Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0683443	11/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Valley Pathology, Llc	1221 13th Ave Se, Decatur, AL	

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
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: Based on review of laboratory policies and procedures, nongynecologic specimen slides, observation and interviews the laboratory failed to establish and follow written policies and procedures to ensure patient specimens were labeled with a unique patient identifier during all phases of testing. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure patient specimens were labeled with a unique patient identifier during all phases of testing. a. The Survey Team reviewed 45 nongynecologic specimen slides for 40 consecutive patient specimens from October 2024. Forty-five of 45 nongynecologic specimen slides from the 40 patient specimens failed to be labeled with a unique patient identifier. Specimen slides include: Accession number Specimen slide(s) -N24-00901 -901 -N24-00902 -902 -N24-00903 -903 -N24-00904 -904 -N24-00905 -905 -N24-00906 -906 -N24-00907 -907 -N24-00908 -908 -N24-00909 -909 -N24-00910 -910 -N24-00911 -911 (2 slides) -N24-00912 -912 -N24-00913 -913 (2 slides) -N24-00914 -914 -N24-00915 -915 -N24-00916 -916 -N24-00917 -917 -N24-00918 -918 -N24-00919 -919 -N24-00920 -920 -N24-00921 -921 -N24-00922 -922 -N24-00923 -923 -N24-00924 -924 (2 slides) -N24-00925 -925 -N24-00926 -926 (2 slides) -N24-00927 -927 -N24-00928 -928 -N24-00929 -929 -N24-00930 -930 -N24-00931 -931 -N24-00932 -932 (2 slides) -N24-00933 -933 -N24-00934 -934 -N24-00935 -935 -N24-00936 -936 -N24-00937 -937 -N24-00938 -938 -N24-00939 -939 -N24-00940 -940 2. During an observation of nongynecologic specimen processing (specimen N24-01024) on November 19, 2024 at 8:45 AM, Staff A failed to label the

	specimen container, centrifuge tube, Hologic PreservCyt Solution Vial and specimen slide with the unique patient identifier "N24-01024". a. Staff A labeled the specimen container, centrifuge tube, Hologic PreservCyt Solution Vial and specimen slide with the patient identifier "1024". 3. During an interview on November 19, 2024 at 9:35 AM, these findings were confirmed with the Cytotechnologist, Staff A and Staff B. 4. During an interview on November 20, 2024 at 11:00 AM, these findings were confirmed with Technical Supervisor B.
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 interviews the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisors. The laboratory failed to assess the competency of two of two Technical Supervisors in 2022, 2023 and January 1, 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 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 two of two Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B 3. During an interview on November 18, 2024 at 11:15 AM, the Cytotechnologist stated "we don't have that". 4. During an interview on November 19, 2024 at 2:00 PM, these findings were confirmed with the Cytotechnologist. 5. During an interview on November 20, 2024 at 11:00 AM, these findings were confirmed with Technical Supervisor B.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records, nongynecologic specimen slides, observation and interviews the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the general laboratory systems. The laboratory failed to document general laboratory quality assessment activities during 2022, 2023 and January 1, 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 an ongoing program to monitor, assess and correct problems identified in the general laboratory systems. 2. The Survey Team requested and the laboratory failed to provide documentation of general laboratory quality assessment activities

	during 2022, 2023 and January 1, 2024 to the date of the survey in 2024. a. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the labeling of patient specimens to ensure patient specimens were labeled with a unique patient identifier during all phases of testing. Refer to D5203 b. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the competency of the Technical Supervisors. Refer to D5209
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 34 laboratory policies and procedures, laboratory records and interviews the laboratory failed to follow one written policy and procedure. Findings include: 1. The laboratory failed to follow the procedure CORRECTION OF ERRORS, which stated: "In the laboratory, a copy of the original report is retained with the corrected report. When these are filed, notation is made on the original that corrected report was issued." 2. The Survey Team requested and the laboratory failed to provide a duplicate of the original final test report for one of one corrected test reports. Test report includes: -N24-00820 3. During an interview on November 18, 2024 at 3:40 PM, the Cytotechnologist stated that "corrected reports overwrite the original report". 4. During an interview on November 19, 2024 at 2:00, these findings were confirmed with the Cytotechnologist. 5. During an interview on November 20, 2024 at 11:00 AM, these findings were confirmed with Technical Supervisor B.
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 34 laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures for ten laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the laboratory's enrollment in a gynecologic cytology proficiency test (PT) program and how the laboratory personnel participated in a gynecologic cytology PT program. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the cleaning and maintenance protocol for the Hettich Rotofix 32 A centrifuge used for nongynecologic processing and how the performed maintenance was documented. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the cleaning and maintenance protocol for the Tissue-Tek Coverslipper and how the performed maintenance was documented. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the cleaning and maintenance protocol for the Hologic ThinPrep Review Scope and how the performed maintenance was documented. 5. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how cell block preparations were prepared. a. During an interview on November 19, 2024 at 8:45 AM, Staff A described how cell block preparations were prepared for nongynecologic specimens. If there was a cell pellet after processing the cell pellet was wrapped in tissue paper and placed in a labeled cassette. The cassette was placed in formalin for histology to process. 6. The Survey Team requested and the laboratory failed to provide written policies or procedures for calculating the number of slides evaluated, when examining gynecologic slides using the Hologic ThinPrep Imaging System. 7. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for accessioning gynecologic cytology specimens into the laboratory information system (LIS). 8. 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 cytology specimens into the laboratory information system LIS. 9. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for reporting gynecologic cytology test results into the LIS. 10. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for reporting nongynecologic cytology test results into the LIS. 11. During interviews on November 19, 2024 at 2:00 PM and 3:10 PM, these findings were confirmed with the Cytotechnologist. 12. During an interview on November 20, 2024 at 11:00 AM, these findings were confirmed with Technical Supervisor B.
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, observation and interviews the laboratory failed to follow the manufacturer's instructions for processing nongynecologic cytology specimens using the Hologic ThinPrep 2000 Processor. Findings include: 1. The HOLOGIC

	THINPREP 2000 SYSTEM OPERATOR'S MANUAL states: "Specimens must be centrifuged and washed in CytoLyt Solution and transferred to PreservCyt Solution prior to being processed on the ThinPrep 2000 Processor." "Addition of CytoLyt Solution to cell pellets is required to wash the sample." "Concentrate by centrifugation - 600g for 10 minutes The purpose of this procedure is to concentrate the cellular material in order to separate the cellular component(s) from the supernatant. This step is performed with fresh samples and after the addition of CytoLyt Solution." "When a sample is collected in CytoLyt Solution at a ratio less than 30 parts CytoLyt Solution to 1 part sample, this is considered a Collection Step and not a Wash Step. For example, if one collects 15ml of a sample and adds 30ml of CytoLyt Solution to this sample, then the CytoLyt: sample ratio is only 2 to 1 and this is considered a sample collection step and still requires a CytoLyt Solution Wash." 2. During an observation of nongynecologic specimen processing (specimen N24-01024) on November 19, 2024 at 8:45 AM, Staff A poured the fine needle aspiration specimen into a 50ml centrifuge tube and added 5ml's of Lyse Red. The specimen was centrifuged for 5 minutes and decanted. Staff A added an additional 5ml's of Lyse Red, vortexed and centrifuged the specimen, then decanted and the cell pellet added to a Hologic ThinPrep PreservCyt Solution Vial. a. The laboratory failed to follow the manufacturer's instructions when processing nongynecologic specimens. The laboratory failed to perform a CytoLyt wash on nongynecologic specimens during specimen processing. 3. During an interview on November 19, 2024 at 9:35 AM, these findings were confirmed with the Cytotechnologist, Staff A and Staff B. 4. During an interview on November 20, 2024 at 11:00 AM, these findings were confirmed with Technical Supervisor B.
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 2000 SYSTEM OPERATOR'S MANUAL and interviews the laboratory failed to establish performance specifications when the laboratory modified the Hologic ThinPrep test system manufacturer's instructions with an alternate method of processing nongynecologic cytology specimens. 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. Refer to D5411
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, interviews and review of laboratory records the laboratory failed to establish and follow 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 malignant neoplasms with available histopathology. The laboratory failed to determine the cause of discrepancy for five of five cases from January 2024 through June 2024. 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. a. The procedure FOLLOW-UP stated: "A list of atypical cases (ASCUS and above) and positive cases are maintained monthly. Biopsy correlation of each is made." b. The procedure failed to define what the laboratory considered discrepant and how the the laboratory would determine and document the cause of any discrepancy. 2. During an interview on November 18, 2024 at 11:15 AM, the Cytotechnologist stated the laboratory correlated all gynecologic cases with a diagnosis of atypical squamous cells of undetermined significance (ASCUS), LSIL, HSIL or malignancy when the Technical Supervisors reviewed the histopathology. The Cytotechnologist further stated the Technical Supervisors would document discrepancies as "unknown". a. The Survey Team reviewed records titled HISTOLOGY CORRELATION OF ATYPICAL PAPS from January 2024 through June 2024. The laboratory failed to document the cause of discrepancy between the gynecologic cytology report with a diagnosis of LSIL or HSIL and the histopathology diagnosis of Benign or Negative for five of five cases. Cases include: -C24-00655 -C24-01100 -C24-01336 -C24-01455 -C24-01718 b. The records stated the cause of the discrepancies was "unknown". 3. During an interview on November 19, 2024 at 2:00 PM, these findings were confirmed with the Cytotechnologist. 4. During an interview on November 20, 2024 at 11:00 AM, these findings were confirmed with Technical Supervisor B.
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 interviews the laboratory failed to establish and follow 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. The laboratory failed to document the search for prior negative gynecologic specimens for 34 of 38 HSIL or malignant specimens from January 1, 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 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 FIVE YEAR RETROSPECTIVE 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 34 of 38 HSIL or malignant specimens from January 1, 2024 to the date of the survey in 2024. Specimens include: -C24-00013 -C24-00064 -C24-00098 -C24-00261 -C24-00504 -C24-00569 -C24-00580 -C24-00638 -C24-00741 -C24-00799 -C24-00803 -C24-00941 -C24-01247 -C24-01313 -C24-01452 -C24-01455 -C24-01456 -C24-01470 -C24-01534 -C24-01560 -C24-01632 -C24-01718 -C24-01726 -C24-01976 -C24-02027 -C24-02304 -C24-02378 -C24-02492 -C24-02660 -C24-02790 -C24-02868 -C24-02893 -C24-02912 -C24-02967 3. During an interview on November 20, 2024 at 8:25 AM, these findings were confirmed with the Cytotechnologist. 4. During an interview on November 20, 2024 at 11:00 AM, these findings were confirmed with Technical Supervisor B.
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, laboratory records and interviews the laboratory failed to follow written policies and procedures for an annual statistical evaluation of one of six required gynecologic laboratory statistics. The laboratory failed to document one of six required gynecologic laboratory statistics

	for 2022 and 2023. Findings include: 1. The laboratory failed to follow the procedure ANNUAL REPORTS, which stated: "Valley Pathology submits monthly statistics on the following:" "number of discrepant cases where any rescreen of previous negative results in reclassification of pre-malignant or malignant" 2. The Survey Team requested and the laboratory failed to provide one of six required annual gynecologic laboratory statistics for 2022 and 2023. Statistic includes: -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 November 19, 2024 at 2:00 PM, these findings were confirmed with the Cytotechnologist. 4. During an interview on November 20, 2024 at 11:00 AM, these findings were confirmed with 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 and interviews the laboratory failed to establish written policies and procedures to ensure workload limits would be prorated for the Cytotechnologist 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 Cytotechnologist when examining slides in less than an eight-hour day, or with duties other than examining cytology specimen slides. 2. During an interview on November 19, 2024 at 2:00 PM, these findings were confirmed with the Cytotechnologist. 3. During an interview on November 20, 2024 at 11:00 AM, these findings were confirmed with 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 the corresponding final test reports and confirmation by Technical Supervisor B the laboratory failed to follow written policies and procedures to ensure unsatisfactory gynecologic slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report six of 12 gynecologic tests from October 2024 through November 2024 as unsatisfactory for evaluation. Findings include: 1. The laboratory failed to follow the procedure CLASSIFICATION, which stated: "Unsatisfactory: Cases are classified as unsatisfactory:" "Too few cells for evaluation

	as defined by Bethesda 2001" 2. The laboratory failed to identify and report six of 12 gynecologic tests from October 2024 through November 2024 as unsatisfactory for evaluation. These findings were confirmed by Technical Supervisor B on November 22, 2024. Test includes: -C24-02854 -C24-02875 -C24-02994 -C24-03033 -C24-03034 -C24-03087
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, and interviews the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the analytic cytology systems. The laboratory failed to document analytic quality assessment activities during 2022, 2023 and January 1, 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 an ongoing program to monitor, assess and correct problems identified in the analytic cytology systems. 2. The Survey Team requested and the laboratory failed to provide documentation of analytic quality assessment activities during 2022, 2023 and January 1, 2024 to the date of the survey in 2024. a. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL, adenocarcinoma, or malignant neoplasms with available histopathology. Refer to D5623 b. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the program to review prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of HSIL or malignancy and identify cases with a more significant lesion. Refer to D5625
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of final cytology test reports and interviews the laboratory failed to maintain duplicates of one of one original final cytology test report from September 2024 when a correction was made to the original final cytology test report. Findings

	include: 1. The Survey Team requested and the laboratory failed to provide a duplicate of the original final cytology test report for one of one corrected cytology test reports. Refer to D5401
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, specimen slides, observation 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); and failed to ensure the competency of two of two Technical Supervisors (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, specimen slides, observation 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 patient specimens were labeled with a unique patient identifier during all phases of testing. Refer to D5203 2. The Laboratory Director failed to provide direction and oversight to ensure the laboratory followed one written policy and procedure. Refer to D5401 3. The Laboratory Director failed to provide direction and oversight to ensure written policies and procedures were established for all laboratory test processes. Refer to D5403 4. The Laboratory Director failed to provide direction and oversight to ensure manufacturer's instructions were followed. Refer to D5411, D5423 5. The Laboratory Director failed to provide direction and oversight to ensure a program was established to compare clinical information with cytology reports and to compare all gynecologic cytology

	reports with a diagnosis of HSIL, adenocarcinoma, or malignant neoplasms with available histopathology. Refer to D5623 6. The Laboratory Director failed to provide direction and oversight 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 7. The Laboratory Director failed to provide direction and oversight to ensure the compilation, documentation and evaluation of the required annual laboratory statistics. Refer to D5629 8. The Laboratory Director failed to provide direction and oversight to ensure written policies and procedures were established to ensure workload limits would be prorated for the Cytotechnologist when examining slides in less than an eight-hour work day. Refer to D5641 9. The Laboratory Director failed to provide direction and oversight to ensure unsatisfactory gynecologic slide preparations were identified and reported as unsatisfactory. Refer to D5655 10. The Laboratory Director failed to provide direction and oversight to ensure duplicates of original final test reports were maintained when a correction was made to the original final test report. Refer to D5821
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, nongynecologic specimen slides and interviews the Laboratory Director failed to ensure quality assessment programs were established to assure the quality of cytology services. The Laboratory Director failed to identify failures in quality as they occur. Findings include: 1. The Laboratory Director failed to ensure quality assessment programs were established to monitor, assess and correct problems identified in the general laboratory systems. Refer to D5291 2. The Laboratory Director failed to ensure quality assessment programs were established to monitor, assess and correct problems identified in the analytic cytology systems. Refer to D5791
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 interviews the Laboratory Director failed to ensure written policies and procedures were established and followed to assess, monitor and maintain the competency of the Technical Supervisors. Findings include: 1. The Laboratory

	Director failed to provide written policies and procedures to assess the competency of two of two Technical Supervisors to perform cytology test procedures and report cytology test results. Refer to D5209.
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 332 gynecologic cases/slides from October 2024 through November 2024 and confirmation by Technical Supervisor B on November 22, 2024 the Technical Supervisor failed to verify the accuracy of six gynecologic cytology tests. Findings include: 1. C24-02854 10/24/2024 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation. Insufficient Cellularity. TECHNICAL SUPERVISOR B DIAGNOSIS: Unsatisfactory for Interpretation. Partially Obscuring Blood. 2. C24-02875 10/24/2024 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation. Insufficient Cellularity and Lubricant TECHNICAL SUPERVISOR B DIAGNOSIS: Unsatisfactory for Interpretation. Lubricant Contamination. 3. C24-02994 11/06/2024 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation. Insufficient Cellularity and Lubricant TECHNICAL SUPERVISOR B DIAGNOSIS: Unsatisfactory for Interpretation. Lubricant. 4. C24-03033 11/12/2024 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation. Insufficient Cellularity and Lubricant TECHNICAL SUPERVISOR B DIAGNOSIS: Unsatisfactory for Interpretation. Lubricant. 5. C24-03034 11/12/2024 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation. Insufficient Cellularity and Lubricant TECHNICAL SUPERVISOR B DIAGNOSIS: Unsatisfactory for Interpretation. Lubricant. 6. C24-03087 11/15/2024 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation. Insufficient Cellularity and Lubricant TECHNICAL SUPERVISOR B DIAGNOSIS: Unsatisfactory for Interpretation. Lubricant Contamination.
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.