

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2022549	(X3) Date Survey Completed 04/30/2025
Name of Provider or Supplier Atmore Urgent Care	Street Address, City, State 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the environmental logs, Sysmex XN-330 operator's manual, and an interview the Technical Consultant (TC), the laboratory failed to record the Room Temperature (RT) and Humidity in the room where the analyzer was operated were within the manufacturer's acceptable limits. The surveyor noted no documentation of the RT and Humidity for 2 out of the 12 months in 2023. The findings include: 1. A review of the environmental logs revealed the June-July 2023 RT and Humidity records were missing during the survey. 2. A review of the Sysmex XN-330 General Information Manual revealed the manufacturer's operating environment requirements on Chapter 5 to be: A) Ambient temperature: 15-35 degrees Celsius B) Relative Humidity: 20-85 percent 3. The TC confirmed the above findings during the exit conference on 04-30-2025 at 2:30 PM.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:
Based on a review of the Hematology maintenance logs for the Sysmex XN-300, and an interview with the Technical Consultant (TC), the laboratory failed to perform and document the analyzer's required maintenance. The surveyor noted maintenance documentations were missing for 2 of the 12 months in 2023. The findings include: 1. A review of the Sysmex XN-300 maintenance logs revealed the daily, weekly, and as needed maintenance were not performed and documented from June-July 2023. 2. The TC confirmed the above findings during the exit conference on 04-30-2025 at 2:30 PM.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on reviews of the Hematology calibration records, laboratory's policy and procedure manual for the Sysmex XN-300 analyzer and an interview with the Technical Consultant (TC), the laboratory failed to perform calibration at least every six months. This was noted for three of the four possible calibrations from 2023-2025. The findings include: 1. A review of the Hematology calibration records revealed the Sysmex XN-300 was not calibrated according to the laboratory's established policy of at least every six months. Laboratory's calibration records revealed the following: A) The calibration due on 02-21-2023 was not performed and completed until 5-10-2023, approximately three months later. B) The calibration due on 11-08-2023 was not performed and completed until 1-18-2024, approximately two months later. C) The calibration due on 07-18-2024 was not performed and completed until 1-15-2025, approximately six months later. 2. The TC confirmed the above findings on 04-30-2025 at 2:30 PM during the exit conference.