Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2160839	10/24/2025
Name of Provider or Supplier	**Street Address, City, State**	
Primary Pediatrics, Bonaire	104 Bluff Chase, Suite A, Bonaire, 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 24, 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:
D3003	FACILITIES CFR(s): 493.1101(a)(2) (a)(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: A tour of the laboratory facility revealed that the laboratory did not minimize risks of potential cross contamination. THE FINDINGS INCLUDE: 1. A tour of the laboratory facility revealed the following: a. A separate Clean Sink was not available to testing personnel. b. The Eyewash Station was mounted on the Dirty Sink. 2. An exit interview, with Testing Personnel, on October 24, 2025, at 2:00 pm, in Break Room confirmed that the laboratory did not minimize risks of potential cross contamination.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (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. This STANDARD is not met as evidenced by: A review of current Laboratory Procedure Manual, in use, revealed that the procedures did not include the required information as defined by CLIA Regulation 493.1251(b)(1) - (b)(14). FINDINGS INCLUDE: 1. A review of the current Laboratory Procedure Manual revealed the following: a. The procedure did not include a Down Time Procedure. b. The Laboratory Safety Procedure did not contain detailed instructions on how to properly use the fire extinguishers in case of a fire or how to properly use the eyewash station in the event of a biohazard event. 2. A review of the current Cell-Dyn Procedure, current Throat Culture Procedure, current Quality Assurance Procedure, and the Corrective Action Procedure revealed that the procedures did not contain the following: " STEP-BY-STEP performance of the procedure, including test calculations and interpretation of results " Calibration and calibration verification procedures. " The reportable range for test results for the test system as established or verified in 493.1253 " Control procedures. [The stand alone Quality Control Procedure only addressed Throat Culture quality controls, which did not meet the manufacturer's requirements.] " Corrective action to be take when calibration or control results fail to meet the laboratory's criteria for acceptability " Limitations in the test methodology, including interfering substances " Reference intervals (normal values) " Imminently life-threatening test results, or panic or alert values " Pertinent literature references " Description of the course of action to take if a test system becomes inoperable. 3. An exit interview, with Testing Personnel, on October 24, 2025, at 2:00 pm, in the Break Room confirmed that the procedures in use did not include the mandated information as defined by CLIA Regulation 493.1251(b)(1) - (b)(14).
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) (d)(3)(v) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: A review of 2023 - 2025 Quality Control Records confirmed that quality control metrics were not met per the manufacturers' requirements. THE FINDINGS

	INCLUDE: 1. A review of the manufacturers instructions for the BD BBL Taxo Disc, for the Differentiation of Group A Streptococci, revealed under the PROCEDURE heading step #3, the manufacturer states "At the time of use, check performance with pure cultures of stable control organisms producing known, desired reactions. The use of Streptococcus pyogenes CTu ATCC 12384 is recommended to demonstrate zone formation. One or more beta-hemolytic streptococcal species belonging to groups B, C, D and/or G may be employed to demonstrate the lack of zone formation." This manufacturer's mandate meets the quality control requirements set forth in CLIA Regulations 493.1256(b)(3) and 493.1256(d)(3)(ii). 2. A review of the 2023 - 2025 Quality Control Records confirmed that performance and documentation of the required quality control measure was not performed. 3. Interview with theTesting Personnel to confirmed that quality control for the Throat Culture procedure had not been performed as required. 4. An exit interview, with Testing Personnel, on October 24, 2025, at 2:00 pm, in Break Room, confirmed that quality control were not met performed per the manufacturers' requirements.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. This STANDARD is not met as evidenced by: A review of the current Procedure Manual confirmed that Testing Personnel did not test patient specimens per manufactuers reccomendations. THE FINDINGS INCLUDE: 1. A review of the manufacturers instructions for the BD BBL Taxo Disc for the Differentiation of Group A Streptococci, the manufacturer states: "A zone of inhibition is formed around the Taxo A disc if the organism is a group streptococcus. It is recommended that any zone of inhibition, regardless of diameter, be reported as "beta-hemolytic Streptococcus, PRESUMPTIVELY group A by bacitracin." 2. A review of the manufacturers instructions for the BD BBL Taxo Disc for the Differentiation of Group A Streptococci, the manufacturer states: "The Taxo A" disc test is PRESUMPTIVE, and a positive result should be followed with more specific physiological and/or serological tests." 3. While the manufacturer's Instructions of Use explicitly states that the testing results are PRESUMPTIVE, a review of the Throat Culture Procedure, in use by the laboratory, under Paragraph C. Interpretation of Results (a) p.2 states: A positive test is indicated by inhibition of Beta-Hemolysis Group A Streptococci in a zone around the A disc. Any zone of inhibition, regardless of diameter, is a positive test. Such results are reported as a definitive Positive for Group A Streptococci by Testing Personnel. 3. A review of 2023 - 2025 Quality Assurance Records found that documentation of an Individual Quality Control Plan (IQCP) establishing this deviation from the FDA approved testing methodology was not available on the date of survey. 4. An exit interview with Testing Personnel, on October 24, 2025, at 2:00 pm, in the Break Room confirmed that Testing Personnel did not test patient specimens per manufacturers reccomendations.
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: A tour of the laboratory facility and review of the 2023 - 2025 Maintenance Records, 2023 - 2025 Quality Control Records, 2023 - 2025 Personnel Records, 2023 - 2025 Temperature Records confirmed that the Laboratory Director failed to provide proper oversight for the overall operation and administration of the laboratory. Reference D2130, D3003, D5403, D5455, D5479, D6020, and D6046
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: A review of 2023 - 2025 Maintenance Records, 2023 - 2025 Quality Control Records, 2023 - 2025 Personnel Records, 2023 - 2025 Temperature Records confirmed that the Laboratory Director failed to conduct quality assurance review of records in a timely manner to identify failures to assure the quality of laboratory services. THE FINDINGS INCLUDE: 1. A review of Form 209: Laboratory Personnel Report disclosed that the Laboratory Director also acted in the capacity of the Technical Consultant. 2. A review of A review of 2023 - 2025 Maintenance Records, 2023 - 2025 Quality Control Records, 2023 - 2025 Personnel Records, 2023 - 2025 Temperature Records found monthly quality assurance review documentation by the Technical Consultant not performed. 3. Interview with Testing Personnel confirmed that the Laboratory Director visited the laboratory facility three to four times a year to oversee the laboratory operations. 4. An exit interview, with Testing Personnel, on October 24, 2025, at 2:00 pm, in Break Room confirmed that the Laboratory Director failed to perform quality assurance review of records in a timely manner to identify failures to assure the quality of laboratory services.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: A review of 2023 - 2025 Personnel Records confirmed that the Technical Consultant failed to perform personnel competencies. THE FINDINGS INCLUDE: 1. A review of 2023 - 2025 Personnel Records revealed that personnel competencies were

	performed by the Office Manager, whose highest level of education was a High School Diploma with no applicable laboratory experience. 2. An exit interview, with Testing Personnel, on October 24, 2025, at 2:00 pm, in Break Room confirmed that the Technical Consultant failed to perform personnel competencies.