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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 15D0353522 | (X3) Date Survey Completed 05/12/2021 |
| Name of Provider or Supplier Cytology Pathology Services, Inc | Street Address, City, State 5865 N Michigan Rd, Indianapolis, IN | |
| 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 |
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| 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, slide preparations, observation and interviews it was determined the laboratory failed to establish written policies and procedures to assess the competency of one of one Technical Supervisors (refer to D5209); failed to establish policies and procedures for the collection, labeling, storage and preservation, and transportation of Hologic ThinPrep Pap Tests (refer to D5311); failed to establish written policies and procedures for seven laboratory test processes (refer to D5403); failed to ensure that 81 of 92 written procedures were approved, signed and dated by the Laboratory Director (refer to D5407); failed to follow the manufacturer's instructions for processing gynecologic cytology specimens (refer to D5415); failed to ensure that reagents and solutions were used before their expiration date (refer to D5417); failed to establish performance specifications when the laboratory modified the Hologic ThinPrep Pap Test system manufacturer's instructions with an alternate method of processing gynecologic cytology specimens and when preparing gynecologic slides from Hologic ThinPrep Pap Test vials utilizing cytospin preparations (refer to D5423); 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 malignancy was performed, and failed to document the search for prior negative gynecologic cytology cases (refer to D5625); failed to establish written policies and procedures for the evaluation and comparison of six of six laboratory statistics, and failed to document six of six required annual statistics (refer to D5629); failed to establish written policies and procedures to ensure</p> |

that a maximum workload limit was established and reassessed at least every six months by the Technical Supervisor for one of one Technical Supervisors (refer to D5633 and D5637); failed to establish written policies and procedures to ensure the workload limit for one of one Technical Supervisors, when examining slides in less than an 8-hour workday and with duties other than slide examination, would be prorated to determine the number of slides that may be examined (refer to D5641); failed to ensure that the laboratory maintained records for one of one Technical Supervisors of the total number of slides and the total number of hours spent evaluating slides per 24-hour period (refer to D5645); failed to establish written policies and procedures to ensure that records were available to document the workload limit for one of one Technical Supervisors (refer to D5647); failed to follow written policies and procedures to ensure that gynecologic cytology slide preparations were identified and reported as unsatisfactory (refer to D5655); and failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report gynecologic cytology test results (refer to D5657).

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 laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of one of one Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for assessing the competency of one of one Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for one of one Technical Supervisors who performed microscopic evaluations during 2019, 2020 and to the date of the survey in 2021. Technical Supervisor includes: - Technical Supervisor 3. During an interview on May 11, 2021 at 11:15 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures for the collection, labeling, storage and preservation, and transportation of Hologic

ThinPrep Pap Tests. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the collection, labeling, storage and preservation, and transportation of Hologic ThinPrep Pap Tests submitted to the laboratory. 2. During an interview on May 11, 2021 at 8:15 AM, the Laboratory Manager provided to the Survey Team the Hologic ThinPrep Pap Test Quick Reference Guide and stated "this is what we use for collection instructions." 3. During an interview on May 11 at 12:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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 92 laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures for seven laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for receiving and accessioning cytology 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 laboratory's step-by-step process for the entering and reporting of cytology test results into the LIS. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the retention requirements for cytology final test reports, cytology slide preparations, requisitions, and quality control/quality assessment records. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for preparing cell block preparations from Hologic ThinPrep Pap Test vials. a. During an interview on May 12, 2021 at 9:00 AM, Staff A stated that if there were fragments in the vial Staff A would remove the fragments and place them in tissue paper. The tissue paper was then placed into a labeled tissue cassette and placed into formalin for processing by histology staff. b. During an interview on May 12, 2021 at 10:40 AM, the Survey Team reviewed the laboratory procedures PROCEDURE FOR PREPARATION OF CELL BLOCK and PREPARATION OF CELL BLOCKS with Staff A. Staff A was unfamiliar with the procedures and stated cell block preparations

were never prepared according to the two procedures. 5. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for preparing fine needle aspiration specimens. a. The laboratory provided the procedure FINE NEEDLE ASPIRATES (FNA) which was a reference from the Hologic ThinPrep 2000 System Operator's Manual and failed to provide step-by-step details. 6. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for preparing body fluid specimens. a. The laboratory provided the procedure BODY FLUIDS which failed to provide step-by-step details. 7. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for preparing bronchial brush specimens. a. The laboratory provided the procedure NON-GYNECOLOGIC SAMPLE PREPARATION FOR BRONCHIAL BRUSHES which failed to provide step-by-step details. 8. During interviews on May 11, 2021 at 11:15 AM and May 12, 2021 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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 92 laboratory procedures and interview it was determined that the laboratory failed to ensure that 81 of 92 written procedures were approved, signed and dated by the Laboratory Director prior to the start of the survey on May 10, 2021. Findings include: 1. The Laboratory Director failed to sign and date 80 laboratory procedures prior to the start of the survey. Procedures include: - CHANGE OF PROCEDURES - CREDENTIALS OF MEDICAL STAFF AT CYTOPATHOLOGY SERVICES - JOB DESCRIPTION OF TECHNICAL SUPERVISOR - JOB DESCRIPTIONS - CYTOTECHNOLOGIST RESPONSIBILITIES - CYTOLOGY GENERAL SUPERVISOR RESPONSIBILITIES - LABORATORY DIRECTOR RESPONSIBILITIES - ADVANTAGES AND DISADVANTAGES OF THIN PREP - ABNORMAL FEATURES CODES - SPECIMEN ADEQUACY CODES - HORMONAL EVALUATION CODES - MICROBIAL FLORA CODES - DIAGNOSTIC CODES - RECOMMENDATION CODES - SOURCE CODES - SPECIAL FEATURES CODES - URINE CYTOLOGY CODES - EXAMINATION AND REPORTING OF EXTRAGENITAL SPECIMENS - PROCEDURE FOR DETERMINING ADEQUACY ON THINPREP SLIDES - GUIDELINES FOR ESTIMATING CELLULARITY OF LIQUID-BASED PREPARATIONS - HORMONAL EVALUATION - NORMAL AVERAGES OF MI - STAINING PROCEDURE FOR CYTOLOGY - STAINING PROCEDURE FOR CYTOLOGY (CONV. PAPS) - THIN PREP PREPARATION PROCEDURE - NON GYN STAINING - SLIDE REFERRAL/SEND OUT CYTOLOGY/HISTOLOGY PROCEDURE - CYTOLOGY STAIN FORMULAS - KOSS DIAGNOSTIC CYTOLOGY 3RD EDITION - SAFETY - ACETIC ACID WASH SOLUTION - UNSATISFACTORY CYTOLOGY SPECIMENS - DISPOSAL OF TISSUE AND CHEMICALS - COVERSLIPPING PROCEDURE - THINPREP SPECIMEN PROCESSING INSTRUCTIONS - BLOODY AND MUCOID REF FROM CYTC - PROCEDURE FOR PREPARATION OF CELL BLOCK - FINE NEEDLE ASPIRATES (FNA) - BODY FLUIDS - NON-GYNECOLOGIC SAMPLE

PREPARATION FOR CSF (CEREBRAL SPINAL FLUIDS) - NON-GYNECOLOGIC SAMPLE PREPARATION FOR BRONCHIAL BRUSHES - URINE CYTOLOGY PROCEDURE - PROCEDURE FOR UNFIXED SPECIMENS - CYTOCENTRIFUGE PREPARATIONS - QUALITY CONTROL - QA-CYTOLOGY PROCEDURE/CRITERIA FOR DEFICIENCY OF SPECIMENS - QA-CYTOLOGY RECORDS OF MEETINGS - PERFORMANCE EVALUATION FOR CYTOTECHNOLOGIST - PROCEDURE FOR MONITORING WORKLOAD - RETROSPECTIVE REVIEW OF HIGH GRADE LESIONS - QA.CYTOLOGY CYTOLOGY-HISTOPATHOLOGY CORRELATION - QA CYTOLOGY INCONSISTENCIES - CYTOLOGY DEFICIENCIES OF SMEARS - CYTOLOGY SLIDETHIN PREP IDENTIFICATION QA - CYTOLOGY FINAL REPORT REVIEW QA - RETRIEVAL AND INTEGRITY OF CYTOLOGY SLIDES - CYTOLOGY STAINING QA - CYTOLOGY REPORTS (SEARCHING FOR ADDENDUM REPORTS) - QUALITY ASSURANCE OF THIN PREP MAINTENANCE - MAINTENANCE SCHEDULE - QA-CYTOLOGY TURN AROUND TIME - QA-CYTOLOGY COMPLAINTS - QA-CYTOLOGY NEGATIVE FOLLOW-UP RESPONSE - TELEPHONE CALLS REGARDING LABORATORY EXAMINATIONS - MANUAL FOR FILLING OUT REQUISITIONS - COLLECTION OF GYNECOLOGICAL SMEARS (PAP SMEAR) - FIXATIVE - TECHNIQUE FOR COMBINED FAST SMEAR - ACQUISITION OF SPECIMEN OTHER THAN PAP-SMEARS - HISTOLOGY ACCESSION OF SPECIMENS (LOOKUP OF PREVIOUS/CURRENT CYTOLOGY) - INSTRUCTIONS FOR COLLECTION OF SPUTUM - SPUTUM CYTOLOGY - INSTRUCTIONS FOR BUCCAL SMEARS - INSTRUCTIONS FOR NIPPLE SECRETIONS - PROCEDURE FOR FINE NEEDLE ASPIRATION OF SOLID AND CYSTIC MASSES - FINE NEEDLE ASPIRATION OF BREAST MASSES AND CYSTS - FNA BIOPSY TECHNIQUE - SMEAR PREPARATION - SPECIMEN PREPARATION - RE-EVALUATION OF UNSATISFACTORY CASES OF THINPREP PAPS 2. The Laboratory Director failed to date one laboratory procedure prior to the start of the survey. - 50% QC RESCREEN GUIDELINES 3. During an interview on May 11, 2021 at 11:15 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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:
 Based on review of the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL and interviews it was determined that the laboratory failed to follow the manufacturer's instructions for processing gynecologic cytology specimens using the Hologic ThinPrep 2000 Processor. Findings include: 1. The laboratory failed to follow the manufacturer's instructions when processing gynecologic specimens with the Hologic ThinPrep 2000 Processor. 2. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL states to use Sequence 4 for: "Gynecologic Samples Includes cell samples from the ectocervix and endocervix. Use this sequence for the ThinPrep Pap Test." a. During an interview on May 11, 2021 at 10:20 AM, Staff A stated that mucoid Hologic ThinPrep Pap Vials were processed on the Hologic

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| | <p>ThinPrep 2000 Processor using Sequence 3. b. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL states to use Sequence 3 for: "Mucoïd Samples Includes sputum samples, bronchial brush and wash samples, and gastrointestinal samples." 3. During interviews on May 11, 2021 at 11:15 AM and 12:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor.</p> |
| <p>D5415</p> | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interviews it was determined that the laboratory failed to ensure that 23 of 23 reagents and solutions were labeled to indicate content. Findings include: 1. During an observation of the cytology processing area on May 10, 2021 at 2:45 PM, the Survey Team identified 23 of 23 staining dishes in the Leica Autostainer XL that were not labeled to indicate content. 2. During an interview on May 11, 2021 at 10:20 AM, these findings were confirmed with Staff A. 3. During an interview on May 11, 2021 at 11:15 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.</p> |
| <p>D5417</p> | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interviews it was determined that the laboratory failed to ensure that reagents and solutions were used before their expiration date. Findings include: 1. During an observation of the cytology processing area on May 11, 2021 at 3:30 PM, the Survey Team identified the following expired reagents and solutions: - one bottle Hologic ThinPrep CytoLyt Solution (expired 8/28/17) - one bottle Richard-Allan Scientific Gill 1 Hematoxylin (expired 6/18) - one bottle Richard-Allan Scientific Gill 1 Hematoxylin (expired 5/19) - one bottle Richard-Allan Scientific Gill 1 Hematoxylin (expired 5/20) - one bottle Surgipath Alcoholic Eosin Y (expired 6/21/12) - one bottle Surgipath Hematoxylin (expired 8/7/11) - one bottle Surgipath Hematoxylin (expired 5/4/12) 2. During an interview on May 12, 2021 at 9:00 AM, these findings were confirmed with Staff A. 3. During an interview on May 12, 2021 at 11:45 AM, these findings were confirmed with the Laboratory Director//Technical Supervisor.</p> |
| <p>D5423</p> | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces</p> |

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:

A. Based on review of the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL and interviews it was determined that the laboratory failed to establish performance specifications when the laboratory modified the Hologic ThinPrep Pap Test system manufacturer's instructions with an alternate method of processing gynecologic cytology specimens. Cross refer to D5411 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. B. Based on review of cytology glass slides and interviews it was determined that the laboratory failed to establish performance specifications when preparing gynecologic cytology slides from Hologic ThinPrep Pap Test vials utilizing cytospin preparations. Findings include: 1. The Survey Team reviewed cytology glass slides from 22 cases from August 2020 through March 2021 utilizing cytospin preparations to prepare slides from Hologic ThinPrep Pap Test vials. Cases include: - F20-000120-1 - F20-000124-1 - F20-000126-1 - F20-000127-1 - F20-000128-1 - F20-000129-1 - F20-000130-1 - F20-000131-1 - F20-000132-1 - F20-000133-1 - F20-000134-1 - F20-000135-1 - F20-000136-1 - F20-000137-1 - F20-000138-1 - F20-000139-1 - F20-000140-1 - F20-000168-1 - F21-000010-1 - F21-000020-A - F21-000041-1 - F21-000088-1 2. During an interview on May 11, 2021 at 10:20 AM, Staff A stated that sometimes the Laboratory Director/Technical Supervisor requested a cytospin preparation be prepared from the Hologic ThinPrep Pap Test vial. 3. During an interview on May 11, 2021 at 11:15 AM, the Laboratory Director/Technical Supervisor confirmed the laboratory failed to determine the performance characteristics of the test when preparing cytospin preparations from the Hologic ThinPrep Pap Test vial.

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 it was determined that 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 malignancy was performed. The laboratory failed to document the search for prior negative gynecologic cytology cases for one of one malignant case from March 2021. 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 malignancy reported by the laboratory. a. The laboratory procedure RETROSPECTIVE REVIEW OF HIGH GRADE LESIONS failed to include a search when a current malignancy was reported by the laboratory. 2. The Survey Team requested and the laboratory failed to provide records documenting the search for prior negatives for one of one malignant case. Case includes: - F21-000081-A 3. During an interview on May 12, 2021 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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:
Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of six of six laboratory statistics. The laboratory failed to document six of six required annual statistics for 2019 and 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of six of six required statistics. 2. The Survey Team requested and the laboratory failed to provide records titled ANNUAL STATISTICAL EVALUATION to document the six required annual statistics for 2019 and 2020: a. Cytology cases examined; b. Specimens processed by specimen type; c. Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); d. Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; e. Gynecologic cases where cytology and histology are discrepant; and f. 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. 3. During an interview on May 11, 2021 at 12:30 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established by the Technical Supervisor for Technical Supervisors who performed the primary evaluation of cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that workload limits were established by the Technical Supervisor for Technical Supervisors who performed the primary evaluation of cytology specimens. 2. During an interview on May 11, 2021 at 11:15 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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 and interview it was determined that the laboratory failed to establish written policies and procedures to reassess a maximum workload limit at least every six months for one of one Technical Supervisors. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to reassess a maximum workload limit at least every six months for one of one Technical Supervisors in 2019, 2020 and to the date of the survey 2021. 2. During an interview on May 11, 2021 at 11:15 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

D5641

CYTOLOGY

CFR(s): 493.1274(d)(2)(ii)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and

procedures to ensure the workload limit for one of one Technical Supervisors, when examining slides in less than an 8-hour workday and with duties other than slide examination, would be prorated to determine the number of slides that may be examined. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to determine how to prorate the workload limit for one of one Technical Supervisors when time was spent on duties other than slide examination or when examining slides in less than an 8-hour day. 2. The Survey Team requested and the laboratory failed to provide records documenting that the workload limit for one of one Technical Supervisors was prorated. 3. During an interview on May 11, 2021 at 11:15 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the laboratory maintained records of the total number of slides and the total number of hours the Technical Supervisors spent evaluating slides per 24-hour period. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained records of the total number of slides and total number of hours the Technical Supervisor spent evaluating slides. 2. During an interview on May 11, 2021 at 11:15 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

D5647

CYTOLOGY
CFR(s): 493.1274(d)(4)

(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.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that records were available to document the workload limit for the Technical Supervisors who performed the primary evaluation of cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that records were available to document the workload limit for Technical Supervisors who performed the primary evaluations of cytology specimens. 2. During an interview on May 11, 2021 at 11:15 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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| D5655 | <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, cytology slide preparations and interview it was determined that the laboratory failed to follow written policies and procedures to ensure that one of one gynecologic cytology slide preparation from April 2021 was identified and reported as unsatisfactory. Findings include: 1. The laboratory failed to follow the procedure PROCEDURE FOR DETERMINING ADEQUACY ON THINPREP SLIDES which stated: "Must have 10 fields with 5 or more cells on 40x." 2. The laboratory failed to identify one gynecologic cytology case as being unsatisfactory for evaluation. Case includes: - F21-000206-1 3. During an interview on May 12, 2021 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.</p> |
| D5657 | <p>CYTOLOGY CFR(s): 493.1274(e)(5)</p> <p>(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report gynecologic 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. During an interview on May 11, 2021 at 11:15 AM, the Laboratory Director/Technical Supervisor stated the laboratory used The Bethesda System.</p> |
| D6076 | <p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this</p> |

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| | <p>subpart. The Laboratory Director failed to ensure that quality assessment programs were followed to assure the quality of laboratory services and identify failures in quality as they occur (refer to D6094).</p> |
| <p>D6094</p> | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the Laboratory Director failed to ensure that quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to monitor the quality of the general laboratory cytology system. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to monitor the quality of the preanalytic cytology system. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures to monitor the quality of the analytic cytology system. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures to monitor the quality of the postanalytic cytology system. 5. The Survey Team requested and the laboratory failed to provide documentation of any quality assessment activities or problems. 6. During an interview on May 11, 2021 at 11:15 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.</p> |
| <p>D6115</p> | <p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)</p> <p>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on the microscopic review of 385 random negative gynecologic cases/416 slides and the corresponding final test reports from January 2020 through May 2021 and confirmation by the Technical Supervisor on May 11 and May 26, 2021 it was determined that the Technical Supervisor failed to verify the accuracy of two gynecologic cytology tests. 1. F20-000174-1 08/25/2020 ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 2. F21-000206-1 04/26/2021 TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation - Insufficient Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory - Low Cellularity</p> |
| <p>D6130</p> | <p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3)</p> |

(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 the lack of laboratory records and interview it was determined that the Technical Supervisor failed to establish individual workload limits and to reassess the workload limits at least every six months for one of one Technical Supervisors performing primary slide examinations in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the Technical Supervisor failed to provide documentation that the Technical Supervisor established a maximum workload limit for one of one Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisor includes: - Technical Supervisor A 2. The Survey Team requested and the Technical Supervisor failed to provide records of a workload reassessment at least every six months for one of one Technical Supervisor in 2019, 2020 and to the date of the survey in 2021. Technical Supervisor includes: - Technical Supervisor A 3. During an interview on May 11, 2021 at 11:15 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

D6133

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(c)(6)

In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.

This STANDARD is not met as evidenced by:

Based on the lack of laboratory records and interviews it was determined that one of one Technical Supervisors performing primary slide screening failed to document the number of slides screened and the number of hours devoted to screening slides during each 24-hour period in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide accurate records of the total number of slides and total number of hours one of one Technical Supervisors spent screening slides during each 24-hour period in 2019, 2020 and to the date of the survey in 2021. Technical Supervisor includes: - Technical Supervisor A 2. During an interview on May 10, 2021 at 11:20 AM, the Laboratory Manager described how the laboratory completed workload records for the Technical Supervisor: The Laboratory Manager generated a report from the LIS that included the accession number and report date of cases reported by the Technical Supervisor. The Laboratory Manager counted all cases as one slide and used the total number of slides screened to determine the amount of time the Technical Supervisor should have spent screening slides. a. The records failed to include additional slides that were prepared for cases. b. The records failed to document the actual time spent screening slides. 3. During an interview on May 11, 2021 at 11:15 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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