Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D1051973	02/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Nwa Pathology At Wrmc Fs Room	3214 North North Hills Blvd, Fayetteville, 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
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 review of laboratory policies and procedures, lack of competency assessment records and interviews the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisors. The laboratory failed to assess the competency of 12 of 12 Technical Supervisors in 2023 and 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process for assessing the competency of the Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for 12 of 12 Technical Supervisors in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F -Technical Supervisor G -Technical Supervisor H -Technical Supervisor I -Technical Supervisor J -Technical Supervisor K -Technical Supervisor L 3. During interviews on February 11, 2025 at 9:30 AM and February 12, 2025 at 11:15 AM, these findings were confirmed with the Survey Contact/Quality Specialist.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of nine laboratory policies and procedures in the manual and interviews the laboratory failed to establish written policies and procedures for six laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the microscopic examination of nongynecologic specimens, including the detection of inadequately prepared slides. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the step-by-step performance of the fine needle aspiration biopsy (FNA) procedure, to include the collection, preparation, staining, documentation of specimen description, interpretation and reporting of test results. a. During an interview on February 10, 2025 at 10:15 AM the Laboratory Director/Technical Supervisor A stated, "We do the FNA's here. The pathologist goes to radiology and prepares the specimen. Those slides do not go to (FACILITY B) to be screened by Cytotechnologists, only the pathologist here looks at them." 3. The Survey Team requested and the laboratory failed to provide written policies and procedures for the coverslipping of FNA specimen slides, to include the method and the mounting media used. 4. The Survey Team requested and the laboratory failed to provide written policies and procedures for the process to check the quality of the Hematoxylin and Eosin (H&E) stains used for the rapid staining and evaluation of FNA slides. 5. The Survey Team requested and the laboratory failed to provide written policies and procedures for the process to check the quality of the THREE STEP STAIN solutions and stains used for the rapid staining and evaluation of air dried FNA slides. 6. The Survey Team requested and the laboratory failed to provide the laboratory's system for entering results in the patient record and reporting patient results. 7. During interviews on February 11, 2025 at 9:30 AM and February 12, 2025 at 11:15 AM, these findings were confirmed with the Survey Contact/Quality Specialist.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (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, lack of statistical records and interviews the laboratory failed to establish and follow written policies and procedures for an annual statistical evaluation of three of three required nongynecologic cytology laboratory statistics. The laboratory failed to maintain statistical records for three of three statistics in 2023 and 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of the three required nongynecologic cytology laboratory statistics. a. The laboratory failed to establish written policies and procedures to detail how a program would be established and followed to evaluate the three required statistics specifically for only the cases evaluated and reported from the laboratory being surveyed. Statistics include: -Number of cases examined; -Number of specimens processed by specimen type; -Number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). 2. The Survey Team requested and the laboratory failed to provide three of three annual nongynecologic cytology statistics for 2023 and 2024. Statistics include: -Number of cases examined; -Number of specimens processed by specimen type; -Number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). a. The Survey Team was provided ANATOMIC PATHOLOGY QUARTERLY STATISTICS reports for 2023 and 2024 which reflected combined specimen statistical evaluations for multiple testing locations. The reports failed to reflect statistical evaluations for the laboratory being surveyed. b. During an interview on February 11, 2025 at 9:30 AM, the Laboratory Director/Technical Supervisor A stated, "we do not separate out the specimens, they are combined for the entire system and not broken out". 3. During interviews on February 11, 2025 at 9:30 AM and February 12, 2025 at 11:15 AM, these findings were confirmed with the Survey Contact/Quality Specialist.
D5631	CYTOLOGY CFR(s): 493.1274(c)(6) (c)(6) An evaluation of the case reviews of each individual examining slides against the laboratorys overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken. (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interviews the laboratory failed to establish and follow written policies and procedures for a program to evaluate the case reviews of 12 of 12 Technical Supervisors against the laboratory's overall statistical values in 2023 and 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for a program to evaluate the case reviews of Technical Supervisors against the laboratory's overall statistical values. 2. The Survey Team requested and

	the laboratory failed to provide records documenting the evaluation of the case reviews of 12 of 12 Technical Supervisors against the laboratory's overall statistical values in 2023 and 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F -Technical Supervisor G -Technical Supervisor H -Technical Supervisor I -Technical Supervisor J -Technical Supervisor K -Technical Supervisor L 3. During interviews on February 11, 2025 at 9:30 AM and February 12, 2025 at 11:15 AM, these findings were confirmed with the Survey Contact/Quality Specialist.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, workload limit records and interviews the laboratory failed to establish and follow written policies and procedures to reassess and adjust when necessary, a maximum workload limit at least every six months for the Technical Supervisors who performed primary screening of cytology specimens. The Technical Supervisor failed to reassess a maximum workload limit for 12 of 12 Technical Supervisors in 2023 and 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how a workload limit would be reassessed and adjusted when necessary by the Technical Supervisor, to include the criteria used to evaluate individual performance. 2. The Survey Team requested and the laboratory failed to provide documentation the Technical Supervisor reassessed a maximum workload limit based on performance, for 12 of 12 Technical Supervisors in 2023 and 2024. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F -Technical Supervisor G -Technical Supervisor H -Technical Supervisor I -Technical Supervisor J -Technical Supervisor K -Technical Supervisor L 3. During an interview on February 11, 2025 at 9:30 AM, the Laboratory Director/Technical Supervisor A stated, "I am the Technical Supervisor" and confirmed the reassessments had not been performed by the Technical Supervisor but signed by the groups Medical Director. 4. During interviews on February 11, 2025 at 9:30 AM and February 12, 2025 at 11:15 AM, these findings were confirmed with the Survey Contact/Quality Specialist.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, workload records and interviews the laboratory failed to establish laboratory policies and procedures for the laboratory's process to maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining

	slides in the 24-hour period. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the laboratory's process to maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period. 2. The laboratory provided computer-generated records titled NONGYN PRIMARY SCREENING BY PATHOLOGIST for 2023 and 2024. There were no written policies or procedures to detail what data was collected and how the data was recorded. 3. During interviews on February 11, 2025 at 9:30 AM and February 12, 2025 at 11:15 AM, these findings were confirmed with the Survey Contact/Quality Specialist.
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (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 and interviews the laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory 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 ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. During interviews on February 11, 2025 at 9:30 AM and February 12, 2025 at 11:15 AM, these findings were confirmed with the Survey Contact /Quality Specialist.
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interviews the laboratory failed to establish and follow written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report 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 nongynecologic cytology test results. 2. During interviews on February 11, 2025 at 9: 30 AM and February 12, 2025 at 11:15 AM, these findings were confirmed with the Survey Contact/Quality Specialist.
D5659	CYTOLOGY CFR(s): 493.1274(e)(6) (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 and interviews the laboratory failed to establish and follow written policies and procedures to ensure corrected cytology test reports indicated 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 cytology test reports indicated the basis for correction on the corrected test report. 2. During interviews on February 11, 2025 at 9:30 AM and February 12, 2025 at 11:15 AM, these findings were confirmed with the Survey Contact/Quality Specialist.
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 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); and failed to ensure quality control and quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur (refer to D6093).
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 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 written policies and procedures were established for requirements and test processes that were specific to the laboratory. Refer to D5403, D5629, D5631, D5637, D5645, D5655, D5657, D5659. 2. During an interview on February 11, 2025 at 9:30 AM, the Laboratory Director stated that most policies and procedures were kept at the main facility, were signed as approved by the system Medical Director and were not specific to this location.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 and interviews the Laboratory Director failed to ensure quality control and quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur in all phases of testing. Findings include: 1. The Laboratory Director failed to ensure written policies and procedures were established and maintained for a quality control program, to detail the quality control activities performed for all phases of cytology testing at the laboratory. 2. The Laboratory Director failed to ensure written policies and procedures were established and maintained for a quality assessment program, to detail the quality assessment activities performed for all phases of cytology testing at the laboratory. 3. During interviews on February 11, 2025 at 9:30 AM and February 12, 2025 at 11:15 AM, these findings were confirmed with the Survey Contact/Quality Specialist.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) 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 and interviews the Laboratory Director failed to ensure that policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure they maintain their competency to perform test procedures and report test results promptly and proficiently. Findings include; 1. The Survey Team requested and the laboratory failed to provide written policies and procedures established and approved by the Laboratory Director to detail the laboratory's process for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing. 2. During interviews on February 11, 2025 at 9:30 AM and February 12, 2025 at 11: 15 AM, these findings were confirmed with the Survey Contact/Quality Specialist.
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c)(2) Must establish the workload limit for each individual examining slides; (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;

	This STANDARD is not met as evidenced by: Based on review of workload limit records and interview the Technical Supervisor failed to establish and reassess a maximum workload limit for 12 of 12 Technical Supervisors in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Technical Supervisor failed to provide documentation the Technical Supervisor reassessed a workload limit at least every six months for 12 of 12 Technical Supervisors who performed primary cytology slide examinations in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Refer to D5637
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.