

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0976863	(X3) Date Survey Completed 10/15/2020
Name of Provider or Supplier Prime Pediatrics Pc	Street Address, City, State 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 15, 2020. 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:
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assurance (QA) document review and interview with the laboratory director, the laboratory failed to document all general laboratory systems QA activities as required. Findings include: 1. QA documents review revealed the laboratory director who is also the Technical Consultant (TC) did not review and sign the Hematology QC logs, temperature logs and maintenance logs in 2019 and 2020 as required. 2. An interview with the laboratory director in the break room on 10/15/2020 at approximately 11:20 a.m. confirmed there were no QA reviews for the aforementioned periods in 2019 and 2020.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(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.</p>

This STANDARD is not met as evidenced by:

After a review of the procedure manual, personnel records and an interview with the laboratory director, it was determined that the laboratory did not have a comprehensive competency assessment policy with CLIA six(6) standards for its testing personnel specific to the specialty of Hematology. Findings include: 1.) Testing Personnel (TP) record review revealed that competency assessment was performed in 2018, 2019 and 2020. However, the policy did not clearly contain the six (6) CLIA criteria for personnel competency assessment. 2.) The laboratory director and office manager confirmed after interview on 10/15/2020, at approximately 11:45 am, in the break room that the laboratory competency assessment policy needs upgrading with the current six (6) CLIA standard criteria.