Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2141095	04/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Associated Pathologist Llc	4321 Carothers Pkwy, Pathology Dept, Franklin, TN	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
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 an approved 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; 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 an HHS-approved cytology PT program for gynecologic

	examination for 2021 and 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide records of enrollment in an approved cytology PT program for 2021 and 2022. 2. During an interview on April 18, 2023 at 11:05 AM, the Pathology Support Manager stated "we don't have that." 3. During an interview on April 19, 2023 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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 the lack of laboratory policies and procedures, review of laboratory records and interviews the laboratory failed to establish written policies and procedures to ensure confidentiality of patient information (refer to D5201); failed to establish written policies and procedures to assess the competency of the Technical Supervisors, and failed to assess the competency of eight of eight Technical Supervisors (refer to D5209); failed to ensure a written procedures manual for all cytology tests and examinations performed by the laboratory was available to laboratory personnel (refer to D5401); failed to establish written policies and procedures for six laboratory test processes (refer to D5403); failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the Hologic ThinPrep Pap Test (refer to D5411); 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 high-grade squamous intraepithelial lesion (HSIL) or malignant neoplasms with available histopathology, and failed to provide records for a correlative review program to determine the causes of any discrepancies (refer to D5623); failed to establish written policies and procedures for the review of all negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy, and failed to provide records documenting a search and review of prior negative specimens for each patient with a current HSIL or malignancy was performed (refer to D5625); failed to establish written policies and procedures for an annual statistical evaluation of the required gynecologic laboratory statistics, and failed to document the required laboratory statistics for 2021 and 2022 (refer to D5629); failed to establish written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory (refer to D5655); failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report cytology test results (refer D5657); and failed to establish written policies and procedures to ensure corrected test reports indicated the basis for the correction on the test report, and failed to indicate the basis for the correction on one of two corrected test reports (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 the lack of laboratory policies and procedures and interviews 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 April 17, 2023 at 11:30 AM, the Survey Team reviewed electronic procedures with the Pathology Support Manager. The Pathology Support Manager stated that the procedures were for Facility B (CLIA 44D0934312) and not for the laboratory being surveyed. 3. During an interview on April 19, 2023 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures, interviews and lack of competency assessment records, the laboratory failed to establish written policies and procedures to assess the competency of the Technical Supervisors. The laboratory failed to assess the competency of eight of eight Technical Supervisors in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process for assessing the competency of the Technical Supervisors. a. During an interview on April 17, 2023 at 11:30 AM, the Survey Team reviewed electronic procedures with the Pathology Support Manager. The Pathology Support Manager stated that the procedures were for Facility B and not for the laboratory being surveyed. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for eight of eight Technical Supervisors in 2021, 2022 and to the date of the survey in 2023. Technical Supervisors include: - Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F -Technical Supervisor G -Technical Supervisor H 3. During an interview on April 19, 2023 at 10:30 AM, 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 the lack of a policy and procedures manual and interviews a written procedure manual for all cytology tests and examinations performed by the laboratory

	was not available to laboratory personnel. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written procedures manual for all cytology tests and examinations performed at the laboratory. 2. During an interview on April 17, 2023 at 11:30 AM, the Survey Team reviewed electronic procedures with the Pathology Support Manager. The Pathology Support Manager stated that the procedures were for Facility B and not for the laboratory being surveyed. 3. During an interview on April 19, 2023 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures for six laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process of receiving slides from Facility B and transporting slides to Facility B. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures for the microscopic examination of gynecologic cytology specimens, including the detection of inadequately prepared specimen slides. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures for the microscopic examination of nongynecologic cytology specimens, including the detection of inadequately prepared specimen slides. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how cytology test results were reported in the laboratory information system (LIS). 5. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for cytology PT enrollment and participation of personnel that perform gynecologic cytology testing. 6. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the laboratory's retention requirements. 7. During an interview on April 17, 2023 at 11:30 AM, the Survey Team reviewed electronic procedures with the Pathology Support Manager. The Pathology Support Manager stated that the procedures were for Facility B and not for the laboratory being surveyed. 8. During an interview on April 19, 2023 at 10:30

	AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, lack of morphology certification records and interview the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the Hologic ThinPrep Pap Test in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL states: "Evaluation of microscope slides produced with the THINPREP 2000 SYSTEM should be performed only by cytotechnologists and pathologists who have been trained to evaluate THINPREP prepared slides by HOLOGIC or by organizations or individuals designated by HOLOGIC." 2. The Survey Team requested and the laboratory failed to provide the required morphology certification for eight of eight Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests in 2021, 2022 and to the date of the survey in 2023. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F -Technical Supervisor G -Technical Supervisor H 3. During an interview on April 18, 2023 at 11:05 AM, these findings were confirmed with the Laboratory Director /Technical Supervisor A and the Pathology Support Manager.
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 the lack of laboratory policies and procedures, interviews and lack of laboratory records the laboratory failed to establish written policies and procedures for a program to compare clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL or malignant neoplasms with available histopathology. The laboratory failed to provide records for a correlative review program to determine the causes of any discrepancies in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for a program to compare

	clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasms with available histopathology to determine the causes of any discrepancies. a. During an interview on April 17, 2023 at 11:30 AM, the Survey Team reviewed electronic procedures with the Pathology Support Manager. The Pathology Support Manager stated that the procedures were for Facility B and not for the laboratory being surveyed. 2. The Survey Team requested and the laboratory failed to provide records of a laboratory comparison of clinical information with cytology reports and a comparison of all gynecologic cytology reports with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasms with available histopathology for 2021, 2022 and to the date of the survey in 2023. a. During an interview on April 18, 2023 at 1:10 PM, the Pathology Support Manager stated that Facility B performed the comparative reviews. 3. During an interview on April 19, 2023 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5625	CYTOLOGY CFR(s): 493.1274(c)(3) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report. This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures, interviews and lack of laboratory records the laboratory failed to establish written policies and procedures for the review of all negative gynecologic specimens received within the previous five years for each patient with a current HSIL or malignancy. The laboratory failed to provide records documenting a search and review of prior negative specimens for each patient with a current HSIL or malignancy was performed in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's current process for the search and review of all negative gynecologic specimens received within the previous 5 years, for each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm reported by the laboratory. a. During an interview on April 17, 2023 at 11:30 AM, the Survey Team reviewed electronic procedures with the Pathology Support Manager. The Pathology Support Manager stated that the procedures were for Facility B and not for the laboratory being surveyed. 2. The Survey Team requested and the laboratory failed to provide records documenting that a search and review of prior negative specimens for each patient with a current HSIL or malignancy reported at this laboratory was performed in 2021, 2022 and to the date of the survey in 2023. a. During an interview on April 18, 2023 at 1:10 PM, the Pathology Support Manager stated that Facility B performed the search and review of prior negative specimens for each patient with a current HSIL or malignancy.. 3. During an interview on April 19, 2023 at 10:30 AM, 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 the lack of laboratory policies and procedures, interviews and review of laboratory records the laboratory failed to establish written policies and procedures for an annual statistical evaluation of six of six required gynecologic laboratory statistics. The laboratory failed to document six of six required gynecologic laboratory statistics for 2021 and 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of six of six required gynecologic statistics. Statistics include: -The number of cytology cases examined; -The number of specimens processed by specimen type; -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation; -The number of gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; -The number of gynecologic cases where cytology and histology are discrepant; -The number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. a. During an interview on April 17, 2023 at 11:30 AM, the Survey Team reviewed electronic procedures with the Pathology Support Manager. The Pathology Support Manager stated that the procedures were for Facility B and not for the laboratory being surveyed. 2. The Survey Team requested and the laboratory failed to provide six of six required annual gynecologic laboratory statistics for 2021 and 2022. Statistics include: -The number of cytology cases examined; -The number of specimens processed by specimen type; -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation; -The number of gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; -The number of gynecologic cases where cytology and histology are discrepant; -The number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. a. During an interview on April 18, 2023 at 8:40 AM, the Pathology Support Manager provided records titled 2022 CYTOLOGY STATISTICS SUMMARY and 2021 CYTOLOGY STATISTICS SUMMARY. The Pathology Support Manager stated the statistics were for all cases accessioned at Facility B and the laboratory did not have a way to compile annual statistics for the laboratory being surveyed. 3. During an interview on April 19, 2023 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. B. Based on the lack of laboratory

	policies and procedures, interviews and review of laboratory records the laboratory failed to establish written policies and procedures for an annual statistical evaluation of three of three required nongynecologic laboratory statistics. The laboratory failed to document three of three required nongynecologic laboratory statistics for 2021 and 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of three of three required nongynecologic statistics. Statistics include: -The number of cytology cases examined; -The number of specimens processed by specimen type; -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation. a. During an interview on April 17, 2023 at 11:30 AM, the Survey Team reviewed electronic procedures with the Pathology Support Manager. The Pathology Support Manager stated that the procedures were for Facility B and not for the laboratory being surveyed. 2. The Survey Team requested and the laboratory failed to provide three of three required annual nongynecologic laboratory statistics for 2021 and 2022. Statistics include: -The number of cytology cases examined; -The number of specimens processed by specimen type; -The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation. a. During an interview on April 18, 2023 at 8:40 AM, the Pathology Support Manager provided records titled 2022 CYTOLOGY NONGYN STATISTICS-GN SITE CODE and 2021 CYTOLOGY NONGYN STATISTICS-GN SITE CODE. The Pathology Support Manager stated the statistics were for all cases accessioned at Facility B and the laboratory did not have a way to compile annual statistics for the laboratory being surveyed. 3. During an interview on April 19, 2023 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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 the lack of laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory gynecologic slide preparations were identified and reported as unsatisfactory for evaluation. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory for evaluation. 3. During an interview on April 17, 2023 at 11:30 AM, the Survey Team reviewed electronic procedures with the Pathology Support Manager. The Pathology Support Manager stated that the procedures were for Facility B and not for the laboratory being surveyed. 4. During an interview on April 19, 2023 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5657	CYTOLOGY CFR(s): 493.1274(e)(5)

	(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by: A. Based on the lack of laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report gynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report gynecologic cytology test results. 2. During an interview on April 17, 2023 at 11:30 AM, the Survey Team reviewed electronic procedures with the Pathology Support Manager. The Pathology Support Manager stated that the procedures were for Facility B and not for the laboratory being surveyed. 3. During an interview on April 19, 2023 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. B. Based on lack of laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report 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 nongynecologic cytology test results. 2. During an interview on April 17, 2023 at 11: 30 AM, the Survey Team reviewed electronic procedures with the Pathology Support Manager. The Pathology Support Manager stated that the procedures were for Facility B and not for the laboratory being surveyed. 3. During an interview on April 19, 2023 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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 the lack of laboratory policies and procedures,interviews and review of corrected test reports the laboratory failed to establish written policies and procedures to ensure corrected test reports indicated the basis for the correction on the test report. One of two corrected test reports from November 2022 through April 2023 failed to indicate the basis for the 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 the correction on the test report. a. During an interview on April 17, 2023 at 11:30 AM, the Survey Team reviewed electronic procedures with the Pathology Support Manager. The Pathology Support Manager stated that the procedures were for Facility B and not for the laboratory being surveyed. 2. The Survey Team reviewed two corrected test reports from November 2022 through April 2023. One of two corrected test reports failed to

	indicate the basis for the correction on the corrected test report. Report includes: -22-PS-585512 3. During an interview on April 19, 2023 at 10:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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, review of 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 ensure that the laboratory enrolled in an annual gynecologic cytology PT program for 2021 and 2022 (refer to D6088); failed to ensure quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur (refer to D6094); failed to ensure that eight of eight Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests had received the required morphology certification prior to reporting patient specimens (refer to D6102); failed to ensure the competency of eight of eight Technical Supervisors was assessed (refer to D6103); and failed to ensure that an approved procedures manual was available to all personnel (refer to D6106).
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the lack of PT enrollment records and interviews the Laboratory Director failed to ensure the laboratory enrolled in an annual gynecologic cytology PT program for 2021 and 2022. Findings include: 1. The Laboratory Director failed to ensure the laboratory enrolled in an HHS-approved PT program for 2021 and 2022. Refer to D2001
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 the lack of laboratory policies and procedures, review of laboratory records and interviews the Laboratory Director failed to ensure quality assessment programs were established and followed 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. 2. The Laboratory Director failed to provide records of an established quality assessment program and failed to identify failures in quality as they occurred in 2021, 2022 and to the date of the survey in 2023. a. The Laboratory Director failed to establish a program for monitoring the comparison of clinical information with cytology reports and to compare all gynecologic cytology reports with a diagnosis of HSIL or malignant neoplasms with available histopathology. Refer to D5623 b. The Laboratory Director failed to establish a program for monitoring the review of prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of HSIL or malignancy. Refer to D5625 c. The Laboratory Director failed to establish a program for monitoring the annual statistical evaluation of the required laboratory statistics. Refer to D5629
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, lack of laboratory certification records and interview the Laboratory Director failed to ensure that eight of eight Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests had received the required morphology certification prior to reporting patient specimens in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide the required morphology certification for eight of eight Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests in 2021, 2022 and to the date of the survey in 2023. Refer to D5411
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures, interviews and lack of competency assessment records the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain the competency of the Technical Supervisors performing cytology duties. Findings

	include: 1. The Laboratory Director failed to ensure competency was assessed for eight of eight Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Refer to D5209
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on the lack of a policy and procedures manual and interviews the Laboratory Director failed to ensure that an approved procedures manual was available to all personnel. Findings include: 1. The Laboratory Director failed to ensure an approved procedures manual was available to all personnel. Refer to D5401
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 325 non-negative gynecologic cases/327 slides from January 2022 through April 2023 the Technical Supervisor failed to verify the accuracy of one gynecologic cytology test. 1. 23-PS-051170 01/31/2023 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Atypical Squamous Cell of Undetermined Significance SURVEY TEAM DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy Herpes TECHNICAL SUPERVISOR A DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy Cellular Changes Consistent With Herpes Simplex Virus
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.