 4.14 for more details.
⑦	Inset macroscopic view of the cell spot

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

The Genius cervical AI algorithm in the Genius Digital Diagnostics System analyzes the images of the whole cell spot on a Gyn case to identify the most diagnostically relevant objects. These objects of interest are presented on the Review Station at 20x magnification as a gallery of images.

- Review each of the tiles in the gallery. A reviewer can add marks to images.
If additional information is necessary to diagnose the case or determine specimen adequacy, optional rows of tiles in the gallery and the whole slide image to the right of the gallery are available. Refer to “The Gallery, Gyn Case” on page 4.9 and “The Whole Slide Image, all Sample Types” on page 4.14 for more information. The Review Station also provides the option of adding comments to a case. Refer to “Adding Comments” on page 4.14.
- When a reviewer finishes reviewing a case, from the review screen, click on the **Complete Review** button in the upper right.
- Next, click on **Confirm Review**.
All marks and any comments made by the reviewer are saved in the case.
In the Case List, the status for the case changes to “Reviewed”. A case in the “Reviewed” status can be reviewed by one or more subsequent reviewers.

The Gallery, Gyn Case

Cell count, date and algorithm version

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

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

4

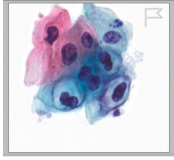

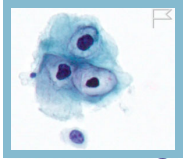

OPERATION

The count includes the entire cell region. It is not based on a partial sampling. This count is rounded off to provide an estimate.

Tiles of Objects of Interest

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

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


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

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

Navigate the Gallery and Mark Objects with a Mouse

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

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

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

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

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

Navigate the Gallery and Mark Objects with the Keyboard

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

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

To mark an image of a cell in a tile in the gallery with the keyboard, navigate to that tile and press the space bar.

The marked tile is added to the “Shortlist” of tiles at the bottom of the gallery.

To delete a mark, navigate to that tile and press the space bar.

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

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

Informational Messages from the Genius Cervical AI Algorithm

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



Figure 4-4 Gyn case with an informational message, text displayed, example

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

To read the informational message, click on the down arrow at the right edge of the pink bar. The messages are informational, intended as supplemental information that may help the reviewer

review the case. A reviewer can review the gallery of images and may opt to also check the whole slide image.

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

Table 4.1 Informational Messages

Message for Gyn Case	Possible Cause	Suggested Next Steps
Very few cells detected	The case has very low number of objects.	Review gallery. Check WSI. Check slide preparation.
Large amount of dark content	Something obscured part of the slide or part of the camera during slide imaging.	Review gallery. Check WSI. Check slide preparation.
High quantity of debris detected	The objects on the slide are mostly debris or other artifacts, not cells.	Review gallery. Check WSI. Check slide preparation.
Out of focus objects detected	The images of the case are focused well enough to be presented, but the image also includes some objects that are out of focus.	Review gallery. Check WSI. Check slide preparation.
Stain is very light	The nuclei are very light.	Review gallery. Check WSI. Check slide preparation.
Stain is very dark	The nuclei are very dark.	Review gallery. Check WSI. Check slide preparation.
High quantity of clumping detected	The case has clumped objects. These could be the result of a biological event where the sample may contain abundant clumpy inflammation or bacteria. The clumped objects could include blood, lysed blood cells, mucus, and lubricant. Typically there is some detectable background material in the clumps.	Review gallery. Check WSI. Check slide preparation.
High quantity of dark edges detected.	The case may have air bubbles, material retracted under the coverslip in the slide, or other hard-edged content, such as long strands of debris.	Review gallery. Check WSI. Check slide preparation.

The Whole Slide Image, all Sample Types

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

For Non-Gyn and UroCyte cases, the whole slide image is centered on the display.

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

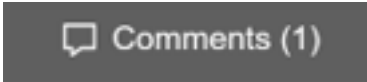
There are different options for navigating the whole slide image with the mouse and keyboard. And, there are different options for marking images in the tiles with the mouse and keyboard. A reviewer can switch between the mouse and keyboard at all times.

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

Adding Comments

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



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

3. Type in a comment, if any.

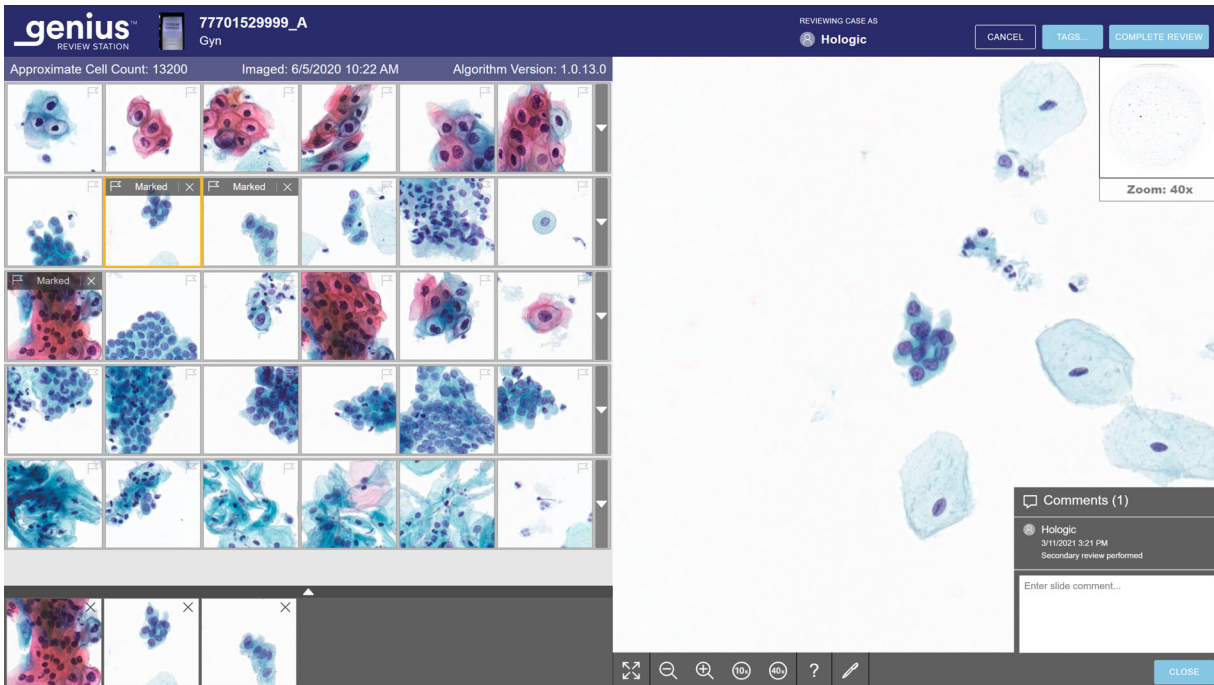


Figure 4-5 Add comments, view existing comments, Gyn example

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

Navigate the Whole Slide Image and Mark Objects with a Mouse

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

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

4

OPERATION

The toolbar under the whole slide image has several tools.

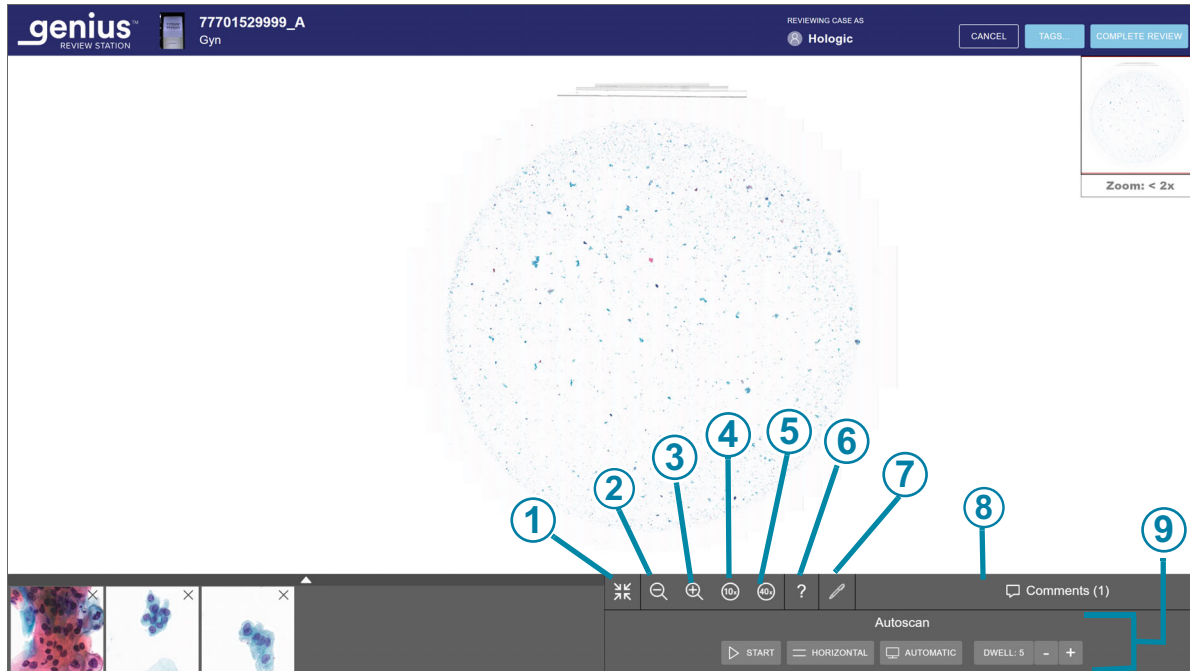







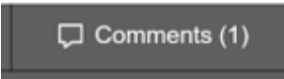


Figure 4-6 Toolbar under the whole slide image, example

Key to Figure 4-6	
①	 Expand to full screen (available only when a gallery is present) Select the icon to change the screen display so that the whole slide image fills the entire display area. To return to the gallery view, click the full screen tool again.
②	 Zoom out Click the mouse as many times as desired on the - button to zoom out.
③	 Zoom in Click the mouse as many times as desired on the + button to zoom in.

Key to Figure 4-6	
④	 <p>Zoom to 10x Click on the 10x button and the magnification zooms to the 10x view.</p>
⑤	 <p>Zoom to 40x Click on the 40x button and the magnification zooms to the 40x view.</p>
⑥	 <p>Object Information Click on the Object Information tool (the question mark) to select the tool. Then, click on a marked object in the Shortlist of tiles to see the name of the reviewer who made the mark.</p>
⑦	 <p>Mark Click on the mark tool (the pen) to select the tool. Then, click on the cell to mark in the whole slide image.</p>
⑧	 <p>Comments Click the comments button to read existing comments or to add new comments. The number of comments already in the case appears in parentheses on the button.</p>
⑨	Autoscan settings - The Autoscan settings are visible when the view of the whole slide image is expanded to fill the screen. For Gyn cases, expand to full screen to see the Autoscan settings.

Zoom and move the view in the whole slide image

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

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

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

4

OPERATION

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

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

Add marks

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

Click an image of a cell.

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

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

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

Add a tag

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

Note: On the Review Station, a bookmark lets one reviewer have cases readily available to that one reviewer. Cases with the same tag are available to all reviewers in the same Review Station network.

1. A tag must be set up by a manager before the tag can be associated with a case. A manager can set up a tag using the Settings menu. Refer to “Tags” on page 3.22.
Or, a manager set up a new tag from the **Tags...** button in a Case Review screen.

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

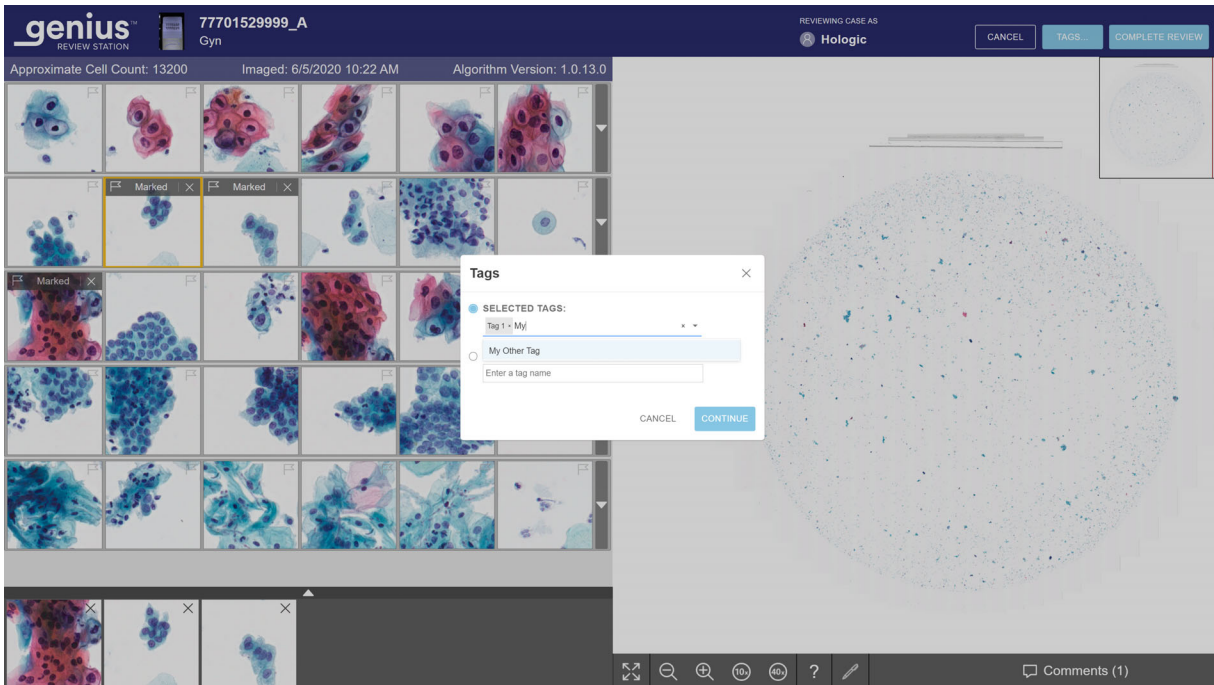


Figure 4-7 Tags, manager role shown

3. In the box that appears on the screen, select the name of the tag from the available options in the drop-down list, or type in the first few characters of the name of the tag to navigate to and select the tag in the list. The tags' names are listed in alphabetical order in the drop-down list.
- Note:** A manager can also create a new tag from this screen.
4. Click **Continue** to tag the case, or click **Cancel** to return to the review screen without tagging the case.

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

The screenshot displays the 'All Cases' screen in the Genius Review Station. The left sidebar contains navigation options like 'Dashboard', 'All Cases', 'New Cases', 'In Progress Cases', 'My Reviewed Cases', and various filters. The main area shows a table of cases with columns for Accession ID, Case Type, Status, and Imaged On. The case with Accession ID 70296179999 is highlighted. A blue circle with the number 1 points to the 'Tagged Case' icon (a document with a tag) next to this case in the list. On the right, the 'Case Details' section for case 70296179999 is shown, including a 'TAGS' button and a list of tags. A blue circle with the number 2 points to the 'TAGS' button.

Figure 4-8 Case Details screen for a case with a tag

Key to Figure 4-8	
①	The tagged case icon shows in the Case List.
②	<p>Tags... button in the Case Details screen The name of the tag (or tags) associated with the case appear in the Case Details section.</p> <p>A reviewer can click this Tags... button to add or remove a tag from the case. The steps are the same as adding a tag on the Case Review screen.</p> <p>If a manager changes the name of a tag, the name of the tag updates in the case details screen.</p> <p>If a manager deletes a tag from the Review Station network, that tag will no longer appear in the Case Details screen for a case.</p>

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

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

To remove a tag from this one case, in the Case Review screen, click the **Tags...** button again.

After a slide is tagged, that case and all of the cases with the same tag can be found by using the **Search by tag...** feature on the Case List. Refer to “**Search by tag**” on page 3.33.

Note: For Non-Gyn cases comprised of multiple slides grouped together with a primary ID, each slide in the group can use the same tag. Each slide in the group must be tagged individually to apply the same tag to each slide within the group.

Remove a tag

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

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

Autoscan

The Autoscan feature presents the entire cell spot in a defined path at 10x magnification view. A reviewer can choose the Autoscan to move in horizontal path or a vertical path. A reviewer can choose the Autoscan to move continuously or to automatically pause. Preferences can be set in a reviewer’s settings (refer to Figure 3-11), and a reviewer can change them with the Autoscan toolbar under the whole slide image.

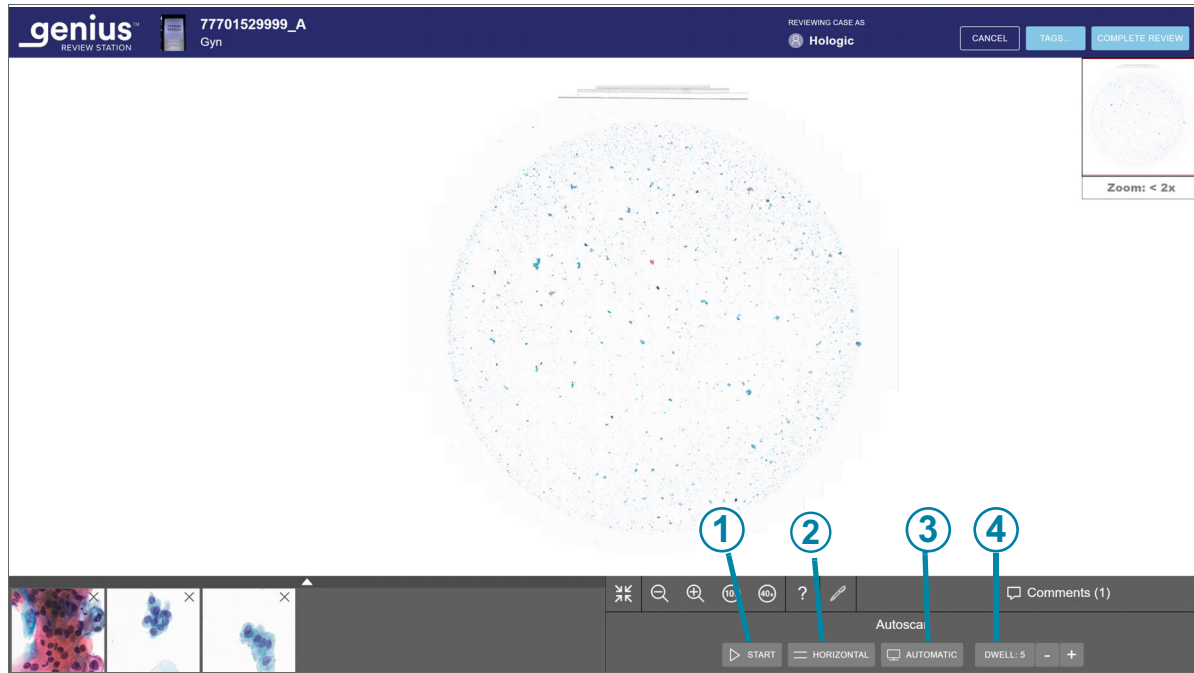


Figure 4-9 Autoscan toolbar

Key to Figure 4-9	
①	<p>Autoscan Start button</p> <p>When Autoscan has started, the Start button changes to a Pause button. When Autoscan is paused, the button changes to a Resume button. Use the buttons to start, pause, and resume the movement of the whole slide image through the Autoscan.</p> <p>After the Autoscan is started, a Stop button is available next to the Pause button. Click the stop button to stop and cancel the Autoscan.</p>
②	<p>Autoscan orientation button</p> <p>The Autoscan orientation button toggles between Horizontal and Vertical orientation. Click the button before starting the Autoscan to change the orientation.</p>
③	<p>Autoscan mode button</p> <p>The Autoscan mode button toggles between Continuous and Automatic modes. Click the button before starting the Autoscan to change the mode. Refer to Figure 3-11.</p>

Key to Figure 4-9

④

Autoscan speed or dwell time.

In Continuous mode, click the +/- buttons to increase or decrease the speed of the Autoscan movement. The speed ranges from 1 to 15, and the current speed is shown.

In Automatic mode, click the +/- buttons to increase or decrease the amount of time that the view will dwell in one position. The dwell time can be set from 1 to 15, and the current setting is shown.

In the whole slide image expanded to full screen, select the **Start** button in the Autoscan toolbar to start the Autoscan feature.

Note: For Gyn cases, the view must be expanded to the full screen view to run Autoscan.

While the Autoscan is running, a shaded path advances across the thumbnail image of the cell spot in the upper right of the screen, depicting the location of the portion of the whole slide image in view. The yellow path in the thumbnail view also shows the progress across the entire cell spot.

While the Autoscan is running, the **Pause** button and **Stop** button are available. The **Stop** button stops the Autoscan. Pressing the spacebar on the keyboard also pauses or resumes the Autoscan.

There are two ways to adjust the speed of the Autoscan while the Autoscan is in progress:

- Click the mouse as many times as desired on the + button to increase the speed or the – button to decrease the speed.
- On the keypad, press the right arrow to increase the speed or the left arrow to decrease the speed.

These selections persist for the review of this case and between cases, unless the reviewer changes them again.

Navigate the Whole Slide Image and Mark Objects with the Keyboard

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

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

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

About Shortlists of marked objects

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

The Shortlist is a gallery of marked tiles. For Gyn cases, the Shortlist is below the gallery. When a mark is added to a tile in the gallery, a flag icon is added to the tile in the gallery. Refer to “The Gallery, Gyn Case” on page 4.9.

For Non-Gyn cases and UroCyte cases, the Shortlist appears below the whole slide image.

For all sample types, when the Shortlist exceeds six tiles, the sixth tile changes to a number. For example, “+3” means marks have been made on three tiles that are not immediately in view.

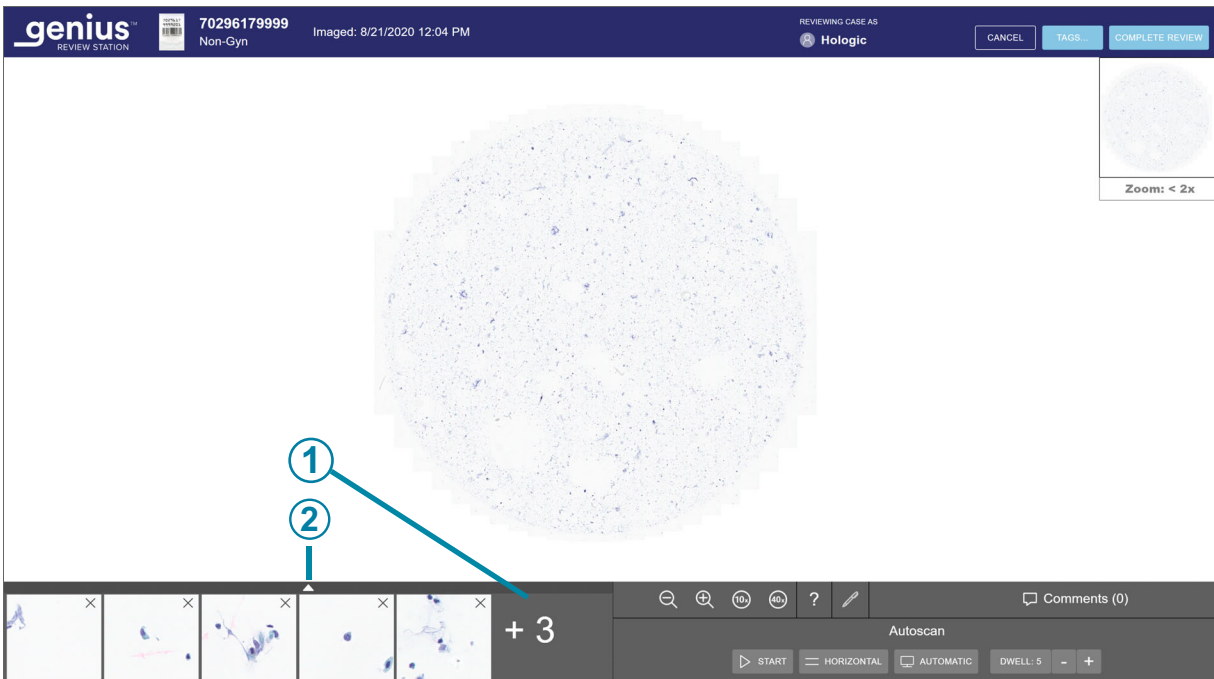


Figure 4-10 Shortlist of marked objects

Key to Figure 4-10	
①	The number indicates a longer Shortlist. In this example, three tiles are not immediately in view.
②	To expand the view to see all tiles, click the up arrow. Click the down arrow in the marked Shortlist to return to the six-tile view.

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

Non-Gyn cases grouped with a primary ID

For Non-Gyn cases that consist of multiple slides, the Digital Imager can be set up to group the individual slides together using the concept of a primary ID and a secondary ID. The primary ID is the portion of the accession ID that each of the slide IDs have in common, and the method for identifying a primary ID is configured on the Digital Imager.

On the Review Station, the primary ID “behaves” like a folder, grouping the individual slides together. Images from each individual slide in the grouped case are available within that folder. The folder is listed under the primary ID, and the individual slides that comprise the group are listed under the secondary ID.

Accession ID	Case Type	Status	Imaged On	Last Reviewed	Reviewed By
30000879999_200...	Gyn	New	1/3/2020 5:05 PM	N/A	N/A
19191149999_191...	Gyn	New	12/13/2019 5:04 PM	N/A	N/A
70296399999_190...	Non-Gyn	New	8/22/2019 5:05 PM	N/A	N/A
ABC	Non-Gyn	N/A	8/19/2019 5:17 PM	N/A	N/A
0001	Non-Gyn	New	8/19/2019 5:17 PM	N/A	N/A
0002	Non-Gyn	New	8/19/2019 5:17 PM	N/A	N/A
12240869999TK-1...	Gyn	New	3/21/2019 1:56 PM	N/A	N/A
83783549999BC-1...	Gyn	New	3/21/2019 6:12 AM	N/A	N/A

Figure 4-11 Case List with Non-Gyn case, slides grouped under primary ID, example

Key to Figure 4-11	
①	<p>Primary ID The ID for the group Click anywhere in the case listing to see each of the slides in a group. Or, click the arrow to the left of the primary ID to view or hide each of the slides in a group.</p>
②	<p>Secondary ID In case lists, the individual slide is listed by the secondary ID. The secondary ID is the unique slide ID.</p>

4

OPERATION

The steps for reviewing each slide within a Non-Gyn case grouped with a primary ID are the same as with other Non-Gyn reviews.

In Reports, data for each individual slide is reported as a separate entry, rather than as a grouped case.

In the search results from searching by tag, data for each individual slide is reported as a separate entry, rather than as a grouped case.

In Bookmarks, if more than one individual slide from a group is part of the same Bookmark category, those slides are grouped in the Bookmark view.

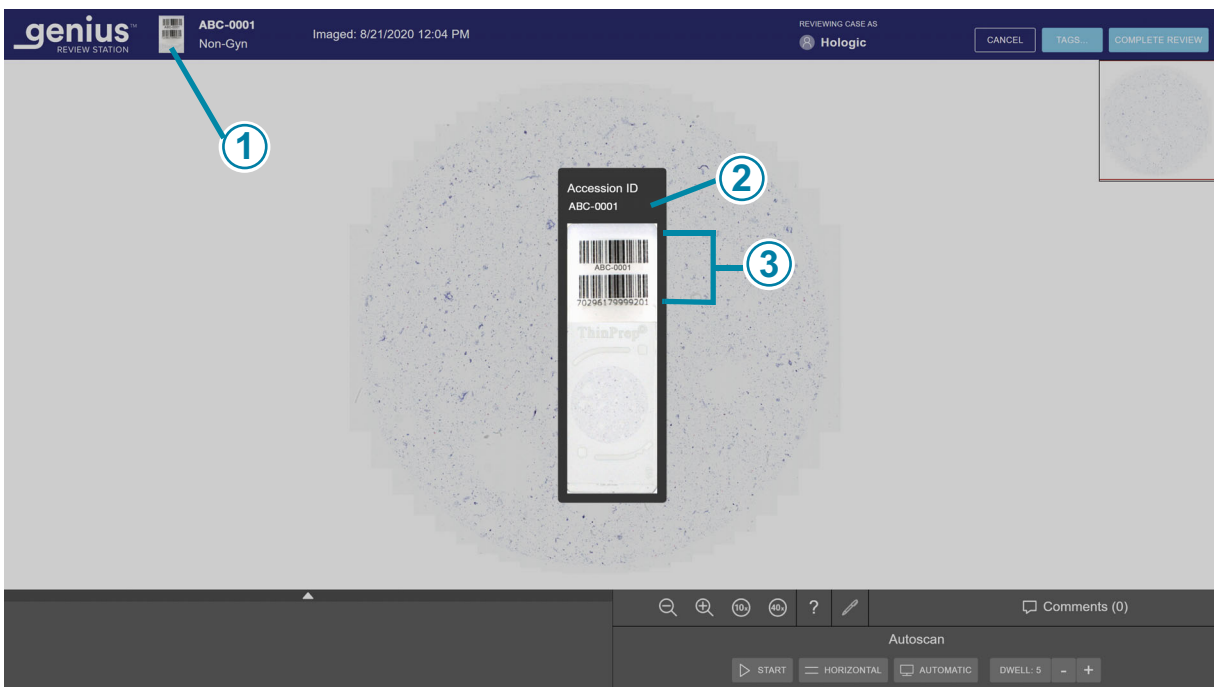


Figure 4-12 Macro image shows slide label area, Non-Gyn example

Key to Figure 4-12	
①	When an individual slide is open, to see the accession ID, click to the left of the Accession ID to view the macro image of the slide.
②	For Non-Gyn slides that are part of a grouped case, the Accession ID takes the form of “primary ID-secondary ID” with a hyphen separating the primary ID from the secondary ID.
③	The macro image itself also shows what is printed on the slide label.

Note: Consider filtering options and the Review Station status when working with Non-Gyn cases grouped with a primary ID.

For example:

A new case consists of three slides. Two are imaged on Monday, and one imaged on Tuesday. If a reviewer filters the new Case List with an “imaged on” date for Monday, the Case List will only yield two of the slides, grouped together by the primary ID. If the same Case List is filtered with an “imaged on” date of Tuesday, the Case List will only list one of the slides. It will appear under its complete accession ID, not as part of a group because the filtering of the Case List has separated it from the group.

Keep a Case In Progress (optional)

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

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

4

OPERATION

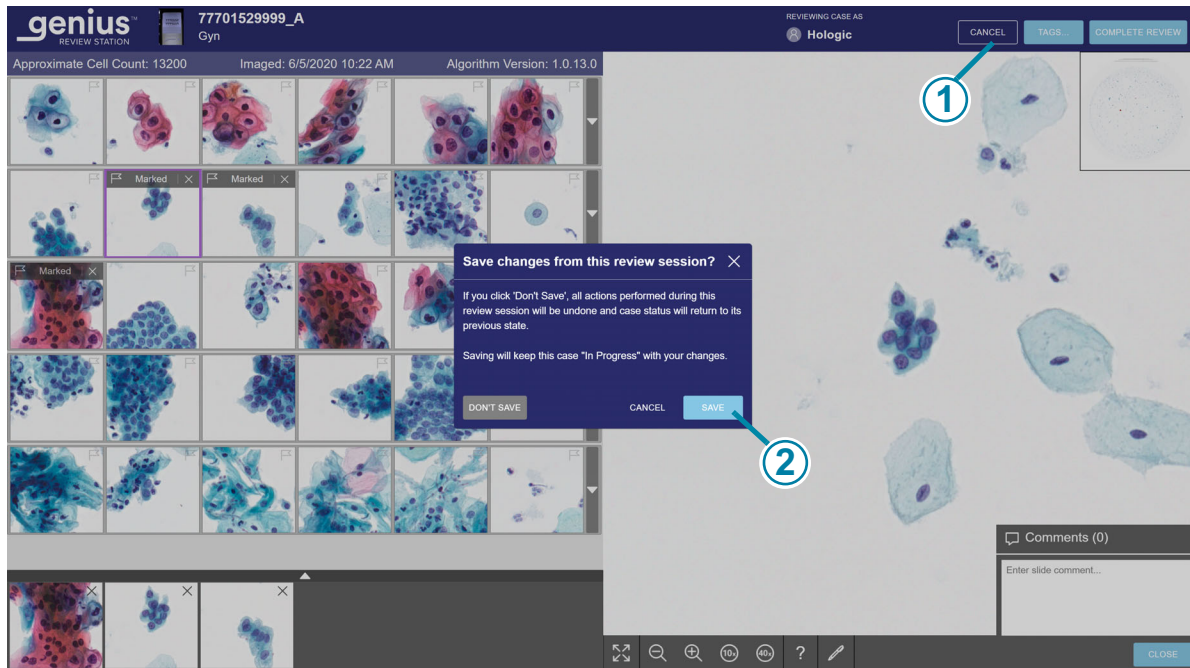


Figure 4-13 Save a case as In Progress, Gyn example

Key to Figure 4-13	
①	Click Cancel .
②	Click Save .

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

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

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

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

Complete a review of a case

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

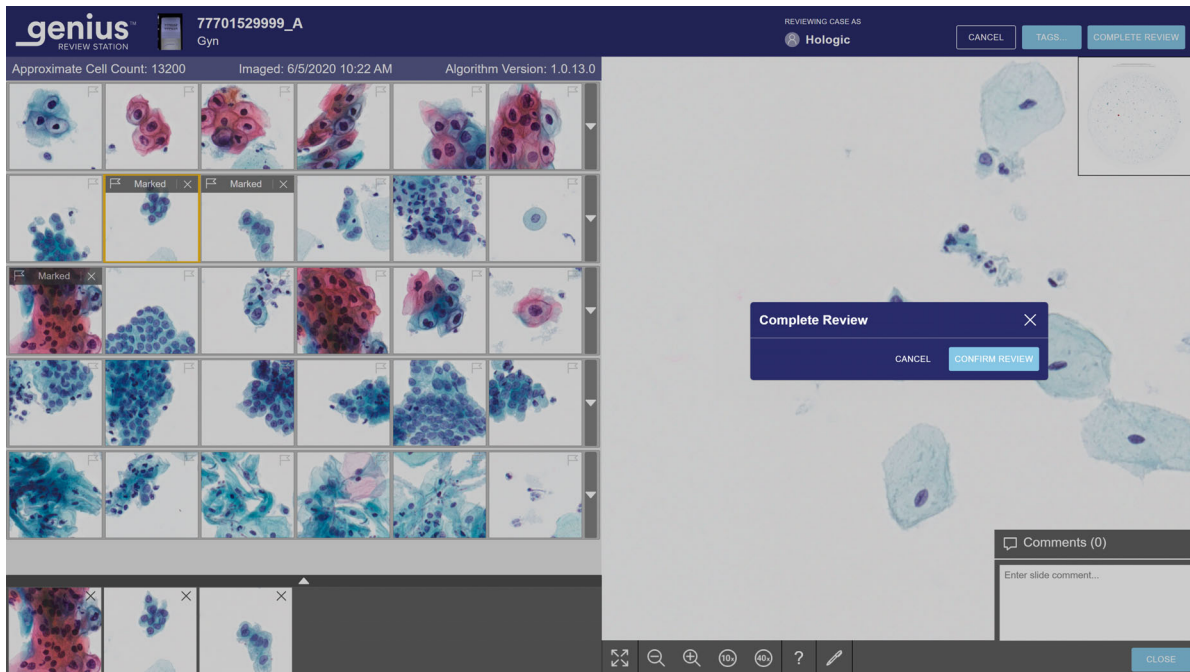







Figure 4-14 Complete the review of a case

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

Table 4.2 Hotkeys and Mouse Clicks

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

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

4

OPERATION

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Chapter Five

Maintenance

SECTION A

GENERAL CLEANING

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

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

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

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

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

5

MAINTENANCE

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Chapter Six

Troubleshooting

SECTION A

NO CONNECTION TO IMAGE MANAGEMENT SERVER

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

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

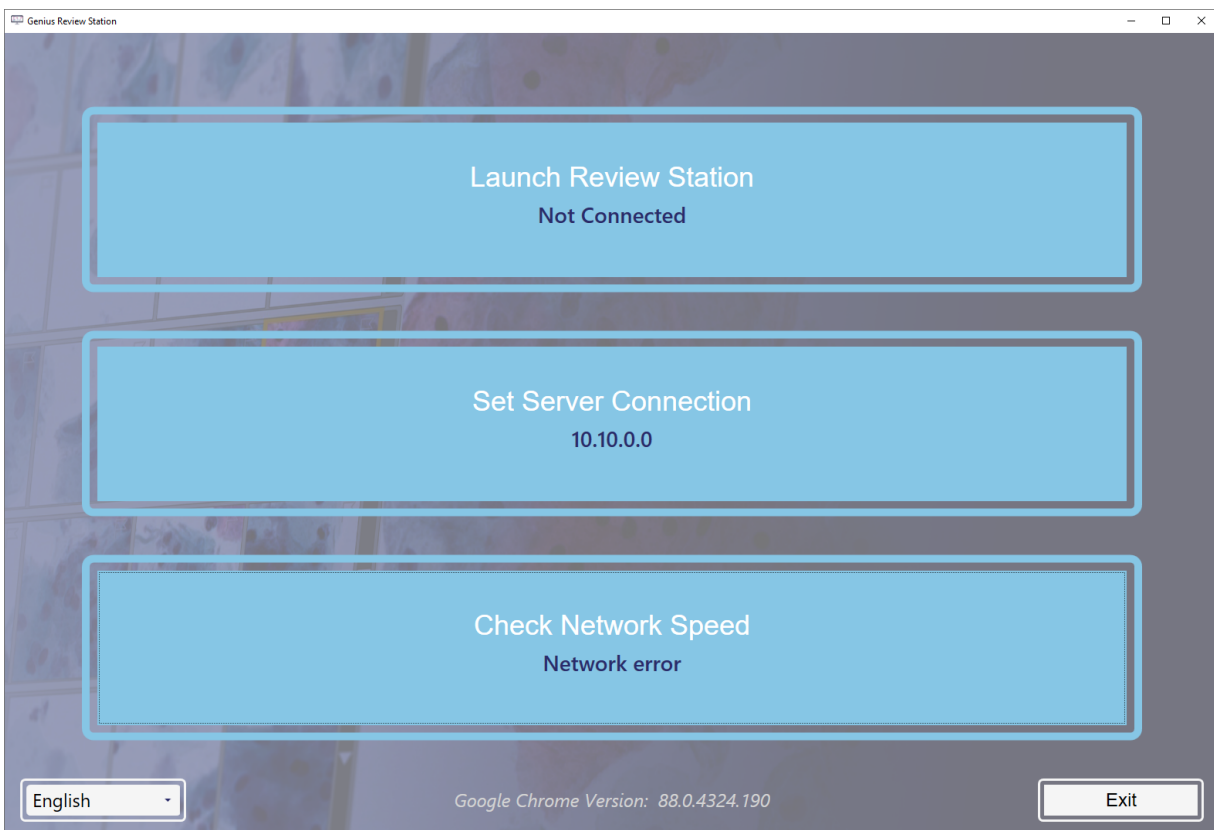


Figure 6-1 Review Station, Not Connected

6

TROUBLESHOOTING

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



Figure 6-2 Review Station Server Connection Error

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

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

SECTION B

DIGITAL IMAGER INFORMATION VIEWED FROM THE REVIEW STATION

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

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

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

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

Table 6.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E0001	Slide was scanned previously	The slide has been imaged.	The slide may undergo review at the Review Station.
		Duplicate slide accession ID.	Confirm if the ID is unique. If there is a duplicate, reconcile both patient records; re-label one and reprocess the slide.
E0002	Slide barcode could not be read	Wrong kind of slide or slide label.	Confirm that a ThinPrep microscope slide is being used. Check that the Imager/Scanner is configured to read the barcode format or OCR format used in your lab.
		Wrong accession ID format. Slide ID misprint.	Check the condition of the label and that the ID is in a format that the Imager/Scanner can read.
		Slide not loaded in slide carrier correctly.	Load the slide into the slide carrier with the label face up and away from the slide carrier handle.
		Possible malfunction at the macro station.	Attempt to process the slide again. If the error persists, contact Technical Support.
E0007	Slide imaging failed due to focus QC	Slide label extending beyond the right-hand side of the slide label area, causing the slide to not sit properly in the imaging stage	Check that the slide label is applied properly, without overhang.
		Possible instrument slide scanning issue	Attempt to process the slide again. If the error persists, contact Technical Support.
E0009	Slide imaging failed due to oversaturated frames	Possible issue with imaging frequency or illumination during imaging.	Attempt to process the slide again. If the error persists, contact Technical Support.

Table 6.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E0010	Slide imaging failed due to an imaging stage disturbance	The stage moved or was disturbed during imaging.	During operation, the Imager/Scanner is sensitive to vibrations. It should be placed on a sturdy flat surface away from centrifuges, vortexors or any equipment that may cause vibrations. Keep away from other environmental activity, such as constant foot traffic, proximity to elevators or doors that are frequently open and shut.
E0013	Barcode contains invalid characters	Barcode contains invalid characters	Label the slide with the correct ID format.
E0014	Failed to grip at macro. Slide manually removed by operator	The slide gripper failed to properly grip a slide, or the slide was manually removed by the operator.	If the slide was manually removed by the operator, process the slide again. Check that the slide is properly coverslipped and labeled. If the error persists, contact Technical Support.
E0015	Failed to parse barcode	The ID printed on the slide label cannot be used by the Genius Digital Diagnostics System.	The Configure Slide ID settings on the Imager/ scanner for are too long or too short for the slide. Change the Configure Slide ID settings.
		The ID printed on the slide label is correct and the settings for Configure Slide ID are wrong.	
		The settings for Configure Slide ID are correct and the ID printed on the slide label is wrong (too long, too short, does not use a specified character).	Check that the ID printed on the slide label is in the correct format for your lab. Label the slide with the correct ID format.

Table 6.1 Slide Event Messages

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E0016	Slide imaging failed due to cell focus error	Sample collection or slide preparation issue causing the cell spot to be blank or very faint.	Possible sample collection or slide preparation issue
		An issue with the Imager/Scanner has the slide in a position that is difficult to image.	Attempt to process the slide again. If the error persists, contact Technical Support.
E0004, E0005, E0006, E0008, E0011, E0012, E0017, E0018	Slide processing events	---	Attempt to process the slide again. If the error persists, contact Technical Support.

Table 6.2 Imager Error Codes

Event code	Event description	Possible cause	Corrective action for the Digital Imager Operator
E0500 through E0512, E0515	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E0514	An error was detected while running periodic check.	Imager conducted a self-check that did not pass.	Power cycle the system. If the error persists, contact Technical Support.
E0516	The error carrier is full.	Error carrier contains 40 slides.	Replace the full slide carrier in position 10 with an empty slide carrier.
E0518	Illumination uniformity across the image is not within specification.	Illumination is misaligned with the objective, or the V-Chip is damaged, dirty or out of position.	Clean the verification chip. If the error persists, contact Technical Support.

Table 6.2 Imager Error Codes

E1000, E1001, E1002, E1004, E1005, E1006	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E1003	The door or window was found open during start unexpectedly.	Door or window lock failed; user opened door or window.	The Imager/Scanner cannot operate with the door or window open. Close the door or window.
E1007	The door or window was found open during resume unexpectedly.	Door or window lock failed; user opened door or window.	The Imager/Scanner cannot operate with the door or window open. Close the door or window.
E1008 through E1012, E1014 through E1017	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E1013	The door or window was found open during periodic check unexpectedly.	Door or window lock failed; user opened door or window.	The Imager/Scanner cannot operate with the door or window open. Close the door or window.
E1018	Unexpected door opening.	Lock failed to prevent user from opening the door.	The Imager/Scanner cannot operate with the door or window open. Close the door or window.
E1019	Unexpected window opening.	Lock failed to prevent user from opening the window.	The Imager/Scanner cannot operate with the door or window open. Close the door or window.
E1500 through E1504	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E2000	An error occurred while starting the process image task.	The camera fails to produce frames; the stage fails to move.	Power cycle the system. If the error persists, contact Technical Support.
E2001	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E2002	An error occurred during processing a swath.	An ImageProcessor component threw an exception.	Power cycle the system. If the error persists, contact Technical Support.

Table 6.2 Imager Error Codes

E2003	An error occurred while waiting for the ending swath.	Camera failed to produce frames. FocalMerger timed out while merging.	Power cycle the system. If the error persists, contact Technical Support.
E2004	An error occurred while ending a swath.	An image processing component threw an exception. Image compression failure.	Power cycle the system. If the error persists, contact Technical Support.
E2005	An error occurred while waiting for the image processing task to complete.	An image processing component threw an exception.	Power cycle the system. If the error persists, contact Technical Support.
E2006 through E4000	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E4001	A slide was found in the gripper at startup.	The instrument was powered off with a slide in the gripper.	Power cycle the system. After the re-start, follow instrument prompts to remove the slide from the slide gripper. If the error persists, contact Technical Support.
E4003	The slide handler failed to home.	Motor move error caused by mechanical obstruction.	Power cycle the system. If the error persists, contact Technical Support.
E4004	A move to a carrier location failed.	Mechanical interference with one or more axes.	Power cycle the system. If the error persists, contact Technical Support.
E4005	A move to the thumbnail location failed.	Mechanical interference with one or more axes.	Power cycle the system. If the error persists, contact Technical Support.
E4006	A move to the macro location failed.	Mechanical interference with one or more axes.	Power cycle the system. If the error persists, contact Technical Support.
E4007	A move to the queue location failed.	Mechanical interference with one or more axes.	Power cycle the system. If the error persists, contact Technical Support.
E4008	A move to the imaging stage location failed.	Mechanical interference with one or more axes	Power cycle the system. If the error persists, contact Technical Support.
E4009	A move to the safe location failed.	Mechanical interference with one or more axes.	Power cycle the system. If the error persists, contact Technical Support.
E4010	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E4011	A multiple-axis concurrent motor move failed.	Mechanical interference with one or more axes.	Power cycle the system. If the error persists, contact Technical Support.

Table 6.2 Imager Error Codes

E4012	A pick from a carrier failed.	The slide was not present in the slot or was incorrectly inserted in the slot.	The system will move to the next slide to pick.
E4013	A pick from the macro nest failed.	The slide on the macro was dropped, or incorrectly placed.	A recovery dialog is displayed.
E4014	A pick from the queue failed.	The slide on the queue was dropped or incorrectly placed.	A recovery dialog is displayed.
E4015	A pick from the imaging stage failed.	The slide on the imaging stage was not in the expected location, or the stage was not in the loading position.	Power cycle the system. If the error persists, contact Technical Support.
E4016	Placing a slide in a carrier failed.	The value for the place location in the carrier was incorrectly calculated.	Power cycle the system. If the error persists, contact Technical Support.
E4017	Placing a slide in the macro nest failed.	One or more axis movements failed, or the gripper failed to open.	Power cycle the system. If the error persists, contact Technical Support.
E4018	Placing a slide in the queue failed.	One or more axis movements failed, or the gripper failed to open.	Power cycle the system. If the error persists, contact Technical Support.
E4019	Placing a slide in the imaging stage failed.	One or more axis movements failed, or the gripper failed to open.	Power cycle the system. If the error persists, contact Technical Support.
E4020	The inventory carrier operation failed.	One or more motor axis movements failed, or the inventory sensor read failed.	Power cycle the system. If the error persists, contact Technical Support.
E4022 through E4513	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E4514	An error occurred during auto-calibration.	Incorrectly configured V-Chip positions.	Power cycle the system. If the error persists, contact Technical Support.

Table 6.2 Imager Error Codes

E4515	Particle defect found during auto-calibration.	Particles on the V-Chip or lens. Incorrectly configured V-Chip position.	Power cycle the system. If the error persists, contact Technical Support.
E4516 through 4518	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E5000	The low-level hardware failed to initialize.	CAN bus communication failure. Hardware failure.	Check that the system has a power connection. Power cycle the system. If the error persists, contact Technical Support.
E5002	The gripper failed to home.	The gripper motor move operation failed.	Power cycle the system. If the error persists, contact Technical Support.
E5003	The gripper failed to open.	The gripper motor move operation failed.	Power cycle the system. If the error persists, contact Technical Support.
E5001, E5004 through E6001	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E6002	Failed to connect to post scan service.	Post Scanning Service is disconnected.	Power cycle the system. If the error persists, contact Technical Support.
E6003 through E6006	Imager error	Error with one of the system components.	Power cycle the system. If the error persists, contact Technical Support.
E6007	Network disruptions, Server Side Error	Network disruptions, Server Side Error	Contact your laboratory's system administrator to power cycle the Image Management Server. Power cycle both the Digital Imager and the Image Management Server. If the error persists, contact Technical Support.
E6500	The workflow proxy cannot connect to the workflow server.	Workflow server is down, IIS in Workflow is not running, or Imager Service in Workflow is not running.	Contact your laboratory's system administrator to power cycle the Image Management Server. Power cycle both the Digital Imager and the Image Management Server. If the error persists, contact Technical Support.

6

TROUBLESHOOTING

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Chapter Seven

Service Information

Corporate Address

Hologic, Inc.

250 Campus Drive

Marlborough, MA 01752 USA

Europe, UK, Middle East

Technical Solutions Cytology can be reached:

Mon-Fri : 08.00 – 18.00 CET

TScytology@hologic.com

And via the toll-free numbers below:

Finland	0800 114829
Sweden	020 797943
Ireland	1 800 554 144
United Kingdom	0800 0323318
France	0800 913659
Luxembourg	8002 7708
Spain	900 994197
Portugal	800 841034
Italy	800 786308
Netherlands	800 0226782
Belgium	0800 77378
Switzerland	0800 298921
EMEA	00800 8002 9892

7

SERVICE INFORMATION

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Chapter Eight

Ordering Information

Europe, UK, Middle East

Technical Solutions Cytology can be reached:

Mon-Fri : 08.00 – 18.00 CET

TScytology@hologic.com

And via the toll-free numbers below:

Finland	0800 114829
Sweden	020 797943
Ireland	1 800 554 144
United Kingdom	0800 0323318
France	0800 913659
Luxembourg	8002 7708
Spain	900 994197
Portugal	800 841034
Italy	800 786308
Netherlands	800 0226782
Belgium	0800 77378
Switzerland	0800 298921
EMEA	00800 8002 9892

Mailing Address

Hologic, Inc.

250 Campus Drive

Marlborough, MA 01752 USA

8

ORDERING INFORMATION

Remittance Address

Hologic, Inc.

PO Box 3009

Boston, MA 02241-3009 USA

Warranty

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

Protocol for Returned Goods

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

Table 8.1 Reordering Supply Items for the Review Station

Item	Description	Quantity	Part Number
Review Station Operator's Manual	Additional operator's manual	ea.	MAN-08802-001

Table 8.2 Optional Accessories

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

8

ORDERING INFORMATION

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Index

A

Accessories 8.3
Add new user 3.24
Add widget 3.32
Alerts 3.41
All Cases 3.33
Archive settings 3.21

B

Bookmarks 3.42

C

Case
 complete review 4.29
 open 4.5
 review 4.1
 Review Gyn case 4.6
 review process 4.3
Case Data Record 4.1
Case Details 3.34
Case Lists 3.8, 3.33
Case Review 4.1
Cleaning 5.1
Complete a review of a case 4.29
Components 1.9
 computer 2.5, 2.6
Computer preparation 2.2
Computer Specifications 1.11
Customize widgets 3.26

D

Data Filters 3.37
Date format 3.13
Delete custom filter 3.41
Delete widget 3.29
Dimensions 1.11

E

Edit custom filter 3.40
Edit widget 3.31
Extended shutdown 2.14

F

Filter
 data 3.37
Forgotten username or password 3.6
Fuses 1.13

G

Gallery 4.9
Grouped Non-Gyn slides 4.25
Gyn Case, gallery 4.9

H

hazards 1.14
Hide archived cases 3.33
humidity range 1.12

I

- Imaging process 1.7
- In Progress Cases 3.34
- Indication for Use 1.3
- Installation 2.1
- Intended Purpose 1.3
- Intended Use 1.3

L

- Lab settings 3.19
- Labels, location on instrument 1.18
- Language 3.13
- Location 2.2, 2.3
- Log out 3.41
- Login 3.3

M

- Manager
 - archive settings 3.21
 - delete a slide 3.37
 - lab settings 3.19
 - reclaim case 3.35
 - reports, data limit 3.22
 - tag set-up 3.22
 - user management 3.22
- materials required 4.4, 4.5
- Menu Bar 3.8
- Monitor 2.5
 - adjust height and tilt 2.6
- Multiple slides in a case 4.25
- My Reviewed Cases 3.34

N

- New Cases 3.34
- Non-Gyn cases grouped with a primary ID 4.25
- Normal shutdown 2.13

O

- Ordering information 8.1

P

- Password 3.6, 3.14
- Power 1.12, 2.2
- power switch
 - computer 2.7
 - microscope 2.7

R

- Reclaim a case 3.35
- Remove widget 3.29
- Report settings 3.22
- Reports 3.43
 - CT Reviews 3.45
 - CT Workload History 3.47
 - CT Workload Summary 3.49
 - Imager error rate 3.50
 - Imager Slide Events 3.52
 - Imager System Errors 3.54
 - Slide Data 3.55
 - System Usage History 3.59
- Reset password 3.6

S

Safety standards 1.13
Save custom filter 3.40
Search by accession ID 3.33
Search by tag 3.33
Shutdown 2.13
Site assessment 2.2
Specifications
 Review Station computer 1.11
 technical 1.9
specimen preparation 1.8
Symbols 1.15

T

Tags 3.22
Temperature range 1.12
Tiles 4.9
Time format 3.13
Troubleshooting 6.1

U

User Interface 3.1
User Management (Manager only) 3.22
Using Data Filters 3.37

W

Warnings 1.14
Weight 1.11, 2.2
Whole Slide Image 4.14
Widgets 3.26

INDEX

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Hologic® Genius™ Review Station Operator's Manual



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



Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium



MAN-08802-001 Rev. 003