

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2119325	(X3) Date Survey Completed 01/10/2024
Name of Provider or Supplier Mid-Valley Pathology, Llc	Street Address, City, State 505 Angelita Drive, Suite 6, Weslaco, TX	
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
D2134	<p>CYTOLOGY CFR(s): 493.855(a)</p> <p>The laboratory must ensure that each individual is tested at least once per year and obtains a passing score. To ensure this annual testing of individuals, an announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. Laboratories will be notified of the time of each announced on-site testing event at least 30 days prior to each event. Additional testing events will be conducted as necessary in each State or region for the purpose of testing individuals who miss the on-site testing event and for retesting individuals as described in paragraph (b) of this section.</p> <p>This STANDARD is not met as evidenced by: Based review of cytology proficiency testing records, laboratory records and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to ensure that one of three Technical Supervisors who examined gynecologic cytology slide preparations in 2022 and 2023 was tested and obtained a passing score on a gynecologic cytology proficiency testing event for 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide records to document one of three Technical Supervisors was enrolled and participated in an approved gynecologic cytology proficiency testing event in 2022. Technical Supervisor includes: -Technical Supervisor C 2. During an interview on January 8, 2024 at 11:40 AM, the Laboratory Director/Technical Supervisor A stated that Technical Supervisor C reported results on 66 gynecologic cytology tests in October 2022 through February 2023. The Laboratory Director/Technical Supervisor A further stated that Technical Supervisor C failed to test and obtain a passing score on a gynecologic proficiency testing event for 2022 and was no longer employed by the laboratory. Tests include: - GC22-00001 - GC22-00015 -GC22-00033 - GC22-00034 -GC22-00038 - GC22-00040 -GC22-00043 - GC22-00048 -GC22-00071 - GC22-00076 -GC22-00080 - GC22-00084 -GC22-00090 - GC22-00091 -GC23-00047 - GC23-00052 -GC23-</p>

00073 - GC23-00074 -GC23-00146 - GC23-00150 -GC23-00157 - GC23-00161 - GC23-00167 - GC23-00173 -GC23-202 -GC23-208

D5032

CYTOLOGY
CFR(s): 493.1221

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.

This **CONDITION** is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to establish written policies and procedures for 13 laboratory test processes (refer to D5403); failed to test staining materials for intended reactivity of the Diff-Quick stain used to stain nongynecologic cytology slides for each day of use (refer to D5473); failed to establish and 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 filtering or changing the stains following staining (refer to D5619); 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 (refer to D5623); failed to establish written policies and procedures to ensure 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 (refer to D5625); failed to establish and follow written policies and procedures for an annual statistical evaluation of the required laboratory statistics (refer to D5629); failed to establish and follow written policies and procedures for a program to evaluate the case reviews of the Technical Supervisors against the laboratory's overall statistical values (refer to D5631); failed to establish and follow written policies and procedures for the establishment, reassessment and documentation of individual workload limits (refer to D5633, D5637 and D5647); failed to establish and follow written policies and procedures to ensure that workload limits would be prorated when examining slides in less than eight hours (refer to D5641); failed to establish and follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined and the total number of hours spent examining slides per 24-hour period (refer to D5645); failed to establish and follow written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory for evaluation (refer to D5655); and failed to establish written policies and procedures to ensure corrected test reports indicated the basis for correction on the corrected test report (refer to D5659).

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 January 9, 2024 at 3:15 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 18 laboratory policies and procedures, maintenance records and interview the laboratory failed to follow one written policy and procedure. Findings include: 1. The laboratory failed to follow the procedure GYN AND NON-GYN CYTOPATHOLOGY QUALITY ASSURANCE AND QUALITY CONTROL SURVEILLANCE, which stated: "Documentation of evidence of daily review of the technical quality of preparation as well as stain quality by the cytology technical staff, cytotechnologist(s), and pathologist(s)." 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. Refer to D5473

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 18 laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures for 13 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

reporting gynecologic test results 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 reporting nongynecologic test results 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 processing gynecologic specimens on the Hologic ThinPrep Genesis Processor. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for processing nongynecologic specimens on the Hologic ThinPrep Genesis Processor. 5. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for processing nongynecologic specimens on the Shandon Cytospin 4. a. The procedure PREPARATION OF CYTOLOGY SPECIMENS failed to describe how specimens were centrifuged prior to being processed in the Shandon Cytospin 4. 6. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the staining protocol to stain gynecologic specimen slides with the Papanicolaou stain. 7. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the staining protocol to stain nongynecologic specimen slides with the Papanicolaou stain. 8. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the staining protocol to stain nongynecologic specimen slides with the Diff Quick stain. 9. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for operating the Tissue-Tek Prisma Plus autostainer and coverslipper. 10. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process to manually coverslip cytology specimen slides. 11. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the use of the Hologic ThinPrep Imaging System. 12. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process to reprocess gynecologic cytology specimens with glacial acetic acid. a. During an interview on January 9, 2024 at 9:30 AM, the Survey Team asked Staff A if there was a procedure to reprocess gynecologic cytology specimens. Staff A stated that Staff A follows the instructions in the HOLOGIC THINPREP GENESIS OPERATOR'S MANUAL. 13. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for cytology proficiency test enrollment and participation of personnel that perform gynecologic cytology testing. 14. During an interview on January 9, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5473

CONTROL PROCEDURES
CFR(s): 493.1256(e)(2)(g)

(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.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview 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 2022, 2023 and January 2024 to

the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide records documenting an assessment of the characteristics of the Diff Quick stain used to stain nongynecologic cytology slides each day of use in 2022, 2023 and January 2024 to the date of the survey in 2024. 2. During an interview on January 8, 2024 at 3:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and Technical Supervisor B.

D5619

CYTOLOGY
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 interviews the laboratory failed to establish and 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 filtering or changing the stains following staining. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to identify nongynecologic specimens with a high potential for cross-contamination and stain them separately from other nongynecologic specimens and filtering or changing the stains following staining. 2. During an interview on January 9, 2024 at 9:30 AM, Staff B stated that prepared slides from fine needle aspirations were stained separately from other slide preparations to reduce the potential for cross-contamination. a. The laboratory failed to provide a written policy or procedure to describe this process. 3. During an interview on January 9, 2024 at 3:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

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 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. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to

describe the laboratory's process 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. During an interview on January 9, 2024 at 3:15 PM, 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 and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish written policies and procedures to ensure 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. 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. 2. During an interview on January 9, 2024 at 3:15 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 and interview with the Laboratory Director/Technical Supervisor A the laboratory failed to establish written

policies and procedures for an annual statistical evaluation of two of six required gynecologic laboratory statistics. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of two of six required gynecologic statistics. Statistics include: - The number of cytology cases examined -The number of specimens processed by specimen type 2. During an interview on January 10, 2024 at 10:15 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. 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 establish and follow written policies and procedures for an annual statistical evaluation of two of three required nongynecologic laboratory statistics. The laboratory failed to document one of three required annual nongynecologic statistics for 2022 and 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of two of three required nongynecologic statistics. Statistics include: -The number of cytology cases examined -The number of cases processed by specimen type 2. The Survey Team requested and the laboratory failed to provide one of three required annual nongynecologic cytology statistics for 2022 and 2023. Statistic includes: -The number of nongynecologic cytology cases examined 3. During an interview on January 10, 2024 at 10:15 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5631

CYTOLOGY
CFR(s): 493.1274(c)(6)

(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) (6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of laboratory records and interview the laboratory failed to establish and follow written policies and procedures for a program to evaluate the case reviews of two of two Technical Supervisors against the laboratory's overall statistical values in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for a program to evaluate the case reviews of two of two Technical Supervisors against the laboratory's overall statistical values. 2. The Survey Team requested and the laboratory failed to provide records documenting the evaluation of the case reviews of two of two Technical Supervisors against the laboratory's overall statistical values in 2022, 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: - Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. During an interview on January 8, 2024 at 3:00 PM, the findings were confirmed with the Laboratory Director/Technical Supervisor A and Technical Supervisor B.

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, lack of workload limit records and interview the laboratory failed to establish and follow written policies and procedures to establish an individual maximum workload limit for each Technical Supervisor who performed primary screening of cytology specimens. The Technical Supervisor failed to establish an individual maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor would establish maximum workload limits for each Technical Supervisor who performed primary screening of cytology specimens. 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor established an individual maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. During an interview on January 8, 2024 at 3:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and Technical Supervisor B.

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, lack of workload limit reassessment records and interview the laboratory failed to establish and follow written policies and procedures to reassess and adjust when necessary, a maximum workload limit at least every six months for the Technical Supervisors who performed primary screening of cytology specimens. The Technical Supervisor failed to reassess a maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor would reassess a maximum workload limit for the Technical Supervisors at least every six months and adjust when necessary. 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor reassessed a maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: -Laboratory Director/Technical Supervisor A - Technical Supervisor B 3. During an interview on January 8, 2024 at 3:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and Technical Supervisor B.

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 workload limit records and interview the laboratory failed to establish and follow written policies and procedures to ensure workload limits for the Technical Supervisors would be prorated when examining slides in less than an eight-hour work day. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate workload limits for the Technical Supervisors when examining slides in less than an eight-hour day, or with duties other than examining cytology specimen slides. 2. The Survey Team requested and the laboratory failed to provide documentation of prorated workload limits for two of two Technical Supervisors when examining slides in less than eight hours. Technical Supervisors include: - Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. During an interview on January 8, 2024 at 3:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and Technical Supervisor B.

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, workload records and interviews the laboratory failed to establish and follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined by each individual per 24-hour period and the number of hours individuals spent examining 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 examined by each individual per 24-hour period and the number of hours individuals spent examining slides per 24-hour period. 2. Two of two Technical Supervisors failed to accurately document the total number of slides examined in each 24-hour period and the number of hours examining slides per 24-hour period in 2022, 2023 and January 2024 to the date of the survey in 2024. Refer to D6133 3. During an interview on January 8, 2024 at 3:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and Technical Supervisor B. Refer to D6133

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, lack of workload limit records and interview the laboratory failed to establish and follow written policies and procedures to ensure records were available to document the workload limit for two of two Technical Supervisors who performed primary screening of cytology specimens in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limit for the Technical Supervisors who performed primary screening of cytology specimens. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for two of two Technical Supervisors who performed primary screening of cytology specimens in 2022, 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B 3. During an interview on January 8, 2024 at 3:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and Technical Supervisor B.

D5655

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

(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.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, gynecologic slide preparations and interview the laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report one of three gynecologic tests from November 2023 as unsatisfactory for evaluation. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory gynecologic slide preparations were identified and reported as unsatisfactory for evaluation. a. The procedure GYN AND NON-GYN CYTOPATHOLOGY QUALITY ASSURANCE AND QUALITY CONTROL SURVEILLANCE failed to describe the required cellularity for a satisfactory gynecologic slide preparation. b. The laboratory failed to identify and report one of three gynecologic tests from November 2023 as unsatisfactory for evaluation. Test includes: -GC23-01185 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 January 8, 2024 at 3:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and Technical Supervisor B.

D5659

CYTOLOGY
CFR(s): 493.1274(e)(6)

(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the

basis for correction.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures and interview the laboratory failed to establish written policies and procedures to ensure corrected test reports indicated the basis for correction on the corrected test report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected test reports indicated the basis for correction on the corrected test report. 2. During an interview on January 8, 2024 at 3:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and Technical Supervisor B.

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 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); and 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).

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 reappoints 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 ensure that one of three Technical Supervisors who examined gynecologic cytology slide preparations in 2022 and 2023 was tested and obtained a passing score on a gynecologic cytology

proficiency testing event for 2022. Refer to D2134 2. The Laboratory Director failed to provide direction and oversight to ensure written policies and procedures were established for all test processes. Refer to D5403 3. The Laboratory Director failed to provide direction and oversight to ensure the compilation, documentation and evaluation of annual laboratory statistics. Refer to D5629 4. The Laboratory Director failed to provide direction and oversight to ensure the compilation, documentation and evaluation of the Technical Supervisors' case reviews against the laboratory's overall statistical values. Refer to D5631 5. The Laboratory Director failed to provide direction and oversight to ensure the Technical Supervisors 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 Technical Supervisors 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, D6133

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 interview 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 2022, 2023 and January 2024 to the date of the survey in 2024. 3. During an interview on January 8, 2024 at 3:00 PM, the findings were confirmed with the Laboratory Director/Technical Supervisor A and Technical Supervisor B.

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 and interview the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of personnel performing cytology processing duties. Findings include: 1. The Laboratory Director failed to ensure written policies and procedures were established to assess the competency of personnel performing

cytology processing duties. 2. During an interview on January 8, 2024 at 3:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and Technical Supervisor B.

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(2)

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.

This STANDARD is not met as evidenced by:

Based on the microscopic review of 63 non-negative gynecologic cases/66 slides from September 2023 through January 2024 the Technical Supervisor failed to verify the accuracy of two gynecologic cytology tests. 1. GC23-01175 11/03/2023 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy TECHNICAL SUPERVISOR B DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy 2. GC23-01185 11/09/2023 I-TPPT LABORATORY DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Unsatisfactory. Insufficient Cellularity TECHNICAL SUPERVISOR B DIAGNOSIS: Unsatisfactory. Obscuring Inflammation. Insufficient Cellularity

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 the lack of workload limit records and interview the Technical Supervisor failed to establish and reassess a maximum workload limit for two of two Technical Supervisors in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. The Technical Supervisor failed to provide documentation the Technical Supervisor established a maximum workload limit for two of two Technical Supervisors who performed primary cytology slide examinations in 2022, 2023 and January 2024 to the date of the survey in 2024. Refer to D5633 and D5647 2. The Technical Supervisor failed to provide documentation the Technical Supervisor reassessed a workload limit at least every six months for two of two Technical Supervisors who performed primary cytology slide examinations in 2022, 2023 and January 2024 to the date of the survey in 2024. Refer to D5637 and D5647 3. During an interview on January 8, 2024 at 3:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and Technical Supervisor B.

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 review of laboratory workload records and interviews two of two Technical Supervisors failed to document the number of slides evaluated and the number of hours devoted to screening during each 24-hour period in 2022, 2023 and January 2024 to the date of the survey in 2024. Findings include: 1. Two of two Technical Supervisors failed to document the total number of slides evaluated during each 24-hour period in 2022, 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: -Laboratory Director/Technical Supervisor A - Technical Supervisor B a. During an interview on January 8, 2024 at 10:45 AM, the Laboratory Director/Technical Supervisor A confirmed the dates on workload records titled ROUTINE NON-GYN & GYN QUALITY ASSURANCE did not reflect the accurate date the slides were evaluated. The Laboratory Director/Technical Supervisor A further confirmed the laboratory failed to count slides requiring field of view evaluation and full manual review evaluation correctly for the purposes of workload recording. 2. Two of two Technical Supervisors failed to document the number of hours devoted to screening slides during each 24-hour period in 2022, 2023 and January 2024 to the date of the survey in 2024. Technical Supervisors include: - Laboratory Director/Technical Supervisor A -Technical Supervisor B a. During an interview on January 8, 2024 at 10:45 AM, the Laboratory Director/Technical Supervisor A confirmed the dates on workload records titled ROUTINE NON-GYN & GYN QUALITY ASSURANCE did not reflect the accurate date the slides were evaluated. 3. During an interview on January 8, 2024 at 3:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and Technical Supervisor B.

D9999

By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.