Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0976863	09/23/2026
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 September 23, 2026. 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:
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and 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 2025 events 1, 2, 3 and 2026 events 1 and 2 revealed the LD did not review or sign 5 of 5 PT event results in hematology. 2. Interview with TP #1 (CMS 209), on 09/23/26, at 10:33 AM, in the breakroom, confirmed the LD failed to review and sign the PT results. **Repeat citation**
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of the Standard Operating Procedures (SOP) and staff interview, the

	laboratory director failed to ensure that approved procedures were signed and dated. Findings: 1. Review of the SOP revealed that the laboratory director had not signed and dated the procedure manual prior to initiating patient testing. 2. An interview with TP#1 (CMS 209) in the breakroom on September 23, 2026, at 10:30 a.m., confirmed that the laboratory director had not reviewed, signed, and dated the procedure manual prior to initiating patient testing.
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: 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 9 of 9 testing personnel. Findings: 1. Review of the competency records for years 2025 and 2026 revealed unqualified testing personnel #1 (CMS 209) was performing the competency assessments rather than the TC (LD) (CMS 209). 2. Interview with TP#1 (CMS 209) on 09/23/26 at 10:40 AM in the breakroom confirmed the TC did not perform the competency assessments. **Repeat Citation**