

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1009104	(X3) Date Survey Completed 04/18/2019
Name of Provider or Supplier Pediatric Medicine Associates Provider Group Inc	Street Address, City, State 10820 Nw 58 St, Miami, FL	
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
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 review of quality assurance (QA) policy, QA record and interview with testing person (TP) the laboratory failed to document the monthly quality assurance (QA) activity for 2 out of 2 years reviewed (2017 and 2018). Findings include: Quality assurance policy stated to perform a monthly review, to evaluate the overall activity of the laboratory. Review of laboratory records revealed that there was no monthly documentation of the QA activity during the years 2017 and 2018. During an interview on 04/18/2019 at 10:30 AM, with the TP, she confirmed that there were no records of monthly QA activity for the years of reference</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel (TP), the laboratory failed to perform annual preventive maintenance to Hematology Analyser Coulter Ac.</p>

T diff for 1 out of 2 years reviewed. Findings include: Review of annual maintenance records showed no records of annual preventive maintenance for Hematology Analyzer Coulter Ac.T diff during 2018. During an interview on 4/18/2019 at 11:30 AM, with the TP, she confirmed the laboratory failed to have documentation that proofs the annual preventive maintenance for 2018.