

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0285849	(X3) Date Survey Completed 09/18/2018
Name of Provider or Supplier Pediatric Associates Inc	Street Address, City, State 1695 N Park Dr #101, Weston, 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
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to receive a passing proficiency test (PT) score for the first testing event of 2017 for the specialty of Hematology. Findings: Review of PT score from American Proficiency Institute for the first event of 2017 showed a score of 33% for White Blood Cells (WBC) Differential. During an interview on 9/18/18 at 1:40 PM, the Laboratory Supervisor confirmed the laboratory had failed proficiency testing for WBC differential.</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, the laboratory failed to perform monthly maintenance of the Medonic Complete Blood Count (CBC) analyzer for July 2017 and July 2018. Findings: Review of the, "QC Review & System Maintenance CBC - CDS / Medonic M-series" log showed that there was no documentation of monthly maintenance for July 2017 and July 2018. Review of the, "Quality Event Review" signed on 8/14/2017 stated "July Medonic monthly cleaning was not done." Review of the "Quality Event Review" signed on 8/9/2018 stated "July Medonic Monthly</p>

cleaning was not done." During an interview on 9/18/18 at 3:35 PM, the Laboratory Supervisor acknowledged that the monthly maintenance was not done.

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 record review and interview, the laboratory failed to maintain documentation of quality control (QC) performed on the bacitracin discs for January 2018 through February 2018. Findings: The policy for Strep A Throat Cultures section 9 Quality Control #3 Taxo A disks (also known as Bacitracin disks) read, "QC is performed on a weekly basis or when a new lot number of culture plates or Taxo A disks are employed. Results are documented in the Daily QC binder." Review of the, "Bacitracin Disc Weekly QC" showed that there was no documentation of QC performed from January 2108 through February 2018. Review of the, "Quality Event Review" form showed that "January and February Agar controls are not in the Quality control book. Lab staff has no ideas as to where or what happened." During an interview on 9/18/18 at 3:40 PM, the Laboratory Supervisor acknowledged that the documentation for the weekly QC for bacitracin for January and February 2018 were missing.