

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1034225	(X3) Date Survey Completed 08/23/2024
Name of Provider or Supplier Advanced Clinical Laboratory	Street Address, City, State 1405 Airline Drive, Metairie, LA	
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 performed at Advanced Clinical Laboratory, CLIA ID 19D1034225, on August 23, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the manufacturers' storage requirements, and interview with personnel, the laboratory failed to monitor the room temperature of the storage room where laboratory supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on August 23, 2024 at 9:25 am revealed the following items stored in a storage room located behind the storage area: a) BD Vacutainer serum blood collection tubes b) BD Vacutainer K2EDTA blood collection tubes c) Aptima Unisex Swab specimen collection kits d) UTM RT specimen collection kit for viruses, Chlamydia, Mycoplasma, Ureaplasma 2. Review of the manufacturers' storage requirements revealed the following: a) BD Vacutainer serum blood collection tubes: storage temperature: 4-25 degrees Celsius b) BD Vacutainer K2EDTA blood collection tubes: storage temperature 4-25 degrees Celsius c) Aptima Unisex Swab specimen collection kits: storage temperature 15-30 degrees Celsius d) UTM RT specimen collection kits: 2-25 degrees Celsius 3. In interview on August 23,</p>

	<p>2024 at 9:25 am the Technical Consultant stated the room temperature was not monitored in the identified storage room.</p>
D6014	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p> <p>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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturers' storage requirements, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5413.</p>
D6036	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturers' storage requirements, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5413.</p>