

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0304961	(X3) Date Survey Completed 03/19/2025
Name of Provider or Supplier Wiregrass Medical Center	Street Address, City, State 1200 W Maple Ave, Geneva, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Technical Consultant (TC) and the Technical Supervisor/General Supervisor (TS/GS), the laboratory failed to ensure the Laboratory Director (or designee) signed the PT attestation statements. This was noted for 3 of the 22 events reviewed from the date of the last survey, 04-19-2023 through the date of the current survey, 03-19-2025. The findings include: 1. A review of the 2023-2024 API PT records revealed the Laboratory Director (or designee) did not sign the attestation statements for the following PT events: A) 2024 Immunology /Immunohematology 1st Event B) 2024 Chemistry Miscellaneous 1st Event C) 2024 Microbiology 3rd Event 2. The TC and TS/GS confirmed the above findings during the day one exit conference on 03-18-2025 at 4:16 PM.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the Technical Consultant (TC) and the Technical</p>

Supervisor/General Supervisor (TS/GS), the laboratory failed to implement a mechanism to verify the accuracy of the Ferritin PT, a regulated analyte. The surveyor noted the PT evaluation failures occurred in two consecutive events out of the three events for 2024. The findings include: 1. A review of the API PT records revealed the laboratory evaluation scores were 50 percent on the Ferritin PT for the following events: A) 2024 Chemistry Core 1st Event B) 2024 Chemistry Core 2nd Event 2. A further review of the PT performance evaluation and corrective action documentation for the unsatisfactory scores noted testing method submitted to API for the Ferritin PT was incorrect. 3. The TC and the TS/GS confirmed the above findings during the day one exit conference on 03-18-2025 at 4:16 PM.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on direct observation, a review of the Beckman Coulter Bicarbonate Calibrator (BCBC) Instructions For Use (IFU), and interview with the Technical Consultant and Technical Supervisor/General Supervisor (TS/GS), the laboratory staff failed to document the open vial stability dates on the BCBC currently in use. The surveyor noted only the open date was written on the BCBC bottle, which had been in use for 26 days from the date of opening. The findings include: 1. During the laboratory tour on 03-19-2025 at approximately 8:28 AM, the surveyor observed the BCBC currently in use was labeled with the open date, "02-22-2025", however the testing personnel had not recorded on the bottle the new expiration date upon opening. 2. A review of the BCBC IFU under Calibrator Storage and Stability, page 2, revealed the following statement, " 2. Opened bottles are stable up to 30 days..." 3. During the day two exit conference on 03-19-2025, the TC and TS/GS confirmed the above findings.