

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0857774	<b>(X3) Date Survey Completed</b> 03/22/2018
<b>Name of Provider or Supplier</b> Pediatric Associates Of Davidson County	<b>Street Address, City, State</b> 2201 Murphy Avenue Suite 201, Nashville, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of daily Hematology quality control records and interview with the lead testing person determined that the laboratory failed to retain daily Hematology quality control records for the Abbott Celldyn complete blood count (CBC) analyzer for 2016 and 2017. The findings include: 1. Lack of review of daily Hematology quality control records determined that the laboratory failed to retain daily Hematology quality control records for the Abbott Celldyn CBC analyzer for 2016 and 2017. 2. Interview with the lead testing person on March 22, 2018 at 13:00 confirmed that the laboratory failed to retain daily Hematology quality control records for the Abbott Celldyn CBC analyzer for 2016 and 2017.</p>
<b>D5447</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of Hematology quality control records and interview with the lead</p>

testing person determined that the laboratory failed to perform daily Hematology quality control prior to patient testing for complete blood count (CBC) in April 2017. The findings include: 1. Review of patient chart audit revealed daily Hematology quality control was not performed on April 3, 2017 on the Hematology Abbott Celldyn 1800 prior to testing and reporting patient results. 2. Interview on March 22, 2018 at 12:30 confirmed that on April 3, 2017 the lead testing person confirmed the laboratory failed to perform daily Hematology quality control for the Hematology Abbott Celldyn 1800 analyzer.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of Testing Personnel (TP) records, personnel report (CMS 209) and interview with the lead testing person determined the Technical Consultant failed to perform new hire semiannual TP competencies for complete blood counts (CBC) in 2017-18. The findings include: 1. Review of TP records revealed the Technical Consultant failed to perform new hire semiannual competencies in CBCs for TP# 1, 3, 7 and 10 due from August 2017-January 2018. 2. Review of the laboratory personnel report revealed 10 testing persons performing CBCs in 2017-18. 3. Interview with the lead testing person on March 22, 2018 at 13:45 confirmed that the Technical Consultant failed to perform new hire semiannual competencies in CBCs for TP# 1, 3, 7, and 10 in 2017-18.