

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0672012	(X3) Date Survey Completed 08/07/2024
Name of Provider or Supplier Dallas Co Dept Of Health & Human Services	Street Address, City, State 2377 N Stemmons Freeway Suite 003, Dallas, TX	
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	An onsite recertification survey conducted August 5-7, 2024, found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 surveyor observation, review of manufacturer's instructions, laboratory environmental records, and confirmed in an interview with laboratory personnel, the laboratory failed to establish an acceptable room temperature range for six of six months reviewed in 2023 and 2024. The findings included: 1. Surveyor observation on August 5, 2024, in the STAT Lab (Room #111) found less than one liter of Reagent Alcohol stored in the flammable cabinet. Lot # 215263 Expiration date: 02-2025 2. Review of the manufacturer's instructions on the outside packaging stated, "Store at 20-30 degrees Celsius". 3. Review of the laboratory's environmental records for the STAT Lab (Room #111) from May, June, July of 2024 and October, November, and December of 2023 found the laboratory established its room temperature range as follows: High Alarm Limit: 30.0 degrees Celsius Low Alarm Limit: 15.0 degrees Celsius 4. The laboratory failed to established an acceptable room temperature range per the manufacturer's instructions for the Reagent Alcohol. 5. In an interview at 10:43 hours on 08/05/2024, technical supervisor 4 (as listed on CMS Form 209) confirmed the laboratory's range was too wide.</p>

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

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

This STANDARD is not met as evidenced by:

Based on surveyor observation, review of manufacturer's instructions, and confirmed in an interview with laboratory personnel, the laboratory failed to follow the manufacturer's instructions to monitor revised expiration dates for one of one box of Blood Bank Saline in use. The findings included: 1. Surveyor observation on August 5, 2024, in the STAT Lab (Room #111) found one box of 0.9% Blood Bank Saline in use. The box did not have an open date or a revised expiration date. Lot # 720284 Expiration date: 05/31/2024 2. Review of the manufacturer's instructions on the outside packaging stated, "Use within 30 days of open date". 3. The laboratory failed to document the open date or revised expiration date in order to ensure the saline was discarded within 30 days of the open date. 4. In an interview at 10:35 hours on 08/05 /2024, testing personnel #8 (as listed on CMS Form 209) confirmed that the neither the revised expiration date or open date was documented.