Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0892601	04/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ar Anatomic Pathology Laboratory/Doctors'	4800 East Johnson, Jonesboro, 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 lack of proficiency testing (PT) enrollment records and interview it was determined that the laboratory failed to enroll in an approved cytology PT program for gynecologic examination (refer to D2001). The cumulative effect of this systemic problem resulted in the laboratory's failure to meet certification requirements to accurately and reliably evaluate patients' gynecologic cytology specimen slides for 2020 and 2021.
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 lack of cytology PT enrollment records and interview it was determined that the laboratory failed to enroll in a CMS-approved cytology PT program for gynecologic examination for 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide records of enrollment in an approved cytology PT program for 2020 and 2021. 2. During an interview with the Survey Team on April 20, 2021 at 1:15 PM, Laboratory Director/Technical Supervisor 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: Based on lack of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of six of six Technical Supervisors in 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 describe the laboratory's process for assessing the diagnostic competency of six of six Technical Supervisors. Technical Supervisors include: - Laboratory Director/Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E - Technical Supervisor F 2. During an interview with the Survey Team on April 20, 2021 at 1:30 PM, Laboratory Director/Technical Supervisor A confirmed these findings.
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 lack of policies and procedures and interview the laboratory failed to have written procedures available to laboratory personnel for 2020 and 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written procedures manual. 2. During an interview with the Survey Team on April 20, 2021 at 1:15 PM, Laboratory Director/Technical Supervisor A confirmed these findings.
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 lack of policies and procedures 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 for entering and reporting of cytology test results in the laboratory information system (LIS). 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process for cytology proficiency testing (PT) enrollment and participation of personnel who perform gynecologic cytology testing. 3. During an interview with the Survey Team on April 20, 2021 at 9:00 AM, Laboratory Director/Technical Supervisor A confirmed these findings.
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 the laboratory failed to ensure three of six Technical Supervisors received the appropriate training to evaluate gynecologic cytology specimens using the Hologic ThinPrep Pap Test in accordance with the manufacturer's instructions for 2020 and to date of the survey in 2021. Findings include: 1. The HOLOGIC THINPREP PROCESSOR OPERATOR'S MANUAL states "Evaluation of microscope slides produced with the ThinPrep processor 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 training records for three of six Technical Supervisors who performed diagnostic interpretations on Hologic ThinPrep Pap Tests in 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor C -Technical Supervisor E -Technical Supervisor F 3. During an interview with the Survey Team on April 20, 2021 at 4:00 PM, Laboratory Director/Technical Supervisor A confirmed these findings.

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 lack of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to compare clinical information with the cytology reports and to compare gynecologic cytology with a diagnosis of HSIL or malignancy with available histopathology reports. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to compare clinical information with cytology reports and to compare HSIL or malignant gynecologic cytology cases with available histopathology reports. 2. During an interview with the Survey Team on April 20, 2021 at 1:30 PM, Laboratory Director/Technical Supervisor A confirmed these findings.
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 lack of laboratory policies and procedures and interview 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. 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. 2. During an interview with the Survey Team on April 20, 2021 at 1:30 PM, Laboratory Director /Technical Supervisor A confirmed these findings.
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 lack of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for the annual evaluation and comparison of six of six laboratory statistics. The laboratory failed to document six 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 the annual statistical evaluation of six of six required laboratory statistics. 2. The Survey Team requested and the laboratory failed to provide records of six of six required annual statistics for 2019 and 2020 for this facility. 3. During an interview with the Survey Team on April 21, 2021 at 9:00 AM, Laboratory Director/Technical Supervisor A confirmed these findings.
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 lack of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that unsatisfactory gynecologic 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 ensure that unsatisfactory gynecologic specimens were identified and reported as unsatisfactory. 2. During an interview with the Survey Team on April 20, 2021 at 1:30 PM, Laboratory Director /Technical Supervisor A confirmed these findings.
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 lack of laboratory policies and procedures 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 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 cytology test results.
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 lack of laboratory policies and procedures, review of laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for issuing a corrected report to include the basis for the correction. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for issuing a corrected report to include the basis for the correction. 2. The Survey Team reviewed 19 corrected final test reports from 2020 and observed that 18 of the 19 final test reports did not contain the basis for correction. Test reports include: - C20-004149 C20-004169 C20-004170 - C20-004175 C20-004176 C20-004229 - C20-004235 C20-004301 C20-004313 - C20-004370 C20-004377 C20-004377 - C20-004415 C20-004419 C20-004496 - C20-004515 C20-004517 C20-004518 3. During an interview with the Survey Team on April 20, 2021 at 1:30 PM, Laboratory Director/Technical Supervisor A confirmed these findings.
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 review of laboratory policies and procedures, lack of laboratory records, and interviews 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. Cross Refer to D5403, D5623, D5625, D5629, D5655 and D5659
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 166 final test reports and interview it was determined that the laboratory failed to ensure that three of 166 final test reports from July to December 2020 did not indicate the address of the laboratory location where the test was performed. Findings include: 1. The Survey Team reviewed 166 final test reports dated July to December 2020. Three of 166 final test reports did not indicate the correct address of the laboratory where the test was performed. Test reports include: - C20-002686 - C20-004941 - C20-005088 2. During an interview with the Survey Team on April 21, 2021 at 9:00 AM, Laboratory Director/Technical Supervisor A confirmed these findings.
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 lack of laboratory policies and procedures, review of laboratory records 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
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 lack of laboratory policies and procedures, review of 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 Section 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); failed to ensure that quality assessment programs were established (refer to D6094); and failed to evaluate the competency and training needs of six of six Technical Supervisors (refer to D6102 and D6103). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with Section 493.1445 of this subpart.

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 lack of laboratory policies and procedures, review of laboratory records and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D5403, D5623, D5625, D5629, D5655, D5659 and D5805
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 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 2020 and 2021. Cross refer to D2001
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 lack of laboratory policies and procedures, review of laboratory records and interviews it was determined that the Laboratory Director failed to ensure that quality assessment programs were established and maintained to assure the quality of cytology testing and identify failures in quality as they occur. Cross Refer to D5791 and D5891
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 laboratory records and interview, it was determined that the Laboratory Director failed to ensure that three of six Technical Supervisors that performed Hologic ThinPrep Pap Test evaluations during 2020 and to the date of the survey in 2021, had received the appropriate morphology training and certification in accordance with manufacturer's instructions. Cross refer to D5411
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 the lack of laboratory policies and procedures and interview it was determined that Laboratory Director/Technical Supervisor A failed to establish policies and procedures to evaluate the competency of six of six Technical Supervisors who performed microscopic evaluations and reporting of gynecologic cytology results for 2020 and to the date of the survey in 2021. Cross refer to D5209
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on lack of laboratory policies and procedures and interview it was determined that Laboratory Director/Technical Supervisor A failed to ensure that an approved procedure manual was available to all personnel. Cross refer to D5401
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 158 random negative gynecologic cases/slides and the corresponding final test reports from June to December 2020 and confirmation by Laboratory Director/Technical Supervisor A on April 21, 2021 it was determined that the Technical Supervisor failed to verify the accuracy of one gynecologic cytology test. 1. C20-004895 11/12/2020 Imaged ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Atypical Squamous Cells - cannot exclude High-Grade Squamous Intraepithelial Lesion (ASC-H) TECHNICAL SUPERVISOR DIAGNOSIS: ASC-H
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.