Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0469942	06/30/2021
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: Based on review of laboratory policies and procedures, observation and interview it was determined that the laboratory failed to establish written policies and procedures to ensure positive patient identification during nongynecologic specimen processing. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for positive patient identification during nongynecologic specimen processing. 2. During observation of nongynecologic specimen processing on June 29, 2021 at 1:05 PM, Cytology Supervisor /Cytototechnologist A failed to label three of three nongynecologic specimen containers with the complete patient identifier accession number. Specimens include: Accession #: # Written on Specimen: -N21-514 514 -N21-515 515 -N21-516 516 a. During further observation it was determined that the laboratory failed to label thee of three previously processed specimen centrifuge tubes with the complete patient identifier accession number. Specimens include: Accession #: # Written on Specimen: -N21-511 511 -N21-512 512 -N21-513 513 3. During an interview on June 30, 2021 at 12:10 PM, the Laboratory Director/Technical Supervisor A and Cytology Supervisor/Cytotechnologist A confirmed these findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish

	and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: A. 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 assess the competency of Technical Supervisors. The laboratory failed to assess the competency of four of four Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. 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. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for four of four Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Laboratory Director/Technical Supervisor A - Technical Supervisor B -Technical Supervisor C -Technical Supervisor D 3. During an interview on June 30, 2021 at 12:10 PM, the Laboratory Director/Technical Supervisor A and Cytology Supervisor/Cytotechnologist A confirmed these findings. B. 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 assess the competency of Cytotechnologists. The laboratory failed to assess the competency of two of two Cytotechnologists in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to assess the competency of the Cytotechnologists for all duties performed. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for two of two Cytotechnologists in 2019, 2020 and to the date of the survey in 2021. Cytotechnologists include: -Cytology Supervisor/Cytotechnologist A - Cytotechnologist B a. Laboratory records titled PERFORMANCE REVIEW failed to include competency assessments for required duties in all phases of testing. 3. During an interview on June 30, 2021 at 12:10 PM, the Laboratory Director/Technical Supervisor A and Cytology Supervisor/Cytotechnologist A confirmed these findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of 51 laboratory policies and procedures and interviews it was determined that the laboratory failed to ensure that 23 of 51 written policies and procedures were approved, signed and dated by the Laboratory Director prior to use. Findings include: 1. The Laboratory Director failed to sign and date 23 of 51 written policies and procedures prior to use. Procedures include: -Requirements for Specimen Collection, Submission and Processing -Directions for Cervical - Vaginal Smear - ThinPrep Imaging Procedure -Reprocessing ThinPrep Procedure -Microscopic Interpretation -Meditech Reporting System -Criteria for Specimen Adequacy for GYN Cytology -Quality Control of Cytology Interpretation -Retrospective Review - Corrected Report Form -Cyto-Histo Correlation -ThinPrep Imager Processor Maintenance -Evaluating Stain Quality -H&E Stain Procedure and Maintenance Schedule -Cytology Instrument Maintenance -Non-GYN ThinPrep Procedure -

	Cytospin Procedure -Cytotechnology Competency Assessment Policy -Cyto- Histo Preparatory Personnel Training -Laboratory Infection Control -Blood, Infectious Waste Spill Procedure -Formaldehyde Disposal -Annual Statistical Evaluation 2. During an interview on June 29, 2021 at 9:40 AM, the Cytology Supervisor /Cytotechnologist A explained that all written procedures were initially signed as "adopted" by the Cytology Supervisor/Cytotechnologist A and the Laboratory Director /Technical Supervisor A signed the procedures as being "reviewed" at a later date. 3. During an interview on June 30, 2021 at 12:10 PM, the Laboratory Director/Technical Supervisor A and Cytology Supervisor/Cytotechnologist A confirmed these findings.
D5621	CYTOLOGY CFR(s): 493.1274(c)(1) (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)(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under 493.1469 or 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section). (c)(1)(i) The review must be performed by an individual who meets one of the following qualifications: (c)(1)(i)(A) A technical supervisor qualified under 493.1449(b) or (k). (c)(1)(i)(B) A cytology general supervisor qualified under 493.1469. (c)(1)(i)(C) A cytotechnologist qualified under 493.1483 who has the experience specified in 493.1469(b)(2). (c)(1)(ii) Cases must be randomly selected from the total caseload and include negatives and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information. (c)(1)(iii) The review of those cases selected must be completed before reporting patient results. 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 detail how at least 10 percent of the gynecologic cases interpreted to be negative would be randomly selected for review and how they would be reviewed before reporting patient results Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how at least 10 percent of the gynecologic cases/slides interpreted to be negative for epithelial cell abnormalities would be randomly selected for review. a. During an interview on June 29, 2021 at 1:00 PM the Survey Team asked the Cytology Supervisor /Cytotechnologist A if there was a written procedure to determine how the cases/slides were randomly selected. The Cytology Supervisor/Cytotechnologist A replied "no." b. The Cytology Supervisor/Cytotechnologist A explained that all cases/slides evaluated by the Cytotechnologist were sent to a pathologist but it was known by the Cytotechnologist which cases/slides would and would not be reviewed by a pathologist. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the review of cases/slides selected would be completed before reporting patient results. a. During an interview on June 29, 2021 at 1:00 PM the Cytology Supervisor/Cytotechnologist A explained that all negative cases /slides evaluated by the Cytotechnologist were sent to a pathologist for review but the Cytotechnologist released some cases prior to being sent to the pathologist.
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 follow written policies and procedures for the evaluation and comparison of six of six laboratory statistics. The laboratory failed to document three of six required annual statistics for 2019 and 2020. Findings include: 1. The laboratory failed to follow the written procedure ANNUAL STATISTICAL EVALUATION which stated: "The laboratory performs and documents an annual statistical evaluation of the following: -Cytology cases examined -Specimens processed by specimen type -Patient cases reported by diagnosis -Gynecologic cases with a diagnosis of ASC-US, LSIL, HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison -Gynecologic cases where cytology and histology are discrepant -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 three of six required annual statistics for 2019 and 2020: -number of total cytology cases examined -number of specimens by specimen type -number of specimens by diagnosis 3. During an interview on June 28, 2021 at 9:45 AM, Cytology Supervisor/Cytotechnologist A stated "the statistics are wrong and we are still working on it." 4. During an interview on June 30, 2021 at 12: 10 PM, the Laboratory Director/Technical Supervisor A and Cytology Supervisor /Cytotechnologist A confirmed that the statistics on the ANNUAL STATISTICAL REPORT document failed to include the total number of cases that were reported at the laboratory being surveyed.
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 cytology test reports and interviews it was determined the laboratory failed to ensure that 12 of 200 cytology test reports from April through June 2021 indicated the name and address of the laboratory where the test was performed. Findings include: 1. Twelve of 200 cytology test reports sampled from April through June 2021 failed to indicate the name and address of the laboratory where the cytology testing was performed. Test Reports include: -P21-1204 -P21-1207 -P21-1216 -P21-1218 -P21-1220 -P21-1225 -P21-1228 -P21-1230 -P21-1231 -P21-1237 -P21-1400 -P21-2051 2. During an interview on June 28, 2021 at 9:50 AM, Cytology Supervisor/Cytotechnologist A stated "we had a problem with the location on the test reports but it was corrected on March 28, 2021." 3. During an interview on June 30, 2021 at 12:10 PM, the Laboratory Director/Technical Supervisor A and Cytology Supervisor/Cytotechnologist A confirmed these findings.
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 fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079); and failed to ensure that written policies and procedures were established to assess, monitor and maintain the competency of four of four Technical Supervisors and two of two Cytotechnologists (refer to D6103).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to assure compliance with the applicable regulations and ensure that all the duties of the Laboratory Director were performed. Cross Refer to D5407, D5621, D5629, D5805

D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and 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 four of four Technical Supervisors and two of two Cytotechnologists. Cross refer to D5209
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.