

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1043255	(X3) Date Survey Completed 05/09/2025
Name of Provider or Supplier Albaree Health Services Llc	Street Address, City, State 900 Tom Frazier Way, Ste 200, Salyersville, KY	
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 recertification survey was initiated on 05/09/2025 and concluded on 05/09/2025. The facility was found to not be in compliance with the laboratory requirements of 42 CFR Part 493 with standard deficiencies cited.
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 direct observation, review of the procedure manual, review of the Sysmex XP-300 Instructions for Use, laboratory environmental records, and confirmed in staff interview, the laboratory failed to document daily room temperature for 17 of 17 months. Findings Included: During a tour of the laboratory area on 05/09/2025 at 11: 15 AM, a Sysmex XP-300 (Serial Number A5261) was observed. Review of Albaree Health Service LLC Laboratory Policy and Procedure Manual (Revised 2022), stated "To assure all reagents, test kits, and equipment are maintained and operated in the correct environmental conditions, the lab will have the temperature and humidity checked and logged daily to confirm that the correct environmental conditions exist." PROCEDURE OUTLINE: "Personnel must log temperature and humidity on work area temperature logs located in all department areas of concern." Review of the Sysmex XP-300 Instructions for Use (Section 14.1 Specifications) revealed an operating environment ambient temperature of 15 C to 30 C (same for the supplied</p>

reagent temperature). A review of the laboratory's environmental records for year 2024, January 2025, February 2025, March 2025, April 2025, and May 2025 revealed the laboratory failed to monitor the room temperature in the laboratory area. In an interview on 05/09/2025 at 12:00 PM in the break room, Testing Personnel #7 confirmed that the room temperature was not monitored daily in the laboratory area. This confirmed the findings.