Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2144056	03/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pathnet Llc	5100 Talley Road, Ste 300, Little Rock, AR	

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 interview it was determined that 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 it was determined that the laboratory failed to enroll in a CMS-approved cytology PT program for

	gynecologic examination for 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide records of enrollment in an approved cytology PT program for 2021. 2. During an interview on March 7, 2022 at 2:30 PM, when asked if the laboratory had enrolled in an approved cytology PT program for 2021, the Cytology Manager replied "no." 3. During a telephone interview on March 7, 2022 at 4:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D2133	CYTOLOGY CFR(s): 493.855(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS by January 1, 1995, if available in the State in which he or she is employed. This STANDARD is not met as evidenced by: Based on the lack of cytology PT enrollment records and interviews it was determined that the laboratory failed to ensure that two of three Technical Supervisors who examined gynecologic preparations were enrolled in a CMS-approved cytology PT event in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide 2021 PT enrollment records for two of three Technical Supervisors who examined gynecologic preparations in 2021 and to the date of the survey in 2022.. Technical Supervisors include: -Technical Supervisor B -Technical Supervisor C 2. During an interview on March 7, 2022 at 2:00 PM, the Cytology Manager stated: "We began gyn testing in February of 2021. All of our gyn were rescreened by the pathologists." 3. During a telephone interview on March 7, 2022 at 4:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D2136	CYTOLOGY CFR(s): 493.855(b) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set as described in 493.945. This STANDARD is not met as evidenced by: Based on review of cytology PT participation records and interviews it was determined that the laboratory failed to ensure that two of three Technical Supervisors participated in an annual cytology PT event in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide 2021 cytology PT participation records for two of three Technical Supervisors. Technical Supervisors include: -Technical Supervisor B -Technical Supervisor C 2. During an interview on March 7, 2022 at 11:15 AM, the Cytology Manager provided records of cytology PT events for staff that occurred at other facilities in 2021. The records failed to include the participation of Technical Supervisor B and Technical Supervisor C. 3. During a telephone interview on March 7, 2022 at 4:15 PM, 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 review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to follow two written policies and procedures (refer to D5401); failed to establish written policies and procedures for the evaluation and comparison of six of six laboratory statistics, and failed to document six of six required annual statistics (refer to D5629); failed to establish written policies and procedures for the establishment and reassessment of individual workload limits at least every six months for the Technical Supervisors (refer to D5633 and D5637); failed to establish written policies and procedures to ensure the laboratory maintained records of the total number of slides examined per 24-hour period, and the total number of hours spent examining slides per 24-hour period (refer to D5645); failed to establish written policies and procedures to document the workload limit for each Technical Supervisor (refer to D5647); and failed to follow written policies and procedures to ensure unsatisfactory slide preparations were identified and reported as unsatisfactory (refer to D5655).
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 27 laboratory policies and procedures, lack of laboratory records and interviews it was determined that the laboratory failed to follow two written policies and procedures. Cross refer to D2001 and D2133 Findings include: 1. The laboratory failed to follow the written policy and procedure CYTOLOGY PROFICIENCY TESTING which stated: -"C. The Cytology Lab participates in the following programs: 2. CAP PAP PT-if gyn testing commences" (See D2001, D2133). 2. The laboratory failed to follow the written policy and procedure LABORATORY QUALITY MANAGEMENT PLAN-ANALYTIC QUALITY CONTROL which stated: -"C. Semi-Annual Proficiency Testing i. CAP PAP PT-if gyn testing commences" (See D2001, D2133).
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 27 laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for one laboratory test process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for the removal of collection devices from Hologic ThinPrep vials. a. The Survey Team observed the Processing/Testing Personnel remove a collection device from one Hologic ThinPrep vial during processing for one of one case on March 8, 2022 at 10: 45 AM. Case includes: -PNG-22-98 2. During an interview on March 8, 2022 at 11:30 AM, these findings were confirmed with the Cytology Manager.
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, laboratory records and interview it was determined that the laboratory failed to follow manufacturer's instructions to evaluate gynecologic cytology specimens using the HOLOGIC THINPREP Pap Test in 2021 and to the date of the survey in 2022. 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 two of three Technical Supervisors who performed diagnostic interpretations of Hologic ThinPrep Pap Tests in 2021 and to the date of the survey in 2022. Technical Supervisors include: -Technical Supervisor B -Technical Supervisor C 3. During an interview on March 8, 2022 at 4: 00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Cytology 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 review of laboratory policies and procedures, laboratory records and interviews it was determined that 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 high-grade squamous intraepithelial lesion (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 and to the date of the survey in 2022. 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 high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with available histopathology to determine the causes of any discrepancies. 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 high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with available histopathology for 2021 and to the date of the survey in 2022. 3. At the Survey Team's request, the Cytology Manager searched cytology case reports from 2021 and 2022 for corresponding clinical information and histopathology. The Cytology Manager identified five cytology cases during the search and confirmed that a program had not been in place to document a comparison and review of the five cases. Cytology Cases Include: -PNG21-045 -PNG21-056 -PNG21-170 -PNG21-197 -PNG22-029 4. During an interview on March 7, 2022 at 2:00 PM, the Cytology Manager stated, "I'm looking now to see if we had any history or followup on our HSIL's. No, we didn't do it but I'm working on it." 5. During an interview on March 8, 2022 at 4:00 PM, these findings were confirmed with the Laboratory Director /Technical Supervisor A and the Cytology Manager.
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 it was determined that the laboratory failed to establish written policies and procedures to ensure that the search and review of prior negative gynecologic

	specimens received within the previous five years for each patient with a current HSIL or malignancy was performed. The laboratory failed to document the search for prior negative gynecologic specimens for three of three HSIL specimens in 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for the search and review of all prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy reported by the laboratory. 2. The Survey Team requested and the laboratory failed to provide records of the search and review of prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy reported by the laboratory in 2021 and to the date of the survey in 2022. a. During an interview on March 7, 2022 at 2:00 PM, the Cytology Manager stated "I'm looking now to see if we had any history or follow-up on our HSIL's. No, we didn't do it but I'm working on it." 3. The laboratory failed to document the search for prior negative gynecologic specimens for three of three HSIL specimens, identified during the review of final test reports from January-December of 2021 and January and February of 2022. Specimen case numbers include: -PNG21-056 -PNG21-120 -PNG22-029 4. During an interview on March 8, 2022 at 4:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Cytology Manager.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of six of six laboratory statistics. The laboratory failed to document six of six required annual statistics for 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of six of six laboratory statistics. 2. The Survey Team requested and the laboratory failed to provide six of six required annual statistics for 2021. a. Statistical records provided by the laboratory included data for urine specimens but failed to include a breakdown for any other specimen type. 3. During an interview on March 7, 2022 at 11:00 AM, the Cytology Manager stated "the laboratory doesn't really have separate GYN (gynecologic) and FNA (fine needle aspiration) statistics as they are added together." 4. During an interview on March 8, 2022 at 4:00 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A and the Cytology Manager.

D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established by the Technical Supervisor for three of three Technical Supervisors who performed primary screening of cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that individual maximum workload limits were established by the Technical Supervisor, for each Technical Supervisor that performed primary screening of cytology specimens. 2. During a telephone interview on March 7, 2022 at 4:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5635	CYTOLOGY CFR(s): 493.1274(d)(1)(i) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(i) The workload limit is based on the individual's performance using evaluations of the following: (d)(1)(i)(A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section. (d)(1)(i)(B) Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to use evaluations of the individual Cytotechnologist's performance when assessing the workload limits for the Cytotechnologists. The laboratory failed to establish workload limits for two of two Cytotechnologists in 2021 using the results of the 10 percent review of negative cases and of the comparison of the individual's interpretations with the Technical Supervisor's confirmation. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the workload limit for Cytotechnologists would be based on individual capabilities to include evaluations of the following: a. A review of 10 percent of the Cytotechnologist's cases interpreted as negative. b. A comparison of the Cytotechnologist's interpretations with the Technical Supervisor's confirmations of patient slides. 2. The Survey Team requested and the laboratory failed to provide documentation that the workload limit for two of two Cytotechnologists was established in 2021, using the results of the 10 percent review of negative cases and the comparison of the individual's interpretations with the Technical Supervisor's confirmation. Cytotechnologists include: -Cytology Manager -Cytotechnologist 3. During an interview on March 9, 2022 at 10:00 AM, these findings were confirmed with the Cytology Manager.

D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to reassess and adjust when necessary a maximum workload limit at least every six months for the Technical Supervisors who performed primary screening of cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor's workload limits would be reassessed at least every six months and adjusted when necessary. 2. During a telephone interview on March 7, 2022 at 4:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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: A. Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the laboratory maintained records of the total number of slides the Technical Supervisors examined per 24-hour period and the number of hours spent examining slides per 24-hour period. Cross refer to D6133 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory maintained records of the total number of slides the Technical Supervisors examined per 24-hour period and the number of hours spent examining slides per 24-hour period. 2. During a telephone interview on March 7, 2022 at 4:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. B. Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to follow written policies and procedures to ensure records were maintained of the total number of slides the Cytotechnologists examined per 24-hour period in 2021 and to the date of the survey in 2022. Cross refer to D6160 and D6166 Findings include: 1. The laboratory failed to follow the written policy and procedure QUALITY ASSURANCE IN THE CYTOLOGY LAB-SCREENING LIMITS /RECORDS which stated: -"Each screener must maintain a daily record of each slide screened with his/her diagnosis and the hours spent screening, processing specimens, clerical duties, teaching, etc." 2. During an interview on March 8 at 3:45 PM, these findings were confirmed with the Cytology Manager.
D5647	CYTOLOGY

	CFR(s): 493.1274(d)(4) (d) Workload limits.The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for three of three Technical Supervisors who performed primary screening of cytology specimens in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limit for the Technical Supervisors who performed primary screening of cytology specimens. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for three of three Technical Supervisors who performed primary screening of nongynecologic cytology specimens in 2021. Technical Supervisors include: -Laboratory Director /Technical Supervisor A -Technical Supervisor B -Technical Supervisor D 3. During a telephone interview on March 7, 2022 at 4:15 PM, 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 review of laboratory policies and procedures, cytology slide preparations and corresponding final test reports and interview it was determined that the laboratory failed to follow written policies and procedures to ensure unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report three of three gynecologic cytology slide preparations from January and February 2022 as "Unsatisfactory for Evaluation". Findings include: 1. The laboratory failed to follow the written policy and procedure CYTOLOGY GYN REPORTING which stated: -"CRITERIA FOR SPECIMEN ADEQUACY-for liquid-based slides, there should be a minimum of 5,000 (estimated) well-preserved, well-visualized squamous cells." 2. The laboratory failed to identify and report three of three gynecologic cytology slide preparations from January and February 2022 as "Unsatisfactory for Evaluation" due to insufficient numbers of required squamous cells. Cases include: -PNG22-14 -PNG22-19 -PNG22-36 3. During an interview on March 9, 2022 at 10:00 AM, these findings were discussed with the Cytology Manager, who stated the three cases would be given to the Laboratory Director/Technical Supervisor A for review. The Laboratory Director /Technical Supervisor A submitted written confirmation of the review to CMS and confirmed the Survey Team findings on March 10, 2022.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441

	The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that 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 (refer to D6088); failed to ensure quality control programs were established to assure the quality of cytology services and identify failures in quality as they occur (refer to D6093); and failed to ensure that two of three Technical Supervisors had received the appropriate morphology training prior to reporting gynecologic patient specimens (refer to D6102).
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, review of laboratory policies and procedures and interview it was determined that the Laboratory Director failed to ensure that the laboratory enrolled in an annual gynecologic cytology PT program for 2021. Cross refer to D2001 Findings include: 1. The Laboratory Director failed to ensure that the laboratory enrolled in a CMS-approved PT program for 2021. (See D2001) 2. The Laboratory Director failed to ensure that the CYTOLOGY PROFICIENCY TESTING policy, signed as approved and effective by the Laboratory Director on 02/24/2021, was followed as stated: -RESPONSIBILITIES "A. Laboratory Director-Responsible for oversight of the proficiency program and the review of all participant summary evaluations and corrective actions as needed. Documentation of review is required." 3. During a telephone interview on March 7, 2022 at 4:15 PM, these findings were confirmed with the Laboratory Director /Technical Supervisor A.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 it was determined that the Laboratory Director failed to ensure that quality control programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur. Cross refer to D5623, D5625, D5629, D5655 Findings include: 1. The Survey Team requested and the laboratory

	failed to provide written polices and procedures to detail a quality control program to identify failures in quality as they occur. 2. The Survey Team requested and the laboratory failed to provide records of a documented quality control program and failed to identify and document failures in quality as they occur (See D5623, D5625, D5629 and D5655).
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, laboratory records and interview it was determined that the Laboratory Director failed to ensure that two of three Technical Supervisors who performed Hologic ThinPrep Pap Test evaluations had received the appropriate morphology training prior to reporting patient specimens in 2021 and to the date of the survey in 2022. Cross refer to D5411 Findings include: 1. The Survey Team requested and the laboratory failed to provide documentation of appropriate training for two of three Technical Supervisors, to accurately report cytology test results prior to performing Hologic ThinPrep Pap test evaluations in 2021 and to the date of the survey in 2022.
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 microscopic review of 180 negative gynecologic cases/182 slides and the corresponding final test reports from October 2021 through February 2022 and confirmation by the Laboratory Director/Technical Supervisor A on March 10, 2022 it was determined that the Technical Supervisor failed to verify the accuracy of three gynecologic cytology tests. 1. PNG22-14 02/04/2022 ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory. Insufficient Cellularity TECHNICAL SUPERVISOR B DIAGNOSIS: Unsatisfactory. 2. PNG22-19 01/21/2022 TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory. Insufficient Cellularity TECHNICAL SUPERVISOR B DIAGNOSIS: Unsatisfactory. 3. PNG22-36 02/02/2022 TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory. Insufficient Cellularity TECHNICAL SUPERVISOR B DIAGNOSIS: Unsatisfactory.
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3)

	(c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on the lack of laboratory records and interviews it was determined that the Technical Supervisor failed to establish individual workload limits and failed to reassess workload limits at least every six months for three of three Technical Supervisors who performed primary slide examinations in 2021. Cross refer to D5633 and D5637 Findings include: 1. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor established a maximum workload limit for three of three Technical Supervisors who performed primary slide examinations in 2021. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor D 2. The Survey Team requested and the laboratory failed to provide documentation that the Technical Supervisor reassessed a workload limit at least every six months for three of three Technical Supervisors who performed primary screening in 2021. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor D 3. During an interview on March 7, 2022 at 1:50 PM, the Cytology Manager stated "the pathologists screened nongyn specimens when I was on vacation." 4. During a telephone interview on March 7, 2022 at 4:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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 the lack of laboratory records and interview it was determined that three of three Technical Supervisors performing primary screening of cytology specimen slides failed to document the number of cytology slides screened and the number of hours devoted to screening during each 24-hour period in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide documentation of the total number of slides and the total number of hours three of three Technical Supervisors devoted to screening cytology specimen slides during each 24-hour period in 2021. Technical Supervisors include: -Laboratory Director/Technical Supervisor A -Technical Supervisor B -Technical Supervisor D 2. A four-page laboratory document PRIMARY SCREENING BY PATHOLOGIST JUNE 5-12 listed 227 cytology specimen cases (PNC-2917 through PNC-3144) that were evaluated and reported by three Technical Supervisors during June 5-12, 2021. The document did not include the number of slides examined or the number of hours the three Technical Supervisors spent examining the slides. 3. During a telephone interview on March 7, 2022 at 4:15 PM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D6160	CYTOLOGY SUPERVISOR RESPONSIBILITIES CFR(s): 493.1471(b)(3) The cytology general supervisor must for each 24-hour period, document the total number of slides he or she examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview it was determined that the Cytology Supervisor failed to document the total number of slides examined and reviewed per 24-hour period in 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the Cytology Manager failed to provide documentation of the total number of slides examined and reviewed per 24-hour period in 2021 and to the date of the survey in 2022. 2. Laboratory records CYTOLOGY SCREENING LOG AND WORKLOAD REPORT included a column titled # OF NG SLIDES for the documentation of the number of nongynecologic specimen slides examined. The record failed to document the examination and review of gynecologic specimen slides. 3. During an interview on March 8 at 3:45 PM, when reviewing the Cytology Managers workload records, the Cytology Manager stated "the records do not include the gyn slide numbers. The time is accurate, but the gyn slides are not recorded."
D6166	CYTOTECHNOLOGIST RESPONSIBILITIES CFR(s): 493.1485(b) The cytotechnologist is responsible for documenting, for each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview it was determined that the Cytotechnologist failed to document the total number of slides examined and reviewed per 24-hour period in 2021 and to the date of the survey in 2022. Findings include: 1. The Survey Team requested and the Cytology Manager failed to provide documentation of the total number of slides examined and reviewed by the Cytotechnologist, per 24-hour period in 2021 and to the date of the survey in 2022. 2. Laboratory records CYTOLOGY SCREENING LOG AND WORKLOAD REPORT included a column titled # OF NG SLIDES for the documentation of the number of nongynecologic specimen slides examined. The record failed to document the examination and review of gynecologic specimen slides. 3. During an interview on March 8 at 3:45 PM, when reviewing the Cytotechnologist's workload records, the Cytology Manager stated "the records do not include the gyn slide numbers. The time is accurate, but the gyn slides are not recorded."
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.