

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0868280	(X3) Date Survey Completed 10/17/2025
Name of Provider or Supplier Medical Specialists Inc	Street Address, City, State 305 Jones Avenue, Waynesboro, 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 October 17, 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:
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: A tour of the facility confirmed that the laboratory failed to monitor and document the temperature of locations in which reagents were stored and/ or in use. THE FINDINGS INCLUDE: 1. A tour of the facility revealed that three locations, in which the room temperature was not monitored, with reagents that required specific storage temperature requirements. 2. The facility tour confirmed that at Nurse Testing Station #1 the following agents were stored and/ or in use: a. APTIMA URINE SPECIMEN COLLECTION KIT: STORAGE TEMP REQUIREMENT = 15C - 30C b. BECTON DICKINSON SERUM COLLECTION TUBES - EDTA: STORAGE TEMP REQUIREMENT = 4C - 25C c. BECTON DICKINSON SERUM COLLECTION TUBES - LITHIUM HEP: STORAGE TEMP REQUIREMENT = 4C - 25C d. BECTON DICKINSON SERUM COLLECTION TUBES - PINK: STORAGE TEMP REQUIREMENT = 4C - 25C e. BECTON DICKINSON SERUM COLLECTION</p>

TUBES - RED: STORAGE TEMP REQUIREMENT = 4C - 25C f. BECTON DICKINSON SERUM COLLECTION TUBES - SST: STORAGE TEMP REQUIREMENT = 4C - 25C g. BECTON DICKINSON URINE CULTURE COLLECTION TUBES - SST: STORAGE TEMP REQUIREMENT = 4C - 25C h. COPAN FLU/ RSV NASAL COLLECTION SWABS: STORAGE TEMP REQUIREMENT = 2C - 30C i. MCKESSON CONSULT hCG COMBO TEST CASSETTES: STORAGE TEMP REQUIREMENT = 15C - 30C j. SIEMANS MULTISTIX 10SG URINALYSIS TEST TRIPS: STORAGE TEMP REQUIREMENT = 15C - 30C k. COPAN FLU/ RSV NASAL COLLECTION SWABS: STORAGE TEMP REQUIREMENT = 2C - 30C 3. A tour of the facility revealed that the Quest Drawing Station had the following reagents stored and/ or in use: a. BECTON DICKINSON SERUM COLLECTION TUBES - EDTA: STORAGE TEMP REQUIREMENT = 4C - 25C b. BECTON DICKINSON SERUM COLLECTION TUBES - GREEN: STORAGE TEMP REQUIREMENT = 4C - 25C c. BECTON DICKINSON SERUM COLLECTION TUBES - PINK: STORAGE TEMP REQUIREMENT = 4C - 25C d. BECTON DICKINSON SERUM COLLECTION TUBES - RED: STORAGE TEMP REQUIREMENT = 4C - 25C e. BECTON DICKINSON SERUM COLLECTION TUBES - SST: STORAGE TEMP REQUIREMENT = 4C - 25C 4. A tour of the facility revealed that the following reagents, in the Reagent Storage Closet, contained the following reagents stored: a. ALFA WASSERMANN SYSTEM DILUENT: STORAGE TEMP REQUIREMENT = 15C - 30C b. ALFA WASSERMAN CAL A REAGENT: STORAGE TEMP REQUIREMENT = 15C - 30C c. APTIMA URINE SPECIMEN COLLECTION KIT: STORAGE TEMP REQUIREMENT = 15C - 30C d. BECKMAN COULTER ACCESS WASH BUFFER II: STORAGE TEMP REQUIREMENT = 15C - 30C e. BECTON DICKINSON SERUM COLLECTION TUBES - EDTA: STORAGE TEMP REQUIREMENT = 4C - 25C f. BECTON DICKINSON SERUM COLLECTION TUBES - RED: STORAGE TEMP REQUIREMENT = 4C - 25C g. COPAN STERILE PLAIN DUAL SWABS: STORAGE TEMP REQUIREMENT = 5C - 25C h. EPENDIA 10% NEUTRAL BUFFERED FORMALIN: STORAGE TEMPERATURE REQUIREMENTS = 15C - 30C 5. An exit interview with the Laboratory Director and the Technical Consultant, on October 17, 2025 at 2:45pm, confirmed the laboratory failed to monitor and document the temperature of areas in which reagents required temperatue monitoring were stored and/or in use.