

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2159309	(X3) Date Survey Completed 06/07/2023
Name of Provider or Supplier Dermatopathology Partners Pc	Street Address, City, State 123 Fox Rd, Second Floor, Knoxville, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5032	<p>CYTOLOGY CFR(s): 493.1221</p> <p>If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, observation and interviews the laboratory failed to establish written policies and procedures to ensure confidentiality of patient information (refer to D5201); failed to establish and follow written policies and procedures to ensure specimen slides were labeled with a unique patient identifier (refer to D5203); failed to establish written policies and procedures to assess the competency of the Technical Supervisors, and failed to assess the competency of four of four Technical Supervisors (refer to D5209); failed to establish written policies and procedures for 10 laboratory test processes (refer to D5403); failed to ensure that four of 23 written procedures were approved, signed and dated by the Laboratory Director (refer to D5407); failed to follow manufacturer's instructions for the Hologic ThinPrep Pap Test (refer to D5411); failed to establish performance specifications when the laboratory modified the Hologic ThinPrep test system manufacturer's instructions (refer to D5423); failed to ensure that the required maintenance for the Hologic ThinPrep 5000 Processor and Hologic ThinPrep 2000 Processor was performed (refer to D5429); failed to test staining materials for intended reactivity of the Diff-Quick stain (refer to D5473); failed to establish written policies and procedures to define effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process (refer to D5617); failed to establish written policies and procedures to identify nongynecologic specimens with a high potential for cross-contamination and stain them separately from other nongynecologic specimens and filter or change the stains following staining (refer to D5619); failed to establish</p>

written policies and procedures for a program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL) or malignant neoplasms with available histopathology, and failed to provide records for a correlative review program to determine the causes of any discrepancies (refer to D5623); failed to establish written policies and procedures for the review of all negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy, failed to provide records documenting a search and review of prior negative specimens for each patient with a current HSIL or malignancy was performed, and failed to identify one of eleven prior negative specimens as having a more significant lesion (refer to D5625); failed to follow written policies and procedures for an annual statistical evaluation of the required laboratory statistics, and failed to document the required laboratory statistics for 2021 and 2022 (refer to D5629); failed to establish written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory (refer to D5655); failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report cytology test results (refer D5657); and failed to ensure final test reports indicated the accurate address of the laboratory where the test was performed (refer to D5805).

D5201

CONFIDENTIALITY OF PATIENT INFORMATION
CFR(s): 493.1231

The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish written policies and procedures to ensure confidentiality of patient information. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the laboratory would ensure confidentiality of patient information. 2. During an interview on June 5, 2022 at 2:20 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5203

SPECIMEN IDENTIFICATION AND INTEGRITY
CFR(s): 493.1232

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

This STANDARD is not met as evidenced by:
A. Based on review of laboratory policies and procedures, specimen slide preparations and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow written policies and procedures to ensure specimen slides were labeled with a unique patient identifier. The laboratory failed to ensure that 63 of 63 specimen slides from 11 patient specimens from May 2023 had specimen slides labeled with a unique patient identifier. Findings include: 1. The laboratory failed to follow the procedure FINE NEEDLE ASPIRATION SPECIMEN PREPARATION,

which stated: "Write accession number on all containers and slides received." 2. The Survey Team reviewed 63 specimen slides from 11 specimens received from May 2023 for specimen labeling. a. Sixty-three of 63 specimen slides failed to have the accession number written on the frosted end of the slide. Slides include: -F23-000374 (2 direct smears) -F23-000375 (8 direct smears) -F23-000376 (6 direct smears) -F23-000377 (6 direct smears) -F23-000378 (9 direct smears) -F23-000379 (6 direct smears) -F23-000380 (4 direct smears) -F23-000381 (2 direct smears) -F23-000383 (6 direct smears) -F23-000384 (8 direct smears) -F23-000385 (6 direct smears) 3. During an interview on June 6, 2023 at 3:45 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. B. Based on review of laboratory policies and procedures, specimen slide preparations and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish written policies and procedures to ensure nongynecologic Hologic ThinPrep specimen slides were labeled with a unique patient identifier. The laboratory failed to ensure that four of four nongynecologic Hologic ThinPrep specimen slides from three patient specimens from May 2023 had specimen slides labeled with a unique patient identifier. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedure to ensure nongynecologic Hologic ThinPrep specimen slides were labeled with a unique patient identifier prior to specimen processing. 2. The Survey Team reviewed four nongynecologic Hologic ThinPrep specimen slides from three specimens from May 2023 for specimen labeling. a. Four of four specimen slides failed to have the accession number written on the frosted end of the slide. Slides include: -F23-000378 (2 ThinPreps) -F23-000380 (1 ThinPrep) -F23-000383 (1 ThinPrep) 3. During an interview on June 6, 2023 at 3:45 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of competency assessment records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish written policies and procedures to assess the competency of the Technical Supervisors. The laboratory failed to assess the competency of four of four Technical Supervisors in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process for assessing the competency of the Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for four of four Technical Supervisors in 2021, 2022 and to the date of the survey in 2023. Technical Supervisors include: -Laboratory Director/Technical Supervisor A - Technical Supervisor B -Technical Supervisor C -Technical Supervisor D 3. During an interview on June 5, 2023 at 2:20 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of 23 laboratory policies and procedures, stain maintenance records and interviews the laboratory failed to follow one written policy and procedure. Findings include: 1. The laboratory failed to follow the procedure PAPANICOLAOU STAIN PROCEDURE, which stated: "All solutions will be changed after every 820 slides." 2. The Survey Team reviewed stain maintenance records titled THINPREP STAIN MAINTENANCE for 2021, 2022 and to the date of the survey in 2023. The records documented the total number of slides stained and when the stains and solutions were changed. a. During an interview on June 6, 2023 at 1:55 PM, Staff A stated the stain maintenance records were not accurate. The number of slides stained did not include nongynecologic slides that were stained in the same stains and solutions as gynecologic slides. b. The maintenance records failed to document the accurate number of slides stained or if the number of slides stained exceeded 820 slides before the stains and solutions were changed. 3. During an interview on June 6, 2023 at 3:45 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor A.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of 23 laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures for 10 laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for receiving and accessioning gynecologic specimens into the laboratory information system (LIS). 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for receiving and

accessioning nongynecologic specimens into the LIS. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for reporting gynecologic test results into the LIS. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for reporting nongynecologic test results into the LIS. 5. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how specimen submission problems were to be documented. a. During an interview on June 6, 2023 at 1:55 PM, Staff A stated the laboratory used records titled REJECTED SPECIMEN and INCIDENT REPORT FOR CYTOLOGY to document specimen submission problems. 6. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the use of the Hologic ThinPrep Imaging System. 7. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe when the cytology stains and solutions in the Sakura Tissue-Tek Prisma autostainer would be filtered and changed. 8. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe when the Diff-Quick stains and solutions would be filtered and changed. 9. The Survey Team requested and the laboratory failed to provide written policies and procedures to test staining materials for intended reactivity of the Diff-Quick stain used to stain nongynecologic cytology slides for each day of use 10. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for sending and receiving cytology specimens for external consultation. 11. During interviews on June 5, 2023 at 2:20 PM and June 6, 2023 at 3:45 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on review of 23 laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to ensure that four of 23 written procedures were approved, signed and dated by the Laboratory Director. Findings include: 1. The Laboratory Director failed to sign and date four of 23 laboratory procedures. Procedures include: -PROCEDURE FOR OBTAINING GYNECOLOGIC CYTOLOGY SPECIMENS -CYTOTECHNOLOGIST, NEW HIRE -SODIUM HYPOCHLORITE (NAOCL) SOLUTION DILUTION - BIOHAZARD WASTE MANAGEMENT 2. During an interview on June 5, 2023 at 2:20 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

A. Based on review of manufacturer's instructions, morphology certification records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the Hologic ThinPrep Pap Test in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The HOLOGIC THINPREP 5000 SYSTEM OPERATOR'S MANUAL states: "Evaluation of microscope slides produced with the THINPREP 5000 SYSTEM should be performed only by cytotechnologists and pathologists who have been trained to evaluate THINPREP prepared slides by HOLOGIC or by organizations or individuals designated by HOLOGIC." 2. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL states: "Evaluation of microscope slides produced with the THINPREP 2000 SYSTEM should be performed only by cytotechnologists and pathologists who have been trained to evaluate THINPREP prepared slides by HOLOGIC or by organizations or individuals designated by HOLOGIC." 3. The Survey Team requested and the laboratory failed to provide the required morphology certification for three of four Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests in 2021, 2022 and to the date of the survey in 2023. Technical Supervisors include: - Laboratory Director/Technical Supervisor A -Technical Supervisor C -Technical Supervisor D 4. During an interview on June 5, 2023 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. B. Based on review of manufacturer's instructions, laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow manufacturer's instructions for reprocessing Hologic ThinPrep Pap Tests following an unsatisfactory result. Findings include: 1. The HOLOGIC THINPREP 5000 PROCESSOR OPERATOR'S MANUAL and the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S state: "Prepare a wash solution of sufficient volume to add 30 mL to every ThinPrep Pap Test specimen being reprocessed. The wash solution is made by mixing 9 parts CytoLyt Solution with 1 part glacial acetic acid." "Pour 30 mL of the CytoLyt Solution and 10% glacial acetic acid mixture into the centrifuge tube and cap securely." "Using the volume markings on the centrifuge tube, pour the necessary quantity of unused (i.e., containing no patient specimens) PreservCyt Solution to the cells and fill to a final volume of 20mL. Secure cap tightly." 2. The Survey Team reviewed the procedure ACID WASH PROCEDURE FOR GROSSLY BLOODY PAP SMEARS, which stated: "Take a mixture containing 30 mL og CytoLyt and 5 mL of glacial acetic acid and pour into 50 mL tube containing pellet. Shake vigorously to resuspend." "Add 20 mL of CytoLyt to pellet and shake vigorously to resuspend." a. The laboratory failed to prepare a 9 part CytoLyt Solution to 1 part glacial acetic acid to reprocess Hologic ThinPrep Pap Tests. b. The laboratory failed to add 30 mL of the CytoLyt Solution and 10% glacial acetic acid mixture to wash the specimen. c. The laboratory failed to add PreservCyt Solution to bring the specimen volume to 20 mL prior to processing. 3. During an interview on June 6, 2023 at 3:45 PM, these findings were confirmed with the Laboratory Director /Technical Supervisor A.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper

use.

This STANDARD is not met as evidenced by:

Based on observation and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to ensure three of three reagents and solutions were labeled to indicate content. Findings include: 1. During an observation of the cytology processing area on June 5, 2023 at 9:40 AM, the Survey Team identified three of three staining dishes used for the Diff-Quick staining line were not labeled to indicate content. 2. During an interview June 6, 2023 at 3:45 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation and interviews the laboratory failed to ensure that reagents and solutions were used prior to their expiration date. Findings include: 1. During an observation of the cytology processing area on June 5, 2023 at 9:40 AM, the Survey Team identified the following expired reagents and solutions: -one bottle Hologic ThinPrep Bluing Solution (expired 04/14/2023) -one bottle Hologic ThinPrep Rinse Solution (expired 04/27/2023) -one bottle Hologic ThinPrep Orange G (expired 05/20/2023) 2. During an interview on June 6, 2023 at 1:55 PM, these findings were confirmed with Staff A. 3. During an interview on June 6, 2023 at 3:45 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on review of the HOLOGIC THINPREP 5000 PROCESSOR OPERATOR'S MANUAL, HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL, laboratory policies and procedures and interview with the Laboratory Director /Technical Supervisor A the laboratory failed to establish performance specifications when the laboratory modified the Hologic ThinPrep test system manufacturer's instructions with an alternate method of reprocessing Hologic ThinPrep Pap Tests

following an unsatisfactory result. Findings include: 1. The laboratory failed to establish performance specifications or evidence that the accuracy, precision, analytical sensitivity and specificity of the modified procedure, reportable range of test results or any other performance characteristic was adequate to provide accurate diagnostic interpretations. 2. The HOLOGIC THINPREP 5000 PROCESSOR OPERATOR'S MANUAL and the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL state: "Prepare a wash solution of sufficient volume to add 30 mL to every ThinPrep Pap Test specimen being reprocessed. The wash solution is made by mixing 9 parts CytoLyt Solution with 1 part glacial acetic acid." "Pour 30 mL of the CytoLyt Solution and 10% glacial acetic acid mixture into the centrifuge tube and cap securely." "Using the volume markings on the centrifuge tube, pour the necessary quantity of unused (i.e., containing no patient specimens) PreservCyt Solution to the cells and fill to a final volume of 20mL. Secure cap tightly." 3. The Survey Team reviewed the procedure ACID WASH PROCEDURE FOR GROSSLY BLOODY PAP SMEARS, which stated: "Take a mixture containing 30 mL of CytoLyt and 5 mL of glacial acetic acid and pour into 50 mL tube containing pellet. Shake vigorously to resuspend." "Add 20 mL of CytoLyt to pellet and shake vigorously to resuspend." a. The laboratory procedure failed to follow manufacturer's instructions for reprocessing Hologic ThinPrep Pap Tests following an unsatisfactory result. 4. During an interview on June 6, 2023 at 3:45 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
A. Based on review of the Hologic ThinPrep 2000 System Operator's Manual, laboratory records and interview the laboratory failed to ensure that the required maintenance for one of one Hologic ThinPrep 2000 Processors was performed, as specified by the manufacturer, for 2022 and to the date of the survey in 2023. Findings include: 1. The Hologic ThinPrep 2000 System Operator's Manual states the following maintenance is to be performed: -Filter cap cleaning - Daily -Cap seal cleaning - Daily -Pneumatic system test - Weekly -General cleaning - Monthly -Waste tubing replacement - Six months 2. The Survey Team reviewed maintenance records titled THINPREP 2000 PROCESSOR for 2022 and to the date of the survey in 2023. The records failed to accurately document that the required daily, weekly and monthly maintenance was performed. a. During an interview on June 6, 2023 at 3:45 PM, the Laboratory Director/Technical Supervisor A confirmed it could not be determined on what days specimens were processed on the Hologic ThinPrep 2000 Processor and the maintenance records were not accurate. B. Based on review of the Hologic ThinPrep 5000 Processor Operator's Manual, laboratory records and interview the laboratory failed to ensure that the required maintenance for one of one Hologic ThinPrep 5000 Processors was performed, as specified by the manufacturer, for 2022 and to the date of the survey in 2023. Findings include: 1. The Hologic ThinPrep 5000 Processor Operator's Manual states the following maintenance is to be performed: -Empty filter waste bin - Every batch -Change fixative reagent every 100 slides or daily, whichever comes first - Daily -Clean around the carousel, dispersion area and filter puncture /disposal area - Weekly -Clean slide holder pneumatic suction cups - Weekly 2. The

	<p>Survey Team reviewed maintenance records titled THINPREP 5000 PROCESSOR for 2022 and to the date of the survey in 2023. The records failed to accurately document that the required daily and weekly maintenance was performed. a. During an interview on June 6, 2023 at 3:45 PM, the Laboratory Director/Technical Supervisor A confirmed it could not be determined on what days specimens were processed on the Hologic ThinPrep 5000 Processor and the maintenance records were not accurate.</p>
<p>D5473</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of laboratory records and interview with the Laboratory Director /Technical Supervisor A the laboratory failed to test staining materials for intended reactivity of the Diff-Quick stain used to stain nongynecologic cytology slides for each day of use in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide records documenting that the characteristics of the Diff Quick stain used to stain nongynecologic cytology slides was assessed each day of use in 2021, 2022 and to the date of the survey in 2023. 2. During an interview on June 6, 2023 at 3:45 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.</p>
<p>D5617</p>	<p>CYTOLOGY CFR(s): 493.1274(b)(2)</p> <p>(b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures to define effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process. 2. During an interview on June 6, 2023 at 1:55 PM, Staff A stated that gynecologic and nongynecologic specimens were stained on the Sakura Tissue-Tek Prisma autostainer. Staff A further stated the stains and solutions were not filtered or replaced between staining gynecologic and nongynecologic specimens. 3. During an interview on June 6, 2023 at 3:45 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.</p>
<p>D5619</p>	<p>CYTOLOGY</p>

CFR(s): 493.1274(b)(3)

(b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow written policies and procedures to identify nongynecologic specimens with a high potential for cross-contamination and stain them separately from other nongynecologic specimens and filter or change the stains following staining. Findings include: 1. The laboratory failed to follow the procedure PAPANICOLAOU STAIN PROCEDURE, which stated: "All non-gynecologic specimens that have a high potential for cross contamination are stained separately or last. These include: All known highly suspicious specimens. All specimens that appear to be exceptionally thick or bloody or known to be malignant through previous detection. If more than one case that has high potential for cross contamination is received, the cases will be stained last and separately. The stains will be filtered between suspicious cases." 2. During an interview on June 6, 2023 at 3:45 PM, the Laboratory Director/Technical Supervisor A stated the stains and solutions were not filtered or changed after specimens with a high potential for cross-contamination from the laboratory's fine needle aspiration clinic were stained.

D5623

CYTOLOGY

CFR(s): 493.1274(c)(2)

(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish written policies and procedures for a program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL or malignant neoplasms with available histopathology. The laboratory failed to provide records for a correlative review program to determine the cause of any discrepancies for 2021 and 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for a program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasms with available histopathology to determine the cause of any discrepancies. 2. The Survey Team requested and the laboratory failed to provide

records of a laboratory comparison of clinical information with cytology reports and a comparison of all gynecologic cytology reports with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasms with available histopathology for 2021 and 2022. 3. At the Survey Team's request, the Laboratory Director/Technical Supervisor A searched HSIL and malignant cytology case reports from 2021 and 2022 for corresponding clinical information and histopathology. The Laboratory Director /Technical Supervisor A identified three cytology cases during the search with discrepant histopathology and confirmed that the laboratory failed to have a program to document a comparison and review of the three discrepant cases. Cytology cases include: -GYC22-002080 -GYC22-002563 -GYC22-003963 4. During an interview on June 6, 2023 at 10:50 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5625

CYTOLOGY
CFR(s): 493.1274(c)(3)

(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish written policies and procedures to ensure that the search and review of prior negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy was performed. The laboratory failed to document the search for prior negative gynecologic specimens for 61 of 71 HSIL or malignant specimens from 2021 and 2022. The laboratory failed to identify three of the 61 HSIL or malignant specimens as having prior negative specimens, and failed to identify one of four prior negative specimens as having a more significant lesion. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for the search and review of all prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy reported by the laboratory. a. The procedure **QUALITY ASSURANCE PROGRAM FOR CYTOLOGY** failed to describe how the search of current HSIL and malignant specimens would be documented if there were no prior negative specimens. 2. The Survey Team requested and the laboratory failed to provide records of the search and review of prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy reported by the laboratory. The laboratory failed to document the search for prior negative gynecologic specimens for 61 of 71 HSIL or malignant specimens from 2021 and 2022. Specimens include: -GYC21-000017 - GYC21-000021 -GYC21-000288 -GYC21-000619 -GYC21-000729 -GYC21-000770 -GYC21-001088 -GYC21-001772 -GYC21-001824 -GYC21-001980 -GYC21-002260 -GYC21-002320 -GYC21-002337 -GYC21-003622 -GYC21-003623 - GYC21-003740 -GYC21-003970 -GYC21-003996 -GYC21-004028 -GYC21-004113 -GYC21-004763 -GYC21-004877 -GYC21-004887 -GYC21-005399 -GYC21-

005469 -GYC22-000281 -GYC22-000742 -GYC22-000956 -GYC22-000964 - GYC22-001276 -GYC22-001404 -GYC22-001913 -GYC22-001963 -GYC22-002080 -GYC22-002203 -GYC22-002576 -GYC22-002563 -GYC22-002578 -GYC22-002658 -GYC22-002778 -GYC22-002898 -GYC22-002934 -GYC22-003170 - GYC22-003193 -GYC22-003318 -GYC22-003382 -GYC22-003387 -GYC22-003444 -GYC22-003541 -GYC22-003548 -GYC22-003963 -GYC22-004263 -GYC22-004347 -GYC22-004360 -GYC22-004548 -GYC22-004681 -GYC22-004899 - GYC22-004945 -GYC22-005578 -GYC22-005873 -GYC22-005988 a. The Survey Team identified three of the 61 HSIL or malignant specimens that had four prior negative specimens that the laboratory failed to identify. Specimens include: -GYC21-003623 -GYC21-004028 -GYC21-004113 b. One of the four prior negative specimens had a more significant lesion than originally identified. Specimen includes: -GYC18-010613 3. During an interview on June 5, 2023 at 2:20 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5629

CYTOLOGY
CFR(s): 493.1274(c)(5)

(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

This STANDARD is not met as evidenced by:
A. Based on review of laboratory policies and procedures, laboratory statistical records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow written policies and procedures for an annual statistical evaluation of six of six required gynecologic laboratory statistics. The laboratory failed to document six of six required gynecologic laboratory statistics for 2021 and 2022. Findings include: 1. The laboratory failed to follow the procedure QUALITY ASSURANCE PROGRAM FOR CYTOLOGY, which stated: "An annual review of the number of" "Cytology cases examined" "Specimen processed by specimen type" "Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation)" "Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison" "Gynecologic cases where cytology and histology are discrepant" "Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms." 2. The Survey Team requested and the laboratory failed to provide six of six required annual gynecologic laboratory statistics for 2021 and 2022. Statistics include: -The number of cytology cases examined; -The number of specimens processed by specimen type; -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); -The number of gynecologic cases with a diagnosis of

HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; -The number of gynecologic cases where cytology and histology are discrepant; -The number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as LSIL, HSIL, adenocarcinoma, or other malignant neoplasms. 3. During an interview on June 5, 2023 at 11:45 AM, the Laboratory Director/Technical Supervisor A stated that the laboratory statistical records reflected cases reported at Facility A and Facility B. B. Based on review of laboratory policies and procedures, laboratory statistical records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow written policies and procedures for an annual statistical evaluation of three of three nongynecologic laboratory statistics. The laboratory failed to document three of three required nongynecologic laboratory statistics for 2021 and 2022. Findings include: 1. The laboratory failed to follow the procedure QUALITY ASSURANCE PROGRAM FOR CYTOLOGY, which stated: "An annual review of the number of" "Cytology cases examined" "Specimen processed by specimen type" "Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation)" 2. The Survey Team requested and the laboratory failed to provide three of three required annual nongynecologic laboratory statistics for 2021 and 2022. Statistics include: -The number of cytology cases examined; -The number of specimens processed by specimen type; -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); 3. During an interview on June 5, 2023 at 11:45 AM, the Laboratory Director/Technical Supervisor A stated that the laboratory statistical records reflected cases reported at Facility A and Facility B. The Laboratory Director/Technical Supervisor A further stated that the nongynecologic statistics provided did not include fine needle aspiration (FNA) cases from the laboratory's FNA clinic.

D5633

CYTOLOGY
CFR(s): 493.1274(d)(1)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, workload limit records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow written policies and procedures to establish a maximum workload limit for the Cytotechnologists who performed screening of cytology specimens. Findings include: 1. The laboratory failed to follow the procedure QUALITY ASSURANCE PROGRAM FOR CYTOLOGY, which stated: "The technical supervisor will establish a maximum workload limit for each individual who performs primary screening." 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor established a maximum workload limit for one of two Cytotechnologists from April through the date of the survey in 2023. Cytotechnologist includes: -Cytotechnologist A 3. During an interview on June 5, 2023 at 9:15 AM, the Laboratory Director/Technical Supervisor A stated that Cytotechnologist A was hired in April 2023 and confirmed the Technical Supervisor failed to establish a maximum workload limit for Cytotechnologist A.

D5637

CYTOLOGY
CFR(s): 493.1274(d)(1)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, workload limit records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow written policies and procedures to reassess and adjust, when necessary, a maximum workload limit at least every six months for the Technical Supervisors and Cytotechnologists who performed screening of cytology specimens. Findings include:

1. The laboratory failed to follow the procedure QUALITY ASSURANCE PROGRAM FOR CYTOLOGY, which stated: "The technical supervisor will establish a maximum workload limit for each individual who performs primary screening." "This can be updated every 6 months and adjusted, when necessary." 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor reassessed a workload limit at least every six months for one of two Cytotechnologists who performed slide examinations in 2022 and to the date of the survey in 2023. Cytotechnologist includes: -Cytotechnologist B a. The Survey Team reviewed records titled CYTOTECHNOLOGIST WORKLOAD LIMIT. The laboratory failed to reassess Cytotechnologist B's workload limit since October 2022.
3. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor reassessed a workload limit at least every six months for one of one Technical Supervisors who performed primary nongynecologic slide examinations in 2021, 2022 and to the date of the survey in 2023. Technical Supervisor includes: -Technical Supervisor B a. The Survey Team reviewed records titled (Technical Supervisor B's) WORKLOAD LIMITS AND WORKLOAD. The records documented Technical Supervisor B's maximum workload limit was 100 slides per day. The records failed to indicate the date the maximum workload limit was established or reassessed.
4. During an interview on June 5, 2023 at 2:20 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5645

CYTOLOGY
CFR(s): 493.1274(d)(3)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of workload records and interviews the laboratory failed to follow written policies and procedures to ensure that the laboratory maintained records of the total number of hours two of two Cytotechnologists spent examining slides per 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. Findings include: 1. The laboratory failed to follow the procedure QUALITY ASSURANCE PROGRAM FOR CYTOLOGY, which stated: "The laboratory must maintain records of the total number of slides examined by each individual during each 24 hour period and the number of hours spent examining slides in the 24 hour

	<p>period irrespective of site or laboratory." 2. The Survey Team requested and the laboratory failed to provide workload records for two of two Cytotechnologists. Refer to D6166, D6167. 3. During an interview on June 5, 2023 at 2:20 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor A.</p>
<p>D5647</p>	<p>CYTOLOGY CFR(s): 493.1274(d)(4)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to follow written policies and procedures to ensure records were available to document the workload limit for one of two Cytotechnologists from April through the date of the survey in 2023. Findings include: 1. The laboratory failed to follow the procedure QUALITY ASSURANCE PROGRAM FOR CYTOLOGY, which stated: "The technical supervisor will establish a maximum workload limit for each individual who performs primary screening." 2. The Survey Team requested and the laboratory failed to provide documentation the laboratory established a maximum workload limit for one of two Cytotechnologists from April through the date of the survey in 2023. Cytotechnologist includes: -Cytotechnologist A 3. During an interview on June 5, 2023 at 2:20 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.</p>
<p>D5655</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(4)</p> <p>(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory gynecologic slide preparations were identified and reported as unsatisfactory for evaluation. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory for evaluation. 3. During an interview on June 5, 2023 at 2:20 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.</p>
<p>D5657</p>	<p>CYTOLOGY CFR(s): 493.1274(e)(5)</p> <p>(e) The laboratory must establish and follow written policies and procedures that</p>

ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report gynecologic cytology test results. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. 3. During an interview on June 5, 2023 at 2:20 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of final test reports and interview with the Laboratory Director Technical Supervisor A 40 of 40 random final test reports from April 2023 failed to indicate the accurate address of the laboratory where the test was performed. Findings include: 1. The Survey Team reviewed 40 random final test reports from April 2023. Forty of 40 final test reports indicated the test was performed at Facility A. Final test reports include: -GYC23-001801 -GYC23-001810 -GYC23-001812 -GYC23-001820 -GYC23-001830 -GYC23-001831 -GYC23-001833 -GYC23-001836 -GYC23-001845 -GYC23-001850 -GYC23-001851 -GYC23-001853 -GYC23-001856 -GYC23-001857 -GYC23-001862 -GYC23-001868 -GYC23-001879 -GYC23-001887 -GYC23-001896 -GYC23-001898 -GYC23-001911 -GYC23-001914 -GYC23-001915 -GYC23-001923 -GYC23-001926 -GYC23-001929 -GYC23-001930 -GYC23-001931 -GYC23-001933 -GYC23-001934 -GYC23-001937 -GYC23-001947 -GYC23-001951 -GYC23-001953 -GYC23-001954 -GYC23-001963 -GYC23-001969 -GYC23-001993 -GYC23-001996 -GYC23-001999 2. During an interview on June 5, 2023 at 11:45 AM, the Laboratory Director/Technical Supervisor A stated that the Laboratory Director/Technical Supervisor A and Technical Supervisor C reported test results at Facility A and Facility B. The Laboratory Director/Technical Supervisor A further stated that it was the laboratory's practice to indicate Facility A reported the test results regardless of the location where the test was performed. a. The Laboratory

Director/Technical Supervisor A confirmed that the 40 final test reports indicated that the tests were performed at Facility A and the laboratory could not determine which facility the test was performed at.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations (refer to D6079); failed to ensure quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur (refer to D6094); failed to ensure that three of four Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests had received the required morphology certification prior to reporting patient specimens (refer to D6102); and failed to ensure the competency of four of four Technical Supervisors and two of two Staff was assessed (refer to D6103).

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records and interviews the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations. Findings include: 1. The Laboratory Director failed to provide direction and oversight to ensure written policies and procedures were established for all test processes. Refer to D5403 2. The Laboratory Director failed to provide direction and oversight to ensure written policies and procedures were approved, signed and dated by the Laboratory Director prior to use. Refer to D5407 3. The Laboratory Director failed to provide direction and oversight to ensure the accurate compilation, documentation and evaluation of annual laboratory statistics. Refer to D5629 4. The Laboratory Director failed to provide direction and oversight to ensure final test

reports indicated the accurate address of the laboratory where the test was performed. Refer to D5805 5. The Laboratory Director failed to provide direction and oversight to ensure Technical Supervisors and Cytotechnologists performing evaluation and reporting of cytology specimens had an established workload limit and failed to ensure criteria were established to reassess workload limits every 6 months. Refer to D5633, D5637, D5647, D6130 6. The Laboratory Director failed to provide direction and oversight to ensure the Cytotechnologists documented the total number of slides examined in each 24-hour period and the number of hours spent examining slides in each 24-hour period. Refer to D5645, D6166, D6167

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records and interviews the Laboratory Director failed to ensure quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur. Findings include: 1. The Laboratory Director failed to ensure the establishment of written policies and procedures for a quality assessment program for all phases of cytology testing. 2. The Laboratory Director failed to provide records of an established quality assessment program and failed to identify failures in quality as they occurred in 2021, 2022 and to the date of the survey in 2023. a. The Laboratory Director failed to provide records to document an established program to monitor the maintenance of the Hologic ThinPrep 5000 Processor and Hologic ThinPrep 2000 Processor to ensure the required maintenance was performed. Refer to D5429 b. The Laboratory Director failed to provide records to document an established program for monitoring the comparison of clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL or malignant neoplasms with available histopathology. Refer to D5623 c. The Laboratory Director failed to provide records to document an established program for monitoring the review of prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of HSIL or malignancy. Refer to D5625 d. The Laboratory Director failed to provide records to document an established program for monitoring the annual statistical evaluation of the required laboratory statistics. Refer to D5629 e. The Laboratory Director failed to provide records to document an established program for monitoring the establishment of maximum workload limits and the reassessment of individual workload limits at least every six months for the Technical Supervisor and Cytotechnologists. Refer to D5633, D5637, D6130 f. The Laboratory Director failed to provide records to document an established program for monitoring workload records to ensure the total number of slides examined in each 24-hour period and the number of hours the Cytotechnologists spent examining slides in each 24-hour period was documented. Refer to D5645, D6166, D6167

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate

training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions, laboratory certification records and interview with the Laboratory Director/Technical Supervisor A the Laboratory Director failed to ensure that three of four Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests had received the required morphology certification prior to reporting patient specimens in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Laboratory Director failed to ensure three of four Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests received the required morphology certification prior to reporting test results. Refer to D5411

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of competency assessment records and interview with the Laboratory Director/Technical Supervisor A the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of personnel performing duties. Findings include: 1. The Laboratory Director failed to ensure competency was assessed for four of four Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Refer to D5209 2. The Laboratory Director failed to ensure the competency of personnel performing cytology accessioning and processing duties in 2021, 2022 and to the date of the survey in 2023. a. The Laboratory Director failed to ensure written policies and procedures were established to assess the competency of personnel performing cytology accessioning and processing duties. b. The Laboratory Director failed to ensure the competency of personnel performing cytology accessioning and processing duties was assessed. Personnel includes: -Staff A -Staff B 3. During an interview on June 5, 2023 at 2:20 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D6130

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(c)(2)(3)

(c) In cytology, the technical supervisor or the individual qualified under 493.1449(k) (2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.

This STANDARD is not met as evidenced by:
 Based on review of workload limit records and interview with the Laboratory Director /Technical Supervisor A the Technical Supervisor failed to establish a maximum workload limit for one of two Cytotechnologists in 2023. The Technical Supervisor failed to reassess individual workload limits at least every six months for one of one Technical Supervisors and one of two Cytotechnologists in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Technical Supervisor failed to provide documentation the Technical Supervisor established a maximum workload limit for one of two Cytotechnologists from April through the date of the survey in 2023. Cytotechnologist includes: -Cytotechnologist A a. During an interview on June 5, 2023 at 9:15 AM, the Laboratory Director/Technical Supervisor A stated that Cytotechnologist A was hired in April 2023 and confirmed the Technical Supervisor failed to establish a maximum workload limit for Cytotechnologist A. 2. The Technical Supervisor failed to provide documentation the Technical Supervisor reassessed a workload limit at least every six months for one of two Cytotechnologists who performed slide examinations in 2022 and to the date of the survey in 2023. Cytotechnologist includes: -Cytotechnologist B a. The Survey Team reviewed records titled CYTOTECHNOLOGIST WORKLOAD LIMIT. The laboratory failed to reassess Cytotechologist B's workload limit since October 2022. 3. The Technical Supervisor failed to provide documentation the Technical Supervisor reassessed a workload limit at least every six months for one of one Technical Supervisors who performed primary nongynecologic slide examinations in 2021, 2022 and to the date of the survey in 2023. Technical Supervisor includes: -Technical Supervisor B a. The Survey Team reviewed records titled (Technical Supervisor B's) WORKLOAD LIMITS AND WORKLOAD. The records documented Technical Supervisor B's maximum workload limit was 100 slides per day. The records failed to indicate the date the maximum workload limit was established or reassessed. 4. During an interview on June 5, 2023 at 2:20 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D6166

CYTOTECHNOLOGIST RESPONSIBILITIES
 CFR(s): 493.1485(b)

The cytotechnologist is responsible for documenting, for each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer.

This STANDARD is not met as evidenced by:
 Based on the lack of workload records and interviews two of two Cytotechnologists failed to document the total number of slides examined and reviewed for each 24-hour period. Findings include: 1. The Survey Team requested and two of two Cytotechnologists failed to provide documentation of the total number of slides examined and reviewed by the Cytotechnologist, per 24-hour period. a. Cytotechnologist A failed to provide workload records from April through the date of the survey in 2023. b. Cytotechnologist B failed to provide workload records from 2021, 2022 and to the date of the survey in 2023. 2. During an interview on June 5, 2023 at 2:20 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor A. 3. During an interview on June 5, 2023 at 2:45 PM, Cytotechnologist A stated that Cytotechnologist A failed to document the total number of slides examined and reviewed in each 24-hour period.

D6167

CYTOTECHNOLOGIST RESPONSIBILITIES

CFR(s): 493.1485(c)

The cytotechnologist is responsible for documenting the number of hours spent examining slides in each 24-hour period.

This STANDARD is not met as evidenced by:

Based on the lack of workload records and interviews two of two Cytotechnologists failed to document the number of hours spent examining slides in each 24-hour period. Findings include: 1. The Survey Team requested and two of two Cytotechnologists failed to provide documentation of the number of hours spent examining slides. a. Cytotechnologist A failed to provide workload records from April through the date of the survey in 2023. b. Cytotechnologist B failed to provide workload records from 2021, 2022 and to the date of the survey in 2023. 2. During an interview on June 5, 2023 at 2:20 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor A. 3. During an interview on June 5, 2023 at 2:45 PM, Cytotechnologist A stated that Cytotechnologist A failed to document number of hours spent examining slides in each 24-hour period.

D9999

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