Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2223306	01/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Summit Pathology Labs, Inc	6767 West 29th Street, Greeley, CO	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the lack of cytology proficiency testing (PT) enrollment records and interviews the laboratory failed to enroll in a CMS-approved cytology PT program for gynecologic examination (refer to D2001).
D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and This STANDARD is not met as evidenced by: Based on the lack of cytology PT enrollment records and interviews the laboratory failed to enroll in a CMS-approved cytology PT program for gynecologic examination

	for 2023 prior to the date of the survey on January 8, 2025. Findings include: 1. The Survey Team requested and the laboratory failed to provide records of enrollment in a CMS-approved cytology PT program for 2023. 2. During an interview on January 6, 2025 at 3:45 PM, when asked if the laboratory had enrolled or was currently enrolled in a CMS-approved cytology PT program the Director of Compliance and Quality replied "no." 3. During an interview on January 8, 2025 at 12:15 PM, the Director of Cytology and Molecular confirmed the laboratory had not been enrolled prior to the survey, and stated the laboratory enrolled in a 2025 PT program during the survey. 4. The laboratory provided a record of enrollment in a CMS-approved PT program for 2024 post-survey, on January 16, 2025.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures and interviews the laboratory failed to establish and follow safety procedures to ensure protection from physical, chemical and electrical hazards. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure protection from physical, chemical and electrical hazards that were specific to the laboratory being surveyed. 2. During an interview on January 6, 2025 at 1:20 PM, the Director of Compliance and Quality stated "the laboratory uses policies and procedures from the main laboratory and the hospital." When asked if the laboratory had its own written policies and procedures that were specific to the laboratory site and operations, the Director of Compliance and Quality replied "no, we use the same procedures for all sites for training." 3. During an interview on January 6, 2025 at 3:45 PM, when asked if the laboratory had written safety procedures to ensure protection from physical, chemical and electrical hazards that were specific to the laboratory being surveyed, the Director of Compliance and Quality replied "the hospital safety person can get the hospital procedures." The Director of Compliance and Quality confirmed there were no written policies and procedures specific to the laboratory site and operations. 4. During a phone interview on January 7, 2025 at 9:30 AM, the Director of Compliance and Quality stated the laboratory "will redo the policies from the main laboratory so they are specific to the laboratory and each site."
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 the lack of laboratory policies and procedures and interviews the laboratory failed to establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of receipt

	of the specimen through completion of testing and reporting of results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the laboratory's process to ensure positive identification and optimum integrity of a patient's specimen from the time the specimen slides are transported and received through the completion of testing and reporting of results. 2. During an interview on January 6, 2025 at 1:20 PM, the Director of Compliance and Quality stated, "the laboratory uses policies and procedures from the main laboratory and the hospital." When asked if the laboratory had its own written policies and procedures that were specific to the laboratory site and operations, the Director of Compliance and Quality replied, "no, we use the same procedures for all sites for training." 3. During a phone interview on January 7, 2025 at 9:30 AM, the Director of Compliance and Quality stated the laboratory "will redo the policies from the main laboratory so they are specific to the laboratory and each site." The Director of Compliance and Quality confirmed there were no written policies and procedures for the laboratory's process to ensure positive identification and optimum integrity of a patient's specimen from the time of receipt of the specimen through completion of testing and reporting of results.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 the lack of laboratory policies and procedures and interviews the laboratory failed to have written policies and procedures specific to the laboratory being surveyed. The laboratory failed to establish written policies and procedures for four laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the laboratory's enrollment in a gynecologic cytology 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 for the laboratory's requirements for specimen slide storage, specimen slide transportation, referral and tracking between facilities, and criteria for specimen acceptability and rejection upon receipt of specimen. 3. The Survey Team requested and the laboratory

	failed to provide written policies and procedures for the laboratory's requirements for microscopic examination, including the detection of inadequately prepared slides. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures for the laboratory's system for entering results in the patient record and reporting patient results. 5. During an interview on January 6, 2025 at 1:20 PM, the Director of Compliance and Quality stated, "the laboratory uses policies and procedures from the main laboratory and the hospital." When asked if the laboratory had its own written policies and procedures that were specific to the laboratory site and operations, the Director of Compliance and Quality replied, "no, we use the same procedures for all sites for training." 6. During a phone interview on January 7, 2025 at 9:30 AM, the Director of Compliance and Quality stated the laboratory "will redo the policies from the main laboratory so they are specific to the laboratory and each site."
D5623	CYTOLOGY CFR(s): 493.1274(c)(2) (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 the lack of laboratory policies and procedures, review of laboratory records and interviews 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 high-grade squamous intraepithelial lesion (HSIL) or other malignant neoplasms with available histopathology. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail 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 the histopathology report and determine the cause of any discrepancies. a. During an interview on January 7, 2025 at 8:45 AM, the Director of Cytology and Molecular stated that FACILITY B (CLIA #06D1024422) was responsible for performing the requirements of the cytology comparative program and confirmed the laboratory did not have written policies or procedures to detail this process. 2. The Survey Team requested and the laboratory failed to provide records for a program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL or other malignant neoplasms with available histopathology. a. The untitled records provided by the laboratory included correlative information for cases evaluated and reported from multiple locations, was completed by staff at FACILITY B, and was not specific to the laboratory being surveyed. The cases evaluated and reported from the laboratory could not be identified from cases evaluated and reported at other facilities. 3. During an interview on January 6, 2025 at 1:20 PM, the Director of Compliance and Quality stated, "the laboratory uses policies and procedures from the main laboratory and the hospital." When asked if the laboratory had its own written policies and procedures that were specific to the laboratory site and operations, the Director of Compliance and Quality replied, "no, we use the same procedures for all sites for training." 4. During a phone interview on January 7, 2025 at 9:30 AM, the Director of Compliance

	and Quality stated the laboratory "will redo the policies from the main laboratory so they are specific to the laboratory and each site."
D5625	CYTOLOGY CFR(s): 493.1274(c)(3) (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 the lack of laboratory policies and procedures, review of laboratory records and interviews the laboratory failed to establish and follow written policies and procedures for a program to review all normal or negative gynecologic specimens received within the previous five years from each patient with a current diagnosis of HSIL or other malignant neoplasms. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the laboratory's process to review all normal or negative gynecologic specimens received within the previous five years from each patient with a current diagnosis of HSIL or other malignant neoplasms. a. During an interview on January 7, 2025 at 8:45 AM, the Director of Cytology and Molecular stated that FACILITY B was responsible for performing the requirements of the retrospective review program and confirmed the laboratory did not have written policies or procedures to detail this process. 2. The Survey Team was provided records titled FIVE YEAR LOOKBACK QUARTERLY SUMMARY from January through December 2023 and January through September 2024. a. The records provided by the laboratory included documentation for cases evaluated and reported from multiple locations, was completed by staff at FACILITY B, and was not specific to the laboratory being surveyed. The cases evaluated and reported from the laboratory could not be identified from cases evaluated and reported at other facilities. 3. During an interview on January 6, 2025 at 1:20 PM, the Director of Compliance and Quality stated, "the laboratory uses policies and procedures from the main laboratory and the hospital." When asked if the laboratory had its own written policies and procedures that were specific to the laboratory site and operations, the Director of Compliance and Quality replied, "no, we use the same procedures for all sites for training." 4. During a phone interview on January 7, 2025 at 9:30 AM, the Director of Compliance and Quality stated the laboratory "will redo the policies from the main laboratory so they are specific to the laboratory and each site."
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (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 the lack of laboratory policies and procedures, review of statistical records and interviews the laboratory failed to establish and follow written policies and procedures for an annual statistical evaluation of six of six required gynecologic cytology laboratory statistics. The laboratory failed to maintain statistical records for six of six statistics in 2023 and 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of the six required gynecologic cytology laboratory statistics. a. The laboratory failed to establish written policies and procedures to detail how a program would be established and followed to evaluate the six required statistics specifically for only the cases evaluated and reported from the laboratory being surveyed. 2. The Survey Team requested and the laboratory failed to provide the six of six annual gynecologic cytology statistics for 2023 and 2024 a. The Survey Team was provided statistical reports for 2023 and 2024 which reflected specimen statistical evaluations for multiple testing locations. The reports failed to reflect statistical evaluations for only the laboratory being surveyed. b. During an interview on January 6, 2025 at 3:20 PM, the Director of Cytology and Molecular stated, "we do not separate out the specimens by site. I asked IT and they said it would take some time to do that." 3. During an interview on January 6, 2025 at 1:20 PM, the Director of Compliance and Quality stated, "the laboratory uses policies and procedures from the main laboratory and the hospital." When asked if the laboratory had its own written policies and procedures that were specific to the laboratory site and operations, the Director of Compliance and Quality replied, "no, we use the same procedures for all sites for training." 4. During a phone interview on January 7, 2025 at 9:30 AM, the Director of Compliance and Quality stated the laboratory "will redo the policies from the main laboratory so they are specific to the laboratory and each site." B. Based on the lack of laboratory policies and procedures, review of statistical records and interviews the laboratory failed to establish and follow written policies and procedures for an annual statistical evaluation of three of three required nongynecologic cytology laboratory statistics. The laboratory failed to maintain statistical records for three of three statistics in 2023 and 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of the three required nongynecologic cytology laboratory statistics. a. The laboratory failed to establish written policies and procedures to detail how a program would be established and followed to evaluate the three required statistics specifically for only the cases evaluated and reported from the laboratory being surveyed. Statistics include: -Number of cases examined; -Number of specimens processed by specimen type; -Number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). 2. The Survey Team requested and the laboratory failed to provide two of three annual nongynecologic cytology statistics for 2023 and 2024. Statistics include: -Number of specimens processed by specimen type; -Number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). a. The Survey Team was provided statistical reports for 2023 and 2024 which reflected specimen statistical evaluations for multiple testing locations. The reports failed to reflect statistical evaluations for only the laboratory being surveyed. b. During an interview on January 6, 2025 at 3:20 PM, the Director of Cytology and Molecular stated, "we do not separate out the specimens by site. I asked IT and they said it would take some time to do that." 3. During an interview on January 6, 2025 at 1:20 PM, the Director of Compliance and Quality stated, "the laboratory uses policies

	and procedures from the main laboratory and the hospital." When asked if the laboratory had its own written policies and procedures that were specific to the laboratory site and operations, the Director of Compliance and Quality replied, "no, we use the same procedures for all sites for training." 4. During a phone interview on January 7, 2025 at 9:30 AM, the Director of Compliance and Quality stated the laboratory "will redo the policies from the main laboratory so they are specific to the laboratory and each site."
D5631	CYTOLOGY CFR(s): 493.1274(c)(6) (c)(6) An evaluation of the case reviews of each individual examining slides against the laboratorys overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken. (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures, lack of laboratory records and interviews the laboratory failed to establish and follow written policies and procedures for a program to evaluate the case reviews of 15 Technical Supervisors against the laboratory's overall statistical values in 2023 and 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 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 15 of 15 Technical Supervisors against the laboratory's overall statistical values in 2023 and 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F -Technical Supervisor G -Technical Supervisor H -Technical Supervisor I -Technical Supervisor J -Technical Supervisor K -Technical Supervisor L -Technical Supervisor M -Technical Supervisor N -Technical Supervisor O 3. During an interview on January 6, 2025 at 1:20 PM, the Director of Compliance and Quality stated, "the laboratory uses policies and procedures from the main laboratory and the hospital." When asked if the laboratory had its own written policies and procedures that were specific to the laboratory site and operations, the Director of Compliance and Quality replied, "no, we use the same procedures for all sites for training." 4. During a phone interview on January 7, 2025 at 9:30 AM, the Director of Compliance and Quality stated the laboratory "will redo the policies from the main laboratory so they are specific to the laboratory and each site."
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures and interviews the laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory gynecologic and nongynecologic cytology slide preparations were identified and

	reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 3. During an interview on January 6, 2025 at 1:20 PM, the Director of Compliance and Quality stated, "the laboratory uses policies and procedures from the main laboratory and the hospital." When asked if the laboratory had its own written policies and procedures that were specific to the laboratory site and operations, the Director of Compliance and Quality replied, "no, we use the same procedures for all sites for training." 4. During a phone interview on January 7, 2025 at 9:30 AM, the Director of Compliance and Quality stated the laboratory "will redo the policies from the main laboratory so they are specific to the laboratory and each site."
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures and interviews the laboratory failed to establish and follow written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report gynecologic and nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report gynecologic cytology test results. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. 3. During an interview on January 6, 2025 at 1:20 PM, the Director of Compliance and Quality stated, "the laboratory uses policies and procedures from the main laboratory and the hospital." When asked if the laboratory had its own written policies and procedures that were specific to the laboratory site and operations, the Director of Compliance and Quality replied, "no, we use the same procedures for all sites for training." 4. During a phone interview on January 7, 2025 at 9:30 AM, the Director of Compliance and Quality stated the laboratory "will redo the policies from the main laboratory so they are specific to the laboratory and each site."
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 the lack of laboratory policies and procedures, laboratory records, and interviews the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The

	Laboratory Director failed to be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations (refer to D6079); failed to ensure the laboratory enrolled in an annual CMS-approved gynecologic cytology PT program for 2023 (refer to D6088); and failed to ensure quality control and quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur (refer to D6093).
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 the lack of laboratory policies and procedures, review of laboratory records and interviews the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory and for assuring compliance with applicable regulations. Findings include: 1. The Laboratory Director failed to provide direction and oversight to ensure written policies and procedures were established for requirements and test processes that were specific to the laboratory. Refer to D3011, D5203, D5403, D5623, D5625, D5629, D5631, D5655, D5657.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on the lack of gynecologic cytology PT enrollment records and interviews the Laboratory Director failed to ensure the laboratory enrolled in an annual CMS-approved gynecologic cytology PT program for 2023. Findings include: 1. The Laboratory Director failed to ensure the laboratory enrolled in a CMS-approved PT program for 2023. Refer to D2001
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 the lack of laboratory policies and procedures and interviews the Laboratory Director failed to ensure quality control and quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur in all phases of testing. Findings include: 1. The Laboratory Director failed to ensure written policies and procedures were established and maintained for a quality control program, to detail the quality control activities performed for all phases of cytology testing at the laboratory. 2. The Laboratory Director failed to ensure written policies and procedures were established and maintained for a quality assessment program, to detail the quality assessment activities performed for all phases of cytology testing at the laboratory. 3. During an interview on January 6, 2025 at 1:20 PM, the Director of Compliance and Quality stated, "the laboratory uses policies and procedures from the main laboratory and the hospital." When asked if the laboratory had its own written policies and procedures that were specific to the laboratory site and operations, the Director of Compliance and Quality replied, "no, we use the same procedures for all sites for training." 4. During a phone interview on January 7, 2025 at 9:30 AM, the Director of Compliance and Quality stated the laboratory "will redo the policies from the main laboratory so they are specific to the laboratory and each site."
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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 the lack of laboratory policies and procedures, review of records and interviews the Laboratory Director failed to ensure that policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure they maintain their competency to perform test procedures and report test results promptly and proficiently. Findings include; 1. The Survey Team requested and the laboratory failed to provide written policies and procedures established and approved by the Laboratory Director to detail the laboratory's process for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing. a. The Director of Compliance and Quality and the Director of Cytology and Molecular provided records of Technical Supervisor performance and educational activities but failed to provide written policies and procedures to detail how these records were utilized by the laboratory to monitor individuals for the duties performed in the laboratory. 2. During an interview on January 6, 2025 at 1:20 PM, the Director of Compliance and Quality stated, "the laboratory uses policies and procedures from the main laboratory and the hospital." When asked if the laboratory had its own written policies and procedures that were specific to the laboratory site and operations, the Director of Compliance and Quality replied, "no, we use the same procedures for all sites for training." 3. During a phone

	interview on January 7, 2025 at 9:30 AM, the Director of Compliance and Quality stated the laboratory "will redo the policies from the main laboratory so they are specific to the laboratory and each site."
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.