Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2022549	04/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Atmore Urgent Care	5850 Hwy 21, Atmore, AL	

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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing (PT) records and an interview with the Technical Consultant, the laboratory failed to attain a score of at least 80% for each analyte submitted for Hematology 1st Event 2023. This was noted for one out of one Proficiency Testing event reviewed. The finding include: 1. A review of the American Proficiency Institute (API) PT records revealed the following failing scores for analytes on the Hematology 1st Event 2023 survey: a) Leukocyte Count - 0% b) White Blood Cell Differential - 7% 2. The surveyor further noted calculated indices for the RBC's (Red Blood Cells) also yielded failing scores, as follows: a) Mean Corpuscular Hemoglobin Concentration (MCHC) - 20% b) Mean Corpuscular Volume (MCV) - 40% c) Red Cell Distribution Width (RDW) - 0% 3. During an interview on 4/25/2023 at 11:00 AM, the Technical Consultant explained the laboratory received the failing scores due to enrollment in the wrong Proficiency Testing program for their Hematology instrument.
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 a review of the Policies and Procedures and an interview with the Technical Consultant, the laboratory failed to establish and follow written policies and procedures to assess the competency of employees. This was noted from the implementation of the Policy and Procedure Manual, 8/30/2022, to the date of the current survey, 4/25/2023. The findings include: 1. A review of the Policies and Procedures revealed no procedure on performance of competency assessments for testing personnel. 2. During an interview on 4/25/2023 at 12:30 PM, the Technical Consultant confirmed no other policies were available to review.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of Policies and Procedures and an interview with the Technical Consultant, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems. This was noted from the implementation of the Policy and Procedure Manual, 8/30/2022, to the date of the current survey, 4/25/2023. The findings include: 1. A review of Policies and Procedures revealed no evidence of a Quality Assurance plan for the facility. 2. During an interview on 4/25/2023 at 12:30 PM, the Technical Consultant confirmed the above 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 a review of Policies and Procedures and an interview with the Technical Consultant, the laboratory failed to have a procedure specifying normal reference

	ranges for CBC's (Complete Blood Counts) performed on the Sysmex XN-330 Hematology Analyzer. This was noted from the implementation of the procedure, 8/30 /2022, to the date of the current survey, 4/25/2023. The findings include: 1. A review of the Policies and Procedures revealed no reference ranges were specified for CBC's performed on the Sysmex XN-330 Hematology analyzer. 2. During an interview on 4 /25/2023 at 12:30 PM, the Technical Consultant confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the Environmental Monitoring records, a review of the Sysmex XN-330 Operators Manual, and an interview with the Technical Consultant, the laboratory failed to ensure the Sysmex XN-330 was operated within environmental parameters specified by the manufacturer. The laboratory failed to monitor and document Room Temperature and Humidity from the start of patient testing on 9/14 /2022 to the date of the current survey, 4/25/2023. The findings include: 1. A review of Environmental Monitoring records revealed only refrigerator temperatures were recorded. 2. A review of the Sysmex XN-330 Operators Manual revealed the following under "Chapter 5: Instrument Specifications", "...Operating environment - Ambient Temperature: 15 to 35 degrees Celsius...Relative Humidity: 20 to 85%...". 3. During an interview on 4/25/2023 at 12:30 PM, the Technical Consultant confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on reviews of the Policy and Procedure Manual, Personnel Records, Sysmex XN-330 validation Records, and interviews with the Technical Consultant, the Laboratory Director: 1) failed to establish and maintain a Quality Assessment program to assure the quality of laboratory services provided; 2) failed to ensure policies and procedures were established to monitor the competency of testing personnel; 3) failed to ensure Sysmex XN-330 verification procedures demonstrated performance characteristics specified by the manufacturer prior to use for patient testing; and 4) failed to ensure education documentation was available for two of four new Testing Personnel (TP) performing moderate-complexity patient testing. The findings include: 1. Refer to D6021. 2. Refer to D6030. 3. Refer to D6013. 4. Refer to D6065.

D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the validation records for the Sysmex XN-330 Hematology analyzer and an interview with the Technical Consultant, the Laboratory Director failed to document review and approval of the validation procedures prior to instrument use for patient testing on 9/14/2022. The findings include: 1. A review of Sysmex XN-330 validation records revealed no evidence of the Laboratory Director's review and approval (as evidenced by signature and date) before the instrument was utilized for patient testing on 9/14/2022. 2. During an interview on 4/25/2023 at 12:00 PM, the Technical Consultant confirmed the above findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the Policies and Procedures and an interview with the Technical Consultant, the Laboratory Director failed to establish and maintain a Quality Assessment program to assure the quality of laboratory services provided. This was noted from the implementation of the Policy and Procedure Manual, 8/30/2022, to the date of the current survey, 4/25/2023. The findings include: 1. A review of Policies and Procedures revealed no evidence of a Quality Assurance plan for the facility. 2. During an interview on 4/25/2023 at 12:30 PM, the Technical Consultant confirmed the above findings.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) 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 a review of the Policy and Procedure Manual and an interview with the Technical Consultant, the Laboratory Director failed to ensure policies and procedures were established for monitoring the competency of testing personnel, and ensure remedial training was provided when necessary. This was noted from the date of implementation of the Policy and Procedure Manual, 8/30/2022, to the date of the current survey, 4/25/2023. The findings include: 1. A review of the Policies and Procedures revealed no procedure on performance of competency assessments for testing personnel, or procedures to follow when remedial training was required. 2. During an interview on 4/25/2023 at 12:30 PM, the Technical Consultant confirmed the above findings.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of Personnel files, and an interview with the Office Manager, the laboratory failed to ensure educational documentation was available for two of four new Testing Personnel (TP) performing moderate-complexity patient testing. The findings include: 1. A review of the personnel files revealed no educational documentation for Testing Personnel #3 and Testing Personnel #4. 2. During an interview on 4/25/2023 at 1:30 PM, the Office Manager explained they were having difficulty locating educational documents for TP #3 and TP #4. The Office Manager was unable to provide the requested documents by the end of survey. .