

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0865177	(X3) Date Survey Completed 10/16/2025
Name of Provider or Supplier Nc County Health Department - Area C	Street Address, City, State Wayne County Health Department, Goldsboro, NC	
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
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 review of laboratory procedures, product inserts, temperature logs for 2024 and 2025, and interview with the Technical Consultant (TC) on 10/16/2025, the laboratory failed to establish a room temperature range consistent with the laboratory procedure and manufacturer requirements from July 16, 2024 to October 16, 2025. Findings: Review of the "URINE MICROSCOPIC" laboratory procedure page 2 revealed, "Materials...Reagent/Supplies...QC materials...Dip&Spin Control Level 1 and 2, Quantimetrix Corporation...Testing:18-25C...Quality Control...Allow the control to come to room temperature (18C- 25C)..." Review of the "Quantimetrix Dip&Spin Urinalysis Dipstick & Microscopics Control Level 1 & 2" product insert on page 1 revealed, "Allow the control to come to room temperature (18C- 25C)..." Review of laboratory temperature logs, "Daily Temperature and Maintenance Log..." for 2024 and 2025 revealed, "...ROOM TEMP 18-30 DEGREES C..." The laboratory does not meet the required ranges for the laboratory procedure 18C- 25C and the manufacturers product insert required ranges of 18C- 25C. During interview at approximately 3:05 p.m., the TC confirmed incorrect temperature ranges listed on the temperature logs and said this was recently discussed this with the lab manager.</p>

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on review of laboratory procedures, manufacturer operating instructions, maintenance logs for 2024 and 2025, and interview with the Technical Consultant (TC) on 10/16/2025, the laboratory failed to document weekly centrifuge maintenance as required from July 16, 2024 to October 16, 2025, approximately 65 weeks. Findings: Review of the "LABORATORY CLEAN-UP PROCEDURE" page 2 revealed, "...Centrifuge Maintenance: The centrifuges are cleaned weekly or more often if needed...1. The interior and exterior of the centrifuges are cleaned with an approved disinfectant according to manufacturer's instructions...2. Initial the appropriate log sheet....." Review of the "LW Scientific, Inc. LWS-V24 Laboratory Centrifuge Installation and Operating Instructions," page 1 revealed, "Care and maintenance... 5) ...Clean and disinfect the rotor, tube shields, and the inside of the centrifuge according to your laboratory protocol..." Review of the "Daily Temperature and Maintenance Log..." for 2024 and 2025 revealed no documentation of the performance of weekly centrifuge maintenance for approximately 65 weeks. During interview with the TC at approximately 4:17 p.m., the TC confirmed weekly centrifuge maintenance was not documented.