

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0671837	(X3) Date Survey Completed 04/02/2025
Name of Provider or Supplier Waycross Regional Laboratory	Street Address, City, State 1751 Gus Karle Parkway, Waycross, GA	
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:</p> <p>I. Based on observation, review of manufacturer's instructions, lack of temperature /humidity records, and interview with staff, the laboratory failed to ensure the temperature and humidity ranges were within manufacturer's specifications for the operation of 2 of 2 Hologic Panther systems. Findings included: 1. Two Hologic Panther systems (serial numbers 01607 and 01608) were observed during a tour of the laboratory at approximately 1pm on 04/02/2025. 2. The operator manual for the Hologic Panther system states the following on page 198 in Table 91. Environmental Specifications: "Temperature (C) Low Range 15C High Range 30C" "Relative Humidity (%) Low Range 20% High Range 85%" 3. The surveyor requested and did not receive records documenting temperature and humidity levels for the area of the laboratory housing the two Hologic Panther systems. 4. During interview on 04/02 /2025 at approximately 1pm, the Laboratory Director stated temperature and humidity levels were not documented for the area of the laboratory housing the two Hologic Panther systems. 38798 II. Based on review of the DiaSorin Liaison XL User Manual and interview with the Laboratory Manager and the Laboratory Director, the laboratory failed to monitor and document room humidity and room temperature per the manufacturer's instructions for operating one of one DiaSorin Liaison XL</p>

instrument (serial # 12706). 1. A review of the DiaSorin Liaison XL User Manual, Revision G, 11-2019, page 10-9, Table 10.7 instructed the following environmental condition standards for operating the instrument: Room Temperature range = 15-32C Room Humidity = 10-85% 2. In an interview on April 2, 2025, at 9:55 AM, the Laboratory Manager confirmed the room humidity levels were not monitored and documented for the purposes of operating the DiaSorin Liaison XL instrument used for qualitative antibody testing of Rubeola, Mumps, Rubella and Treponema. 3. In an interview on April 2, 2025, at 10:35 AM, the Laboratory Director confirmed the room temperature was not monitored and documented by the laboratory for the purposes of operating the DiaSorin Liaison XL instrument used for qualitative antibody testing of Rubeola, Mumps, Rubella and Treponema. 4. The total annual test volume for Rubeola, Mumps, Rubella and Treponema antibody testing using the DiaSorin Liaison XL instrument was 3,366.

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:
Based on observation, record review and interview with staff, the laboratory failed to compare test results for 2 of 2 Hologic Panther Systems twice annually in years 2023 and 2024. Findings included: 1. Two Hologic Panther systems (serial numbers 01607 and 01608) were observed during a tour of the laboratory at approximately 1pm on 04/02/2025. 2. Review of test comparison records for the two Hologic Panther systems revealed the laboratory performed the following test result comparisons: a. Chlamydia trachomatis, Neisseria gonorrhoeae and Trichomonas vaginalis test result comparisons performed 06/07/2023, 06/05/2024 and 12/03/2024. The laboratory failed to perform two test result comparisons in 2023. b. SARS-CoV-2 test result comparisons performed June 2023 and December 2024. The laboratory failed to perform two test result comparisons in 2023 and 2024. 3. During interview on 04/02/2025 at approximately 1:10pm, the Technical Supervisor of Microbiology confirmed the laboratory failed to perform twice a year comparison of test results for the two Hologic Panther systems in 2023 and 2024.