Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0469942	11/08/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Consultation Services Inc	501 Alameda, Suite B, Norman, OK	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: A. Based on review of laboratory policies and procedures, gynecologic specimen slides and interviews the laboratory failed to follow written policies and procedures to ensure specimen slides were labeled with a unique patient identifier during the preanalytic phase of testing. The laboratory failed to ensure forty of forty consecutive specimen slides from October 2023 were labeled with a unique patient identifier. Findings include: 1. The laboratory failed to follow the procedure THINPREP PROCEDURE, which stated: "PCS (P) label accession number and patient name is written on the corresponding Thin Prep slide." 2. The Survey Team reviewed specimen slides for 40 consecutive patient specimens from October 2023. Forty of 40 specimen slides failed to be labeled with a unique patient identifier. Specimen slides include: Accession number Specimen slide -P23-3510 23-3510 -P23-3511 23-3511 -P23-3512 23-3512 -P23-3513 23-3513 -P23-3514 23-3514 -P23-3515 23-3515 -P23-3516 23-3516 -P23-3517 23-3517 -P23-3518 23-3518 -P23-3519 23-3519 -P23-3520 23-3520 -P23-3521 23-3521 -P23-3522 23-3522 -P23-3523 23-3523 -P23-3524 23-3524 -P23-3525 23-3525 -P23-3526 23-3526 -P23-3527 23-3527 -P23-3528 23-3528 -P23-3529 23-3529 -P23-3530 23-3530 -P23-3531 23-3531 -P23-3532 23-3522 -P23-3533 23-3533 -P23-3534 23-3534 -P23-3535 23-3535 -P23-3536 23-3536 -P23-3537 23-3537 -P23-3538 23-3538 -P23-3539 23-3539 -P23-3540 23-3540 -P23-3541 23-3541 -P23-3542 23-3542 -P23-3543 23-3543 -P23-3544 23-3544 -P23-3545 23-3545 -P23-3546 23-3546 -P23-3547 23-3547 -P23-3548 23-3548 -P23-3549 23-3549 3. During an interview on November 7, 2023 at 10:15 AM, Staff A confirmed that the

	full accession number was not written on specimen slides prior to processing. Staff A further stated that after processing an adhesive label was placed on the slide with the full accession number. 4. During an interview on November 7, 2023 at 3:00 PM, these findings were confirmed with Cytotechnologist A and the Office Manager. 5. During an interview on November 8, 2023 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A. B. Based on review of laboratory policies and procedures, observation and interviews the laboratory failed to follow written policies and procedures to ensure positive patient identification during nongynecologic specimen processing. Findings include: 1. The laboratory failed to follow the procedure ACCESSIONING OF CYTOLOGY SPECIMEN, which stated: "Non-gyn specimens are labeled throughout processing with permanent black pens and or labels with the corresponding N or F, year, accession number and last name." 2. During an observation of nongynecologic specimen processing on November 8, 2023 at 10:10 AM, Staff B failed to write N and the year on the specimen centrifuge tube and Hologic PreservCyt Solution specimen vial. Staff B stated that the complete accession number including year was not written on specimens during all phases of specimen processing. Specimen includes: Accession number Number on tube/vial: - N23-778 778 3. During an interview on November 8, 2023 at 11:15 AM, these findings were confirmed with Cytotechnologist A and Staff B. Staff B stated that if a specimen did not come with a label with the full accession number and patient's name "I don't write N and the year or F and the year." 4. During an interview on November 8, 2023 at 11:45 AM, these findings were confirmed with the Laboratory Director /Technical Supervisor A.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of 56 laboratory policies and procedures, maintenance records and interviews the laboratory failed to follow three written policies and procedures. Findings include: 1. The laboratory failed to follow the procedure THINPREP 2000 PROCESSOR MAINTENANCE, which stated: "ThinPrep 2000 Processor Maintenance Schedule" "Waste Tubing Replacement (in Pinch Valve) Six Months" a. The Survey Team reviewed maintenance records for the Hologic ThinPrep 2000 Processor from January 2022 to the date of the survey in 2023. The records failed to document the required six month maintenance was performed. b. During an interview on November 6, 2023 at 2:45 PM, these findings were confirmed with Cytotechnologist A and the Office Manager. 2. The laboratory failed to follow the procedure REPROCESSING THINPREP PROCEDURE, which stated: "Prepare a wash solution of sufficient volume to add 30 ml to every ThinPrep Pap Test specimen being processed. The wash solution is made by mixing 9 parts CytoLyt Solution with 1 part glacial acetic acid." "Pellet the contents of the centrifuge tube by centrifugation at 1200 x g for 5 minutes." "Carefully pour off the supernatant from the centrifuge tube to avoid loss of cells." "Pour 30 ml of the CytoLyt Solution and 10% glacial acetic acid mixture into the centrifuge tube and cap securely." a. During an interview on November 7, 2023 at 10:15 AM, Staff A described the process for reprocessing Hologic ThinPrep Paps Tests: 15 mL of specimen was placed into a centrifuge tube.

	CytoLyt Solution was added to bring the volume to 40 mL. The specimen was centrifuged, decanted and the cell button was added to a new PreservCyt Solution Vial. The specimen was then processed on the Hologic ThinPrep 2000 Processor. b. During an interview on November 7, 2023 at 3:00 PM, these findings were confirmed with Cytotechnologist A and the Office Manager. 3. The laboratory failed to follow the procedure QUALITY CONTROL DESCRIPTION, which stated: "Non-Gyn Cytology Staining" "Replace reagents and stains bi-weekly or as needed" a. The Survey Team reviewed records titled NON GYN I DAILY MONITOR (SMEARS) from January 2023 through October 2023. i. The laboratory failed to replace the reagents and stains bi-weekly for 10 of 10 months. Months include: -January, February, March, April, May, June, July, August, September, October b. The Survey Team reviewed records titled NON GYN II DAILY MONITOR (THINPREP /CYTOSPIN) from January 2023 through October 2023. i. The laboratory failed to replace the reagents and stains bi-weekly for 9 of 10 months. Months include: -February, March, April, May, June, July, August, September, October c. During an interview on November 8, 2023 at 10:15 AM, Staff A stated that Staff A changed the reagents and stains monthly. 4. During an interview on November 8, 2023 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory policies and procedures and interviews the laboratory failed to follow manufacturer's instructions for reprocessing Hologic ThinPrep Pap Tests following an unsatisfactory result. Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL states: "Prepare a wash solution of sufficient volume to add 30 mL to every ThinPrep Pap Test specimen being reprocessed. The wash solution is made by mixing 9 parts CytoLyt Solution with 1 part glacial acetic acid." "Pour 30 mL of the CytoLyt Solution and 10% glacial acetic acid mixture into the centrifuge tube and cap securely." "Using the volume markings on the centrifuge tube, pour the necessary quantity of unused (i.e., containing no patient specimens) PreservCyt Solution to the cells and fill to a final volume of 20mL. Secure cap tightly." 2. During an interview on November 7, 2023 at 10:15 AM, Staff A described the process for reprocessing Hologic ThinPrep Paps Tests: 15 mL of specimen was placed into a centrifuge tube. CytoLyt Solution was added to bring the volume to 40 mL. The specimen was centrifuged, decanted and the cell button was added to a new PreservCyt Solution Vial. The specimen was then processed on the Hologic ThinPrep 2000 Processor. 3. During an interview on November 7, 2023 at 3:00 PM, the Office Manager stated the solution used during specimen reprocessing was a mixture of 160 mL glacial acetic and 786 mL of CytoLyt Solution. 4. The laboratory failed to follow the manufacturer's instructions when reprocessing Hologic ThinPrep Pap Tests. The laboratory failed to use a wash solution made of 9 parts CytoLyt Solution and 1 part glacial acetic acid. 5. During an interview on November 8, 2023 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.

D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL and interviews the laboratory failed to establish performance specifications when the laboratory modified the Hologic ThinPrep test system manufacturer's instructions with an alternate method of reprocessing Hologic ThinPrep Pap Tests following an unsatisfactory result. Findings include: 1. The laboratory failed to establish performance specifications or evidence that the accuracy, precision, analytical sensitivity and specificity of the modified procedure, reportable range of test results or any other performance characteristic was adequate to provide accurate diagnostic interpretations. Refer to D5411 .
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 the HOLOGIC THINPREP 2000 OPERATOR'S MANUAL, maintenance records and interviews the laboratory failed to ensure the required maintenance for one of one Hologic ThinPrep 2000 Processors was performed, as specified by the manufacturer, from January 2022 to the date of the survey in 2023. Findings include: 1. The HOLOGIC THINPREP 2000 OPERATOR'S MANUAL states the following maintenance is to be performed: "Waste tubing replacement - Six months" 2. The Survey Team reviewed maintenance records for the Hologic ThinPrep 2000 Processor from January 2022 to the date of the survey in 2023. The records failed to document the required six month maintenance was performed. 3. During an interview on November 6, 2023 at 2:45 PM, these findings were confirmed with Cytotechnologist A and the Office Manager. 4. During an interview on November 8, 2023 at 11:45 AM, these findings were confirmed with the Laboratory Director /Technical Supervisor A.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and

	procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory statistical records and interviews the laboratory failed to follow written policies and procedures for an annual statistical evaluation of one of six required gynecologic laboratory statistics. The laboratory failed to document one of six required gynecologic laboratory statistics for 2022. Findings include: 1. The laboratory failed to follow the procedure ANNUAL STATISTICAL EVALUATION, which stated: "The laboratory performs and documents annual statistical evaluations of the following, for the total caseload and for just the cases signed out at PCS." "Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as LSIL, HSIL, adenocarcinoma, or other malignant neoplasm." 2. The Survey Team requested and the laboratory failed to provide one of six required annual gynecologic laboratory statistics for 2022. Statistic includes: -The number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as LSIL, HSIL, adenocarcinoma, or other malignant neoplasms. 3. During an interview on November 6, 2023 at 2:45 PM, these findings were confirmed with Cytotechnologist A and the Office Manager. 4. During an interview on November 8, 2023 at 11:45 AM, 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 interviews the laboratory failed to establish and follow written policies and procedures to ensure each Cytotechnologist's maximum workload limit would be based on the individual's performance. The laboratory failed to establish workload limits for two of two Cytotechnologists from January 2022 to the date of the survey in 2023 using the comparison of the Cytotechnologist's interpretations with the Technical Supervisor's confirmation of patient slides. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the

	maximum workload limit for Cytotechnologists would be based on individual performance to include evaluations of the following: -A review of 10 percent of the Cytotechnologist's cases interpreted as negative. -A comparison of the Cytotechnologist's interpretations with the Technical Supervisor's confirmations of patient slides. 2. The Survey Team reviewed records titled TECH PATH COMPARISON for January 2022 to the the date of the survey in 2023. The records identified diagnostic discrepancies between the Cytotechnologists and Technical Supervisors. a. The Survey Team identified one discrepant case for Cytotechnologist A. Case includes: -P23-1931 b. The Survey Team identified one discrepant case for Cytotechnologist B. Case includes: -P23-802 3. The Survey Team reviewed laboratory records titled SEMI ANNUAL PERFORMANCE REVIEW FORM from January 2022 to the date of the survey in 2023. The records documented the results of the review of 10 percent of the Cytotechnologist's cases interpreted as negative and the results of the comparison of the Cytotechnologist's interpretations with the Technical Supervisor's confirmations of patient slides. a. The SEMI ANNUAL PERFORMANCE REVIEW FORM failed to document the two discrepant cases when reassessing maximum workload limits. 4. During an interview on November 8, 2023 at 10:00 AM, Cytotechnologist A confirmed the records failed to include the two discrepant cases on the SEMI ANNUAL PERFORMANCE REVIEW FORM. 5. During an interview on November 8, 2023 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. This STANDARD is not met as evidenced by: Based on 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 two gynecologic specimen slides from May 2023 and September 2023 as unsatisfactory. Findings include: 1. The laboratory failed to follow the procedure CRITERIA FOR SPECIMEN ADEQUACY FOR GYN CYTOLOGY, which stated: "Satisfactory for Evaluation indicates the specimens has all of the following:" "Liquid-based preparations: estimated 5,000 well-visualized and well-preserved squamous epithelial cells; at an average concentration of 4 cells per 40X HPF (high power field)." 2. The laboratory failed to identify and report two of two gynecologic specimen slides from May 2023 and September 2023 as unsatisfactory. Specimen slides include: -P23-1563 -P23-3281
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 review of laboratory policies and procedures, corrected test reports and interviews the laboratory failed to establish written policies and procedures to ensure corrected test reports indicated the basis for correction on the test report. Two of two corrected test reports from May 2021 failed to indicate the basis for correction on the corrected test report. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure corrected test reports indicated the basis for correction on the test report. 2. The Survey Team reviewed two corrected test reports from May 2021. a. Two of two corrected test reports failed to indicate the basis for correction on the corrected test report. Reports include: -P21-1713 -P21-1859 3. During an interview on November 7, 2023 at 10:35 AM, these findings were confirmed with the Office Manager. 4. During an interview on November 8, 2023 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
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 interviews the laboratory failed to maintain duplicates of two of two original final test reports from May 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 two of two corrected test reports. Reports include: -P21-1713 -P21-1859 2. During an interview on November 7, 2023 at 10:35 AM, the Office Manager stated the laboratory did not keep duplicates of original test reports when corrections were made to the original final test report. 3. During an interview on November 8, 2023 at 11:45 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor A.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, gynecologic specimen slides, 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 the competency of two of two Staff (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, gynecologic specimen slides 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 all laboratory polices and procedures were followed. Refer to D5401 2. The Laboratory Director failed to provide direction and oversight to ensure manufacturer's instructions were followed for reprocessing Hologic ThinPrep Pap Tests. Refer to D5411 3. The Laboratory Director failed to provide direction and oversight to ensure performance specifications were established when the laboratory modified the Hologic ThinPrep test system manufacturer's instructions with an alternate method of reprocessing Hologic ThinPrep Pap Tests. Refer to D5423 4. The Laboratory Director failed to provide direction and oversight to ensure the required maintenance for the Hologic ThinPrep 2000 Processor was performed, as specified by the manufacturer. Refer to D5429 5. The Laboratory Director failed to provide direction and oversight to ensure each Cytotechnologist's maximum workload limit would be based on the individual's performance. Refer to D5635 6. The Laboratory Director failed to provide direction and oversight to ensure unsatisfactory gynecologic specimen slides were identified and reported as unsatisfactory. Refer to D5655 7. The Laboratory Director failed to provide direction and oversight to ensure corrected test reports indicated the basis for correction on the test report. Refer to D5659 8. The Laboratory Director failed to provide direction and oversight to ensure duplicates of original final test reports were maintained when a correction was made to the original final test report. Refer to D5821
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 to assure the quality of laboratory services and identify failures in quality as they occur. Findings include: 1. The Laboratory Director failed to ensure the establishment of written policies and procedures for a quality assessment program for all phases of cytology testing. 2. The Laboratory Director failed to provide records of an established quality assessment program and failed to identify failures in quality as they occurred in 2021, 2022 and to the date of the survey in 2023. a. The Laborator Director failed to provide records to document an established program to monitor specimen slides to ensure specimen slides were labeled with a unique patient identifier. Refer to D5203 b. The Laboratory Director failed to provide records to document an established program to monitor the maintenance of the Hologic ThinPrep 2000 Processor to ensure the required maintenance was performed. Refer to D5429 c. The Laborator Director failed to provide records to document an established program to monitor the Cytotechnologist's workload assessment to ensure each Cytotechnologist's maximum workload limits would be based on the individual's performance. Refer to D5635 d. The Laborator Director failed to provide records to document an established program to monitor corrected test reports to ensure corrected test reports indicated the basis for correction on the test report. Refer to D5659 e. The Laborator Director failed to provide records to document an established program to monitor test reports to ensure duplicates of original test reports were maintained when a correction was made to the original final test report. Refer to D5821
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, observation and interviews the Laboratory Director failed to ensure established competency policies and procedures were followed and effective to assess, monitor and maintain the competency of the Technical Supervisor performing cytology duties. Findings include: 1. The Laboratory Director failed to identify training needs for Staff B during nongynecologic specimen processing. a. The Survey Team reviewed records titled CYTO PREPARATORY PERSONNEL TRAINING for Staff B from 2021, 2022 and 2023. The records stated Staff B had acceptable performance when performing specimen processing. Refer to D5203 2. The Laboratory Director failed to identify training needs for Staff A when reprocessing Hologic ThinPrep Pap Tests. a. The Survey Team reviewed records titled PERSONAL COMPETENCY ASSESSMENT for Staff A from 2021 and 2022. The records stated Staff A had acceptable performance when performing specimen reprocessing. Refer to D5401, D5411
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 358 negative gynecologic cases/slides from May 2023 and August through October 2023 the Technical Supervisor failed to verify the accuracy of three gynecologic cytology tests. 1. P23-3261 09/27/2023 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR A DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 2. P23-1563 05/04/2023 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory. Insufficient Cellularity. TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory. Insufficient Cellularity. 3. P23-3281 09//2023 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Unsatisfactory. Insufficient Cellularity. TECHNICAL SUPERVISOR A DIAGNOSIS: Unsatisfactory. Borderline Cellularity and Partially Obscured by Lubricant.
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.