Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0976863	10/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Prime Pediatrics Pc	1610 Broadrick Drive, Dalton, 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 02, 2024. 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	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on standard operators procedure manual (SOP) review and staff interview, the laboratory failed to include all required policy and procedures in the SOP. Findings include: 1. SOP review revealed the laboratory did not have a written procedure for

	actions to take if the test systems become imoperable (downtime). 2. An interview with testing personnel #5 (CMS 209), on 10/2/24, at 10:42 a.m., in the breakroom, confirmed the lack of the aforementioned procedure.
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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the lab failed to monitor, over time, the accuracy and precision of test performance. Findings: 1. A review of the hematology QC documents revealed the laboratory does not monitor QC using Levy-Jennings charts. 2. Interview with testing personnel #5 (CMS 209) , on 10 /2/24, at 10:47 AM, in the breakroom, confirmed the aforementioned finding. **REPEAT DEFICIENCY**
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, for bacteriology, and staff interview, the facility failed to perform the required QC checks on each batch/shipment/lot number of media used to perform urine cultures. Findings include: 1. Review of QC records revealed the laboratory does not perform in-house QC on urine culture media (URICULT). The laboratory currently logs the certificate of analysis from the manufacturer only. 2. Interview with TP#5 (CMS 209), on 10/2/24, at 09:41 am, in the breakroom, confirmed the laboratory did not perform QC as required.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for

	sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for bacteriology and staff interview, the facility failed to perform the required sterility check on each batch of media used to perform urine cultures. Findings include: 1. Review of QC records revealed the laboratory does not perform sterility check on urine culture media (URICULT). 2. Interview with testing personnel #5 (CMS 209), on 10/2/24, at 10:43am, in the breakroom confirmed the laborayory did not perform the sterility checks as required.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency test (PT) results and testing personnel (TP) interview, the Laboratory Director (LD) failed to ensure the PT results were reviewed and signed when returned by API. Findings: 1. A review of the API PT results for 2023 events 1, 2, 3 and 2024 events 1 and 2 revealed the LD did not reviewor sign 10 of 10 PT event results in hematology or bacteriology. 2. Interview with TP #5 (CMS 209), on 10/2/24, at 10:47 AM, in the breakroom, confirmed the LD failed to review and sign the PT results.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff

	interview, the Laboratory Director (LD) failed to specify, in writing , the duties and responsibilities of each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of laboratory testing. Findings include: 1. The SOP review revealed the LD failed to specify, in writing, the duties and responsibilities of each person engaged in the performance of all phases of laboratory testing. 2. An interview with testing personnel #5 (CMS 209) in the breakroom, on 10/2/24, at 10:42 a.m., confirmed the SOP did not contain a policy for the duties and responsibilities for the technical staff.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (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. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel competency assessment checklists as well as testing personnel interview , the Technical Consultant (TC) failed to perform the assessment on 10 of 10 testing personnel. Findings: 1. Review of the competency records of 2023 and 2024 revealed unqualified testing personnel #5 & #6 (CMS 209) were performing the competency assessments rather than the TC (LD) (CMS 209). 2. Interview with TP#5 (CMS 209) on 10/2/24 at 11:30 AM in the breakroom confirms the TC did not perform the competency assessments.