

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2026934	(X3) Date Survey Completed 07/10/2019
Name of Provider or Supplier Primary Pediatrics, Pc	Street Address, City, State 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 July 10, 2019. 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:
D6049	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's maintenance and Quality Assurance(QA) records and an interview with the clinic administrator, the Technical Consultant (TC) who is also the laboratory director failed to review and sign Monthly Quality Assurance report records from October 2017 to June 2019. Findings include: 1. Review of maintenance and Quality Assurance reports revealed QA logs were not reviewed and signed from October of 2017 to June 2019 by the (TC). 2. An interview with the clinic administrator on 07/10/2019 at approximately 12:45 pm in the review room confirmed that maintenance QA reports were not reviewed and signed by the (TC) from October 2017 to June 2019.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p>

This STANDARD is not met as evidenced by:
Based on Personnel competency records review and an interview with the clinic administrator, the technical consultant (TC) who is also the laboratory director failed to perform annual competencies on all Testing Personnel (TP) in 2018 and 2019 as required. Findings include: 1. 2018 and 2019 competency records review revealed the TC did not perform annual competencies on (TP #s 4 - 10 CMS 209). The competencies were instead performed by the laboratory's lead tech. 2. An interview with the clinic administrator on July 10, 2019 in the review room at approximately 01:42 p.m. confirmed annual competencies for the aforementioned testing personnel (TP) were not performed by the Technical Consultant.