

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0265053	(X3) Date Survey Completed 11/18/2025
Name of Provider or Supplier Waycross Internal Medicine	Street Address, City, State 711 Knight Avenue, 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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) Recertification Survey was completed on November 18, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: A review of the current Laboratory Procedure Manual confirmed that the procedure manual was outdated and failed to meet the regulation requirements stated in CLIA</p>

Regulation 493.1251(b). THE FINDINGS INCLUDE: 1. A review of the current Laboratory Procedure Manual confirmed that the manual failed to include the Down Time Procedure and Personnel Procedure. 2. A review of Laboratory In-House Testing menu confirmed that the menu included H. Pylori Testing and Rh Factor testing that had been discontinued. 3. A review of the current procedure manual revealed that the procedure failed to include Normal and Critical Testing Values. 4. An exit interview, with the Laboratory Staff, on November 18, 2025, at 2:30pm, confirmed that the Procedure Manual contained testing procedures that were outdated as well as lacked all required components for a complete procedure manual.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

(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.

This STANDARD is not met as evidenced by:
A review of the facility confirmed that the laboratory failed to document and to maintain proper temperature and humidity requirements as mandated by the manufacturer for required instrumentation operations and accurate testing results. THE FINDINGS INCLUDE: 1. A tour of the facility revealed that the required operating environment was not documented and/or maintained for the testing environment. 2. The facility tour confirmed that the temperature and humidity were not documented and/ or monitored in the testing area which contained one Cepheid GeneXpert analyzer and three Quidel SOFIA 2 analyzers. The Cepheid GeneXpert analyzer has required operating temperature and humidity of 15-30 C (59-86 F) | 10% -95%, non-condensing respectively. The Quidel SOFIA 2 analyzers has required operating temperature and humidity of 15C to 30C (59F to 86F) | 20% to 85% Relative Humidity (RH) respectively. 3. The facility tour revealed the following testing reagents stored in this aforementioned area: a. GeneXpert CoV-2/ Flu/ RSV Plus Test Cartridges: STORAGE TEMP REQUIREMENT of 2C - 28C b. SOFIA Influenza A+B FIA Test Cartridges: STORAGE TEMP REQUIREMENT of 15C - 30C. c. ThermoScientific Washing Solution: STORAGE TEMP REQUIREMENT = 20C - 25C. 4. An exit interview, with the Laboratory Staff, on November 18, 2025, at 2:30pm confirmed that the laboratory failed to document and maintain proper temperature and humidity requirements as mandated by the manufacturer.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel

meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

A review of 2023 - 2025 Temperature Records and the current Laboratory Procedure Manual confirmed that the Laboratory Director failed to provide oversight of the all laboratory operations. Reference D5403 and D5413