Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0483328	03/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Associates Of Tyler, Pa	1726 South Beckham, Tyler, TX	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, interviews and specimen slides the laboratory failed to ensure the required maintenance for two of two Hologic ThinPrep 2000 Processors and eight of eight microscopes was performed, as specified by the manufacturer (refer to D5429); failed to follow written policies and procedures to ensure the review of prior negative gynecologic cases was documented (refer to D5625); failed to establish written policies and procedures to ensure the prorated workload limits would not be exceeded when examining slides in less than eight hours (refer to D5641); failed to establish written policies and procedures to ensure the laboratory maintained records of the total number of hours spent examining slides per 24-hour period (refer to D5645); and failed to follow written policies and procedures to identify and report two of two gynecologic tests as unsatisfactory (refer to D5655).
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, competency assessment records and interviews the laboratory failed to establish written policies and procedures to assess the competency of the Technical Supervisors. The laboratory failed to assess the competency for seven of seven 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 to assess the competency of the Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for seven of seven 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 3. During an interview on February 28, 2023 at 1:15 PM, these findings were confirmed with the Cytology Supervisor. 4. During an interview on March 1, 2023 at 10:45 AM, these findings were confirmed with Technical Supervisor D, Technical Supervisor G and the Cytology Supervisor.
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 60 laboratory policies and procedures, observation and interviews the laboratory failed to follow one written policy and procedure. Findings include: 1. The laboratory failed to follow the procedure BODY CAVITY FLUID PROCESSING PROCEDURE, which stated: "5. Add specimen to PreservCyt Solution Vial and allow to stand for 15 minutes." "6. Process Washings on ThinPrep 2000 using a blue filter on program #2." a. The Survey Team observed Staff A perform nongynecologic specimen processing on February 28, 2023 at 2:20 PM. Staff A added the specimen to a PreservCyt Solution Vial and immediately processed the vial on the Hologic ThinPrep 2000 Processor. Staff A stated that Staff A did not know the PreservCyt Solution Vial needed to stand for 15 minutes. 2. During an interview on February 28, 2023 at 3:30 PM, these findings were confirmed with the Cytology Supervisor. 3. During an interview on March 1, 2023 at 10:45 AM, these findings were confirmed with Technical Supervisor D, Technical Supervisor G and the Cytology Supervisor.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)

	The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of 60 laboratory policies and procedures and interviews 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 to describe the laboratory's step-by-step process for accessioning gynecologic cytology specimens into the laboratory information system (LIS). 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for accessioning nongynecologic cytology specimens into the LIS. 3. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe how the laboratory documented specimen submission problems. a. During an interview on February 28, 2023 at 11:05 AM, Staff A stated that specimen submission problems were documented on the record titled SPECIMEN RECEIPT AND LABELING QUALITY ASSURANCE LOG. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures detailing a maintenance program for eight of eight microscopes. 5. During an interview on February 28, 2023 at 1:15 PM, these findings were confirmed with the Cytology Supervisor. 6. During an interview on March 1, 2023 at 10:45 AM, these findings were confirmed with Technical Supervisor D, Technical Supervisor G and the Cytology Supervisor.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of 60 laboratory policies and procedures and interviews the laboratory failed to ensure 37 of 60 written procedures were approved, signed and dated by the Laboratory Director prior to use. Findings include: 1. The Laboratory Director failed to sign and date 37 of 60 laboratory procedures prior to use. Procedures include: -GROSS ROOM PROCEDURES -SPECIMEN REJECTION POLICY -PAP SMEAR TECHNIQUE -STAINING AND COVERSLIPPING PROCEDURES -PROCEDURE FOR EVALUATING PAPANICOLAOU STAIN QUALITY -PROCEDURE FOR SLIDE EXAMINATION AND MARKING -WORKLOAD SURVEILLANCE POLICY -GYNECOLOGIC CYTOLOGY REPORTING POLICY -REPORTING TIME FRAME POLICY -RETENTION PERIODS AND SLIDE REFERRAL PROCEDURES -GAA (GLACIAL ACETIC ACID) TREATMENT PROCEDURE -CHLAMYDIA AND GONORRHEA DECONTAMINATION PROTOCOL -THINPREP STORAGE AND DISPOSAL

	PROCEDURES -PROCEDURE FOR CASES SENT FOR HPV -CHLAMYDIA AND GONORRHEA SEND OUT PROCEDURE -DATA ENTRY PROCEDURE FOR HPV RESULTS -BIOLOGICAL SAFETY CABINET PROCEDURE -BODY CAVITY FLUID PROCESSING PROCEDURE -FNA PROCESSING PROCEDURE -CYTYC IMAGING PROCESSOR PROCEDURE -THINPREP IMAGING SYSTEM VALIDATION PROTOCOL -CYTOCENTRIFUGATION PROCEDURE - MANUAL CELL BLOCK PROCEDURE -UROVYSION COLLECTION, PROCESSING, AND SEND-OUT PROCEDURES -STANDARDIZED CRITERIA FOR ADEQUACY ASSESSMENT AND DIAGNOSTIC TERMINOLOGY ON THYROID NODULE FINE NEEDLE ASPIRATIONS -ANAL CYTOLOGY REPORTING POLICY -PATHFINDERTG TEST FOR PANCREATIC FNAS - CYTOLOGY LABORATORY QUALITY ASSURANCE PLAN -COMPUTER REPORT GENERATION - CLIA REPORTS -10% QC REVIEW OF GYNECOLOGIC CYTOLOGY AND HIERARCHICAL REVIEW OF ALL CYTOLOGY CASES -QA REVIEW OF PRIOR NEGATIVE SPECIMENS ON CURRENT ABNORMAL CERVICOVAGINAL CASES -PROFICIENCY TESTING -CYTOPATHOLOGY INTERLABORATORY COMPARISON PROGRAM -ANNUAL STATISTICAL EVALUATION -COMPETENCY ASSESSMENT - PROCESSING PERSONNEL -HOW TO COLLECT, PRESERVE, AND SUBMIT NONGYNECOLOGIC CYTOLOGY SPECIMENS FOR LABORATORY PROCESSING -POSITION DESCRIPTION - CYTOTECHNOLOGIST/GENERAL CYTOLOGY SUPERVISOR 2. During an interview on February 28, 2023 at 1:15 PM, these findings were confirmed with the Cytology Supervisor. 3. During an interview on March 1, 2023 at 10:45 AM, these findings were confirmed with Technical Supervisor D, Technical Supervisor G and the Cytology Supervisor.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on review of 60 laboratory policies and procedures and interviews the laboratory failed to maintain the date of discontinuance for seven of 13 discontinued policies and procedures. Findings include: 1. The laboratory failed to maintain the date of discontinuance for seven of 13 discontinued procedures. a. The Survey Team reviewed a black binder titled CYTOLOGY POLICY AND PROCEDURE MANUAL that contained a section titled RETIRED POLICIES & PROCEDURES. Seven of 13 discontinued procedures failed to indicate the date of discontinuance. Procedures include: -QA REVIEW OF NEGATIVE PAP SMEARS WITH SUBSEQUENT POSITIVE HPV RESULTS (initial approval 6/29/04) -QA REVIEW OF NEGATIVE PAP SMEARS WITH SUBSEQUENT POSITIVE HPV RESULTS (initial approval 6/23/06) -FNA PROCESSING PROCEDURE -STAINING AND COVERSLIPPING PROCEDURES -QA REVIEW OF PRIOR NEGATIVE SPECIMENS ON CURRENT ABNORMAL CERVICOVAGINAL CASES - CELLIENT AUTOMATED CELL BLOCK SYSTEM PROCEDURE -COLLODIAN CELL BLOCK METHOD 2. During an interview on February 28, 2023 at 1:15 PM, these findings were confirmed with the Cytology Supervisor. 3. During an interview on March 1, 2023 at 10:45 AM, these findings were confirmed with Technical Supervisor D, Technical Supervisor G and the Cytology Supervisor.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews the laboratory failed to ensure the required maintenance for two of two Hologic ThinPrep 2000 Processors and eight of eight microscopes was performed, as specified by the manufacturer, in 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide maintenance records for two of two Hologic ThinPrep 2000 Processors in 2022 and to the date of the survey in 2023. Hologic ThinPrep 2000 Processors include: -Serial #02840J03A0 -Serial #06688 2. The Survey Team requested and the laboratory failed to provide maintenance records for eight of eight microscopes in 2022 and to the date of the survey in 2023. Microscopes include: -Serial #7D03020 -Serial #7D03018 -Serial #3L09642 -Serial #8A20623 -Serial #0B13645 -Serial #9B42751 -Serial #SB26143 -Serial #7D03017 3. During an interview on February 28, 2023 at 3:30 PM, these findings were confirmed with the Cytology Supervisor. 4. During an interview on March 1, 2023 at 10:45 AM, these findings were confirmed with Technical Supervisor D, Technical Supervisor G and the Cytology Supervisor.
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 follow written policies and procedures to ensure the review of prior negative gynecologic cases received within the previous five years for each patient with a current diagnosis of high grade squamous intraepithelial lesion [HSIL] or malignancy was documented. The laboratory failed to document the review of prior negative gynecologic cases for three of 16 HSIL or malignant cases from 2021 and 2022. Findings include: 1. The laboratory failed to follow the procedure QA REVIEW OF PRIOR NEGATIVE SPECIMENS ON CURRENT ABNORMAL CERVICOVAGINAL CASES, which stated: "Each patient diagnosed with a new high grade intraepithelial lesion or cancer has all negative (within normal limits) gynecologic slides received by the laboratory within the previous 5 years reviewed if available in the laboratory." 2. The Survey Team reviewed records titled HIGH GRADE AND RETROSPECTIVE REVIEW LOG and GYN CYTOLOGY WORKSHEET. The laboratory failed to document the review of prior negative

	gynecologic cases for three of 16 HSIL or malignant cases from 2021 and 2022. Cases include: -TP21-000012 -TP21-002774 -TP22-003631 3. During an interview on February 28, 2023 at 3:30 PM, these findings were confirmed with the Cytology Supervisor. 4. During an interview on March 1, 2023 at 10:45 AM, these findings were confirmed with Technical Supervisor D, Technical Supervisor G and the Cytology Supervisor.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined; This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and procedures, workload records and interviews the laboratory failed to establish written policies and procedures to ensure the prorated workload limits for three of seven Technical Supervisors performing primary slide nongynecologic examinations would not be exceeded when examining slides in less than eight hours. Three of seven Technical Supervisors exceeded the prorated workload limits when examining slides in less than eight hours in July through December 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limits for the Technical Supervisors when examining slides in less than an eight-hour day. 2. The Survey Team reviewed workload records titled PATHOLOGIST (PRIMARY SCREEN) DAILY WORKSHEET for July through December 2022. a. Technical Supervisor A (maximum workload limit - 12.5 slides per hour) exceeded the prorated workload limit on 10 of 17 days that slides were examined. Dates include: Date: 7/18/22 TIME SCREENING: 120 minutes SLIDES EXAMINED: 38 PRORATED SLIDES ALLOWED: 25 Date: 7/22/22 TIME SCREENING: 30 minutes SLIDES EXAMINED: 8 PRORATED SLIDES ALLOWED: 6 Date: 8/1/22 TIME SCREENING: 120 minutes SLIDES EXAMINED: 40 PRORATED SLIDES ALLOWED: 25 Date: 8/5/22 TIME SCREENING: 90 minutes SLIDES EXAMINED: 24 PRORATED SLIDES ALLOWED: 18 Date: 8/17/22 TIME SCREENING: 120 minutes SLIDES EXAMINED: 31 PRORATED SLIDES ALLOWED: 25 Date: 9/2/22 TIME SCREENING: 180 minutes SLIDES EXAMINED: 50 PRORATED SLIDES ALLOWED: 37 Date: 9/9/22 TIME SCREENING: 120 minutes SLIDES EXAMINED: 31 PRORATED SLIDES ALLOWED: 25 Date: 9/12/22 TIME SCREENING: 30 minutes SLIDES EXAMINED: 8 PRORATED SLIDES ALLOWED: 6 Date: 10/10/22 TIME SCREENING: 300 minutes SLIDES EXAMINED: 77 PRORATED SLIDES ALLOWED: 62 Date: 11/11/22 TIME SCREENING: 60 minutes SLIDES EXAMINED: 14 PRORATED SLIDES ALLOWED: 12 b. Technical Supervisor D (maximum workload limit - 12.5 slides per hour) exceeded the prorated workload limit on 6 of 22 days that slides were examined. Dates include: Date: 7/11/22 TIME SCREENING: 120 minutes SLIDES EXAMINED: 29 PRORATED SLIDES ALLOWED: 25 Date: 7/28/22 TIME SCREENING: 75 minutes SLIDES EXAMINED: 17 PRORATED SLIDES ALLOWED: 15 Date: 11/4/22 TIME

	SCREENING: 24 minutes SLIDES EXAMINED: 14 PRORATED SLIDES ALLOWED: 5 Date: 11/16/22 TIME SCREENING: 45 minutes SLIDES EXAMINED: 14 PRORATED SLIDES ALLOWED: 9 Date: 12/1/22 TIME SCREENING: 72 minutes SLIDES EXAMINED: 17 PRORATED SLIDES ALLOWED: 15 Date: 12/28/22 TIME SCREENING: 18 minutes SLIDES EXAMINED: 6 PRORATED SLIDES ALLOWED: 3 c. Technical Supervisor G (maximum workload limit - 12.5 slides per hour) exceeded the prorated workload limit on 14 of 26 days that slides were examined. Dates include: Date: 7/19/22 TIME SCREENING: 35 minutes SLIDES EXAMINED: 15 PRORATED SLIDES ALLOWED: 7 Date: 8/4/22 TIME SCREENING: 57 minutes SLIDES EXAMINED: 13 PRORATED SLIDES ALLOWED: 11 Date: 8/15/22 TIME SCREENING: 47 minutes SLIDES EXAMINED: 20 PRORATED SLIDES ALLOWED: 9 Date: 8/22 /22 TIME SCREENING: 277 minutes SLIDES EXAMINED: 94 PRORATED SLIDES ALLOWED: 57 Date: 8/26/22 TIME SCREENING: 187 minutes SLIDES EXAMINED: 40 PRORATED SLIDES ALLOWED: 38 Date: 8/29/22 TIME SCREENING: 224 minutes SLIDES EXAMINED: 60 PRORATED SLIDES ALLOWED: 46 Date: 9/11/22 TIME SCREENING: 195 minutes SLIDES EXAMINED: 49 PRORATED SLIDES ALLOWED: 40 Date: 9/19/22 TIME SCREENING: 272 minutes SLIDES EXAMINED: 67 PRORATED SLIDES ALLOWED: 56 Date: 10/3/22 TIME SCREENING: 15 minutes SLIDES EXAMINED: 6 PRORATED SLIDES ALLOWED: 3 Date: 10/6/22 TIME SCREENING: 66 minutes SLIDES EXAMINED: 25 PRORATED SLIDES ALLOWED: 13 Date: 10/17/22 TIME SCREENING: 64 minutes SLIDES EXAMINED: 15 PRORATED SLIDES ALLOWED: 13 Date: 11/7/22 TIME SCREENING: 48 minutes SLIDES EXAMINED: 12 PRORATED SLIDES ALLOWED: 10 Date: 12/5/22 TIME SCREENING: 115 minutes SLIDES EXAMINED: 29 PRORATED SLIDES ALLOWED: 23 Date: 12/21/22 TIME SCREENING: 80 minutes SLIDES EXAMINED: 22 PRORATED SLIDES ALLOWED: 16 3. During an interview on February 28, 2023 at 1:15 PM, these findings were confirmed with the Cytology Supervisor. 4. During an interview on March 1, 2023 at 10:45 AM, these findings were confirmed with Technical Supervisor D, Technical Supervisor G and the Cytology Supervisor. B. Based on review of laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures to ensure the prorated workload limits for the Cytology Supervisor would not be exceeded when examining slides in less than eight hours. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limits for the Cytology Supervisor when examining slides in less than an eight-hour day. 2. During an interview on February 28, 2023 at 1:15 PM, these findings were confirmed with the Cytology Supervisor. 3. During an interview on March 1, 2023 at 10:45 AM, these findings were confirmed with Technical Supervisor D, Technical Supervisor G and the Cytology Supervisor.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interviews the laboratory failed to establish written policies and procedures to ensure the laboratory maintained records of the total number of hours the Technical Supervisors and Cytology Supervisor spent examining nongynecologic slides per 24-hour period. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained records of the total number of hours the Technical Supervisors and Cytology Supervisor spent examining slides. 2. During an interview on February 28, 2023 at 1:15 PM, these findings were confirmed with the Cytology Supervisor. 3. During an interview on March 1, 2023 at 10:45 AM, these findings were confirmed with Technical Supervisor D, Technical Supervisor G and the Cytology Supervisor.
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, final test reports and gynecologic specimen slides the laboratory failed to follow written policies and procedures to ensure unsatisfactory gynecologic specimen slides were identified and reported as unsatisfactory. The laboratory failed to identify and report two of 14 gynecologic specimen slides from February 2023 as unsatisfactory. Findings include: 1. The laboratory failed to follow the procedure CRITERIA FOR SPECIMEN ADEQUACY FOR GYN CYTOLOGY, which stated: "Criteria for Specimen Adequacy" "Liquid-based smears: estimated minimum of 5,000 well-visualized /preserved squamous cells." 2. The laboratory failed to identify and report two of 14 gynecologic specimen slides from February 2023 as unsatisfactory. Tests include: - TP23-000656 -TP23-000731
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of final test reports and interviews 40 of 40 consecutive final test reports from February 2023 failed to indicate the name and address of the laboratory where the test was performed. Findings include: 1. The Survey Team reviewed 40 consecutive final test reports from February 2023 (range reviewed: TP23-000576 through TP23-000615). Forty of 40 final test reports failed to indicate the name and

	address of the laboratory where the test was performed. Test reports include: -TP23-000576 -TP23-000577 -TP23-000578 -TP23-000579 -TP23-000580 -TP23-000581 -TP23-000582 -TP23-000583 -TP23-000584 -TP23-000585 -TP23-000586 -TP23-000587 -TP23-000588 -TP23-000589 -TP23-000590 -TP23-000591 -TP23-000592 -TP23-000593 -TP23-000594 -TP23-000595 -TP23-000596 -TP23-000597 -TP23-000598 -TP23-000599 -TP23-000600 -TP23-000601 -TP23-000602 -TP23-000603 -TP23-000604 -TP23-000605 -TP23-000606 -TP23-000607 -TP23-000608 -TP23-000609 -TP23-000610 -TP23-000611 -TP23-000612 -TP23-000613 -TP23-000614 -TP23-000615 2. During an interview on February 28, 2023 at 1:15 PM, these findings were confirmed with the Cytology Supervisor. 3. During an interview on March 1, 2023 at 10:45 AM, these findings were confirmed with Technical Supervisor D, Technical Supervisor G and the Cytology Supervisor.
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, 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 written policies and procedures were established to assess, monitor and maintain the competency of the 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 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 all test processes. (Refer to D5403) 2. The Laboratory Director failed to provide direction and oversight to ensure written policies and procedures were approved, signed and dated by the Laboratory Director prior to use. (Refer to D5407) 3. The Laboratory Director failed to provide direction and oversight to ensure the laboratory maintained the date of discontinuance for discontinued policies and procedures. (Refer to D5409) 4. The Laboratory Director failed to provide direction and oversight to ensure final test reports indicated the name and address of the laboratory where the test was performed. (Refer to D5805)
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and 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 establish a program to monitor specimen submission problems. (Refer to D5403) 2. The Laboratory Director failed to establish a program to monitor the maintenance of the Hologic ThinPrep 2000 Processors and microscopes to ensure the required maintenance was performed. (Refer to D5429) 3. 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) 4. The Laboratory Director failed to establish a system for monitoring the prorated workload limits for the Technical Supervisors performing primary slide nongynecologic examinations to ensure the prorated workload limits would not be exceeded when examining slides in less than eight hours. (Refer to D5641) 5. The Laboratory Director failed to establish a program for monitoring workload records to ensure the number of hours the Technical Supervisors devoted to screening slides during each 24-hour period was documented. (Refer to D6133)
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, laboratory records and interviews 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 seven of seven Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. (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 375 negative and unsatisfactory gynecologic cytology cases/379 slides from February 2023 the Technical Supervisor failed to verify the accuracy of two gynecologic cytology tests. 1. TP23-000656 02/14/2023 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory. Insufficient Cellularity. TECHNICAL SUPERVISOR D DIAGNOSIS: Unsatisfactory 2. TP23-000731 02/15/2023 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory. Insufficient Cellularity. TECHNICAL SUPERVISOR D DIAGNOSIS: Unsatisfactory
D6133	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6) In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides. This STANDARD is not met as evidenced by: Based on review of workload records and interviews three of seven Technical Supervisors failed to document the number of hours devoted to screening slides during each 24-hour period in July through December 2022. Findings include: 1. The Survey Team reviewed workload records titled PATHOLOGIST (PRIMARY SCREEN) for July through December 2022. a. Technical Supervisor C failed to document the number of hours devoted to screening slides on 15 of 15 days that slides were screened. Dates include: July 2022: 20 August 2022: 10, 18, 25 September 2022: 7, 29 October 2022: 6, 12, 20, 24 November 2022: 21, 30 December 2022: 14, 16, 29 b. Technical Supervisor D failed to document the number of hours devoted to screening slides on 4 of 22 days that slides were screened. Dates includes: August 2022: 11, 16, 30 October 2022: 20 c. Technical Supervisor E failed to document the number of hours devoted to screening slides on 22 of 22 days that slides were screened. Dates includes: July 2022: 14, 25 August 2022: 2, 3, 31 September 2022: 12, 13, 22, 26, 28 October 2022: 4, 5, 26, 31 November 2022: 10, 15, 22, 23, 28, 29 December 2022: 8, 12 2. During an interview on February 28, 2023 at 1:15 PM, these findings were confirmed with the Cytology Supervisor. 3. During an interview on March 1, 2023 at 10:45 AM, these findings were confirmed with Technical Supervisor D, Technical Supervisor G and the Cytology Supervisor.
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.