

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0648197	(X3) Date Survey Completed 10/06/2021
Name of Provider or Supplier University Of Kansas Physicians, Inc	Street Address, City, State 3901 Rainbow Blvd, Delp 5019, Kansas City, KS	
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	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>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).</p>
D2001	<p>ENROLLMENT CFR(s): 493.801(a)(1)(2)(i)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: Based on the lack of cytology PT enrollment records and interview it was determined that the laboratory failed to enroll in an HHS-approved cytology PT program for</p>

	<p>gynecologic examination for 2019 and 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide records of enrollment in an approved cytology PT program for 2019 and 2020. 2. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of a policy and procedure manual and interviews it was determined that 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 procedure manual for all cytology tests and examinations performed at the laboratory. a. The laboratory provided the following procedures that belonged to Facility B (CLIA 17D0448802) and were used by this laboratory. Procedures include: -POLICY FOR EDUCATION NOTES TO PROVIDERS -COMPUTER DOWNTIME AND RECOVERY PROCEDURES -EVALUATION OF LIPID LADEN MACROPHAGES PROCEDURE -SECURITY PROCEDURES FOR THE CYTOPATHOLOGY LIS COMPUTER SYSTEM -EQUIPMENT MAINTENANCE PROCEDURE -ACCESSIONING PROCEDURE FOR OUTSIDE SLIDES - ORGANIZATION OF THE CYTOLOGY LABORATORY -CHECKLIST FOR TEST MANAGEMENT POLICIES, TECHNICAL PROCEDURES, RECORDS AND LABORATORY SYSTEMS -OUTSIDE SLIDE RETURN PROCEDURE - CONTINUATION OF CARE REQUEST -POLICY FOR SLIDE STORAGE, RETRIEVAL, HANDLING, AND LOANS -ADDENDUM REPORT PROCEDURE IN CO-PATH -LABORATORY RECORD MANAGEMENT AND RETENTION 2. During an interview on October 4, 2021 at 2:40 PM, the Quality Coordinator stated that the laboratory used Facility B's procedures. 3. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator.</p>
<p>D5403</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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</p>

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 a policy and procedure manual and interview it was determined that the laboratory failed to establish written policies and procedures for two 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 for enrolling and participating in an HHS-approved cytology PT program. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the facility responsible for the filing and storage of cytology slides. 3. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator.

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 and interview it was determined that the laboratory failed to establish written policies and procedures for a program to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the laboratory's program to determine the causes of discrepancies between the cytology diagnosis and the histopathology diagnosis. a. The laboratory provided the procedure POLICY FOR THE CORRELATION OF GYNECOLOGIC AND NON-GYNECOLOGIC SPECIMENS WITH HISTOLOGIC AND CLINICAL FINDINGS that belonged to Facility B and was being used by this laboratory. 2. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator.

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 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 high grade squamous intraepithelial lesion (HSIL) or malignancy was performed. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for the search and review of all prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy reported by the laboratory. a. The laboratory provided the procedure PROCEDURE FOR PREVIOUS NEGATIVE CASE REVIEW ON CURRENT HIGH GRADE OR ABOVE CASES that belonged to Facility B and was being used by this laboratory. 2. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator. 3. During an interview on October 5, 2021 at 9:00 AM, the Cytology Supervisor stated that the search and review of prior negative specimens was performed by Facility B. The Cytology Supervisor further stated that if a discrepancy was identified the specimen was referred to a Technical Supervisor from this laboratory.

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 the lack of laboratory policies and procedures, review of laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation of six of six required laboratory statistics. The laboratory failed to document four of six required annual statistics for

2019 and 2020. 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 statistics. a. The laboratory provided the procedure STATISTICAL REPORTING POLICY that belonged to Facility B and was being used by this laboratory. 2. The Survey Team reviewed laboratory records titled ANNUAL CYTOPATHOLOGY STATISTICAL REPORT. The Survey Team requested and the laboratory failed to provide four of six required annual statistics for 2019 and 2020: a. The number of cytology cases examined; b. The number of specimens processed by specimen type; c. The number of patient cases reported by diagnosis (including the number of reported as unsatisfactory for diagnostic interpretation); d. 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. 3. During an interview on October 4, 2021 at 1:15 PM, the Cytology Supervisor stated that the laboratory's statistics included cases reported at Facility B. The Cytology Supervisor further stated that the diagnostic statistics were based on the Cytotechnologists interpretation and not the final sign out diagnosis for cases requiring technical supervisory review. 4. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator.

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 interview it was determined that the laboratory failed to establish written policies and procedures to ensure unsatisfactory gynecologic and nongynecologic cytology slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to include criteria to ensure unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. a. The laboratory provided the procedure CRITERIA AND DEFINITIONS FOR GYNECOLOGIC SPECIMEN ADEQUACY-POST MICROSCOPY that belonged to Facility B and was being used by this laboratory. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to include criteria to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 3. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator.

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:
Based on the lack of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report gynecologic and nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report gynecologic and nongynecologic cytology test results. a. The laboratory provided the procedure CRITERIA FOR REPORTING MORPHOLOGIC FINDINGS that belonged to Facility B and was being used by this laboratory. 2. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator.

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 and interview it was determined that the laboratory failed to establish written policies and procedures to ensure corrected reports indicated the basis for the correction on the report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected reports indicated the basis for the correction on the report. a. The laboratory provided the procedure PROCEDURE TO AMEND A REPORT IN COPATH that belonged to Facility B and was being used by this laboratory. 2. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on the lack of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the analytic phases of cytology testing. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the analytic phases of testing. a. The laboratory provided the procedures DISPARITY RESOLUTION OF

HISTOLOGIC AND CYTOLOGIC DIAGNOSIS, QUALITY ASSURANCE /PROCESS MANAGEMENT IN THE LABORATORIES and DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE QUALITY MANAGEMENT PLAN that belonged to Facility B and were being used by this laboratory. 2. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator.

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 interview it was determined that 30 of 30 final test reports from June 2021 and September 2021 failed to indicate the name of the laboratory where the test was performed. Findings include: 1. The Survey Team reviewed 20 final gynecologic test reports from June 2021. Twenty of 20 final test reports failed to indicate the name of the laboratory where the test was performed. Reports include: -C21-3805 -C21-3972 -C21-3973 -C21-3977 -C21-3996 -C21-4015 -C21-4018 -C21-4021 -C21-4027 -C21-4029 -C21-4050 -C21-4055 -C21-4068 -C21-4070 -C21-4072 -C21-4076 -C21-4080 -C21-4090 -C21-4096 -C21-4100 2. The Survey Team reviewed five final nongynecologic test reports from September 2021. Five of five final nongynecologic test reports failed to indicate the name of the laboratory where the test was performed. Reports include: -N21-3876 -N21-3877 -N21-3878 -N21-3879 -N21-3880 3. The Survey Team reviewed five final fine needle aspiration (FNA) test reports from September 2021. Five of five final FNA test reports failed to indicate the name of the laboratory where the test was performed. Reports include: -F21-1414 -F21-1415 -F21-1416 -F21-1417 -F21-1418 4. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator.

D5821

TEST REPORT
CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on review of final test reports and interview it was determined that the laboratory failed to maintain duplicates of three of three original final test reports from 2020 and 2021 when a correction was made to the original final test report. Findings include: 1. The Survey Team requested and the laboratory failed to provide a duplicate of the original final test report for three of three reports that were corrected. Reports include: -N20-1161 -C20-235 -C21-3613 2. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on the lack of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the postanalytic phases of cytology testing. Cross refer to D5805 and D5821 Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic phases of testing. a. The laboratory provided the procedures QUALITY ASSURANCE/PROCESS MANAGEMENT IN THE LABORATORIES and DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE QUALITY MANAGEMENT PLAN that belonged to Facility B and were being used by this laboratory. 2. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator.

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 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 2019 and 2020 (refer to D6088); failed to ensure that written policies and procedures were established to assess, monitor and maintain the competency of the Technical Supervisors (refer to D6103); and failed to ensure that an approved procedure manual was available to all personnel (refer to D6106).

<p>D6088</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)</p> <p>The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of PT enrollment records and interview it was determined that the Laboratory Director failed to ensure that the laboratory enrolled in an annual gynecologic cytology PT program for 2019 and 2020. Cross refer to D2001 Findings include: 1. The Laboratory Director failed to ensure that the laboratory enrolled in an HHS-approved PT program for 2019 and 2020.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of laboratory policies and procedures and interview it was determined that the Laboratory Director failed to ensure that written policies and procedures were established to assess, monitor and maintain the competency of the Technical Supervisors. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to assess the competency of the Technical Supervisors. a. The laboratory provided the procedure PATHOLOGY PROFESSIONAL COMPETENCY POLICY that belonged to Facility B and was being used by this laboratory. 2. During an interview on October 4, 2021 at 3:30 PM, these findings were confirmed with the Laboratory Director, Technical Supervisor A, Cytology Supervisor, Anatomic Pathology Administrative Director and the Quality Coordinator.</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of a policy and procedure manual and interviews it was determined that the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Cross refer to D5401 1. The Laboratory Director failed to ensure an approved procedure manual was available to all personnel.</p>
<p>D6115</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)</p>

	<p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the microscopic review of 499 random non-negative gynecologic cases/524 slides and the corresponding final test reports from January 2021 through August 2021 and confirmation by Technical Supervisor A on October 5, 2021 it was determined that the Technical Supervisor failed to verify the accuracy of one gynecologic cytology test. 1. C21-4435 07/06/2021 ThinPrep Pap Test (TPPT) LABORATORY DIAGNOSIS: Atypical Squamous Cells of Undetermined Significance SURVEY TEAM DIAGNOSIS: High Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR DIAGNOSIS A: High Grade Squamous Intraepithelial Lesion</p>
<p>D6116</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(3)</p> <p>The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of PT enrollment records and interview it was determined that Technical Supervisor A failed to ensure that the laboratory enrolled in an annual gynecologic cytology PT program for 2019 and 2020. Cross refer to D2001 Findings include: 1. Technical Supervisor A failed to ensure that the laboratory enrolled in an HHS-approved PT program for 2019 and 2020.</p>
<p>D9999</p>	<p>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.</p>