

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0932951	(X3) Date Survey Completed 12/17/2025
Name of Provider or Supplier Youthcare Pediatrics Of Central Georgia Pc	Street Address, City, State 233 North Houston Road Suite 140 H, Warner Robins, 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 December 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:
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: A review of the Laboratory Procedure Manual, manufacturer's BinaxNOW RSV Card Procedure, and manufacturer's HardyDisk Bacitracin Differentiation Disk Procedure confirmed that the facility failed to follow the established procedures and the existing procedure manual did not contain written procedures for all tests, assays, and examinations performed by the facility. THE FINDINGS INCLUDE: 1. A review of the current procedure manual revealed that the required Complete Blood Count Procedure, Down-Time Procedure, and Personnel Procedure were not completed. 2. A review of the Procedure Manual revealed that the laboartory adopted the manufacturer's BinaxNOW RSV Card Procedure and the manufacturer's HardyDisk Bacitracin Differentiation Disk Procedure as their approved procedures of operation. 3. A review of the manufacturer's BinaxNOW RSV Card Procedure confirmed that testing remained waived only when the approved mandates were adhered. The following mandates were found to be noncompliant: a. FDA classified the test as waived complexity for testing of patients under the age of 5 (five) years of age. The laboratory stated that their testing population included patients older than 5 (five)</p>

years old. b. Additional mandates require that negative test results be confirmed by more complex cell culture or DFA testing procedures. 4. A review of the manufacturer's HardyDisk Bacitracin Differentiation Disk Procedure confirmed the following deviations from the procedure: a. INTENDED USE states that the test is only a screen for Group A Beta Streptococcal. b. LIMITATIONS OF THE PROCEDURE states that more definitive testing is required for a complete identification. c. INTERPRETATION OF RESULTS defines any zone of inhibition beyond the edge of the disk be interpreted as a "PRESUMPTIVE positive identification for Group A Beta strep". d. Facility reported presumptive positive results as positive results. 5. An exit interview, with laboratory staff, on December 17, 2025, at 1:45pm, in the breakroom confirmed that the laboratory failed to follow the established procedures or establish all required procedures per CLIA requirements.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;

This STANDARD is not met as evidenced by:
A review of 2023 - 2025 Quality Control Records confirmed that the laboratory failed to perform quality control for moderately complex procedures as required by CLIA Regulation 493.1256(d)(3)(i). THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 Quality Control Records revealed that controls were not included with the Throat Culture screening procedure. 2. An exit interview, with laboratory staff and Laboratory Director, on December 17, 2025, at 1:30pm, in the breakroom, confirmed that the laboratory failed to perform quality control for procedures as required by the manufacturer and CLIA Regulation 493.1256(d)(3)(i).