

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2268661	(X3) Date Survey Completed 06/09/2025
Name of Provider or Supplier Long Leaf Primary Care	Street Address, City, State 171 Town Center Drive, Anniston, 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
D0000	A desk review, follow-up survey was conducted on 07-21-2025. Based on a review of an acceptable plan of correction and supporting documentation, submitted by the laboratory and received on 07-18-2025, the surveyor determined the laboratory has achieved substantial compliance with the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).
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 records, the Immunocard Mycoplasma (IM) package insert and an interview with the Technical Consultant (TC), the laboratory failed to ensure the room temperature for the Mycoplasma testing was within the manufacturer's acceptable limits. The room temperature was noted out of acceptable range for 11 days from January-March 2025. The findings include: 1. A review of the environmental records revealed the room temperature was out of the manufacturer's acceptable limits when the Mycoplasma patient testing were performed for the following days A) Five days in January 2025, five patient results reported, B) Four days in February 2025, four patient results reported C) Two days in March 2025, two patient results reported 2. A review of the IM package insert revealed under Precautions the following instructions (1-16): "...2. Reagent concentration, incubation</p>

times and temperatures (22-25 degrees Celsius) have been optimized for sensitivity and specificity.7. All reagents should be gently mixed and at 22-25 degrees Celsius before use." 3. During the exit conference on 06-09-2025 at 1:05 PM, the TC confirmed the above findings.

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 Medonic M-Series calibration records, the Policies and Procedure Manual (P&P) and an interview with the Technical Consultant (TC), the laboratory failed to follow their policy to perform and document precision study during calibration for five out of five calibrations in 2023-2025. The findings include:

1. A review of calibration records for the Medonic M-Series Hematology analyzer revealed no precision study was performed and documented during calibrations performed in 2023-2025, as follows: A) March 20, 2023 and September 28, 2023 B) March 26, 2024 and September 30, 2024 C) March 27, 2025
2. A review of the P&P under Quality Control/Calibration Hematology/CBC procedure revealed the following instructions. "...III Precision Study 1. A precision study will be performed according to the following: ~ at a minimum of every 6 months, ~ If there is an instrument problem, ~ Anytime the instrument is recalibrated."
3. During the exit conference on 06-09-2025 at 1:05 PM, the TC confirmed the above findings.