Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2026934	12/10/2025
Name of Provider or Supplier	**Street Address, City, State**	
Primary Pediatrics, Pc	164 North Lee Street, Forsyth, 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 10, 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:
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on Bacteriology quality control documents review and staff interview, the laboratory failed to perform and document quality control on Taxo Disc on days of patients testing and results release from November 2023 to December 2025. Findings: 1. A review of laboratory QC documents revealed that there was no QC data available to review on all days of patient testing in the specialty of Bacteriology for throat cultures. 2. An interview with the office manager in the breakroom on 12/10/2025 at approximately 1:00 PM confirmed Taxo disc controls were not performed on days of patients testing from November 2023 to December 2025.
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 reapportions 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: Based on documents review and interview with the office manager, the lab director failed to ensure that all Quality Assurance (QA) guidelines in the laboratory were followed to identify and fix problems from November 2023 to December 2025 as required by Clinical Laboratory Improvement Amendments (CLIA). Findings: 1. Monthly QA documents review revealed the lab director , who is also the technical consultant (TC) , did not ensure that Taxo disc quality controls (QC) were performed on throat cultures on days of patient testing from November 2023 to December 2025. 2. An interview with the office manager, in the break room, on 12/10/2025, at approximately 1:35 PM, confirmed the lab director failed to ensure QA oversight of the laboratory from November 2023 to December 2025.