

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0918331	(X3) Date Survey Completed 01/22/2020
Name of Provider or Supplier Pediatric Physicians Pc	Street Address, City, State 1172 Vickery Lane, Cordova, TN	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, calibration and quality control (QC) records, patient data logs and patient test reports, and interview with the lead testing personnel, the laboratory failed to follow the quality control procedure in 2018 and 2019. The findings include: 1) Review of the laboratory procedure for Complete Blood Count (CBC) revealed that QC is to be performed "each time the equipment is calibrated or serviced." 2) Review of calibration and quality control records revealed that QC was not performed after calibration on the following dates: May 25, 2018, November 12, 2018 and April 17, 2019. 3) Review of patient data logs and patient final test reports revealed patient testing was performed and reported after calibration with no post-calibration quality control for patient number six on May 25, 2018, patient number seven on November 12, 2018 and patient number eight on April 17, 2019. 4) Interview with the lead testing personnel on January 22, 2020 at 11:50 a.m. confirmed the laboratory failed to follow the procedure for performing QC after calibration in 2018 and 2019 (three of four calibrations reviewed) with patient testing performed.</p>
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures</p>

necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control records, patient test reports, and interview with the lead testing personnel, the laboratory's quality assessment process was ineffective when it did not detect problems with quality control ranges in 2019. the findings include: 1) Review of the laboratory's quality control records revealed lot number 068800 in use from December 5, 2018 to March 18, 2019 with incorrect quality control ranges for the white blood cell count as follows: Range in use = 3.7 - 4.7, correct range= 3.5 - 4.5. The quality control was reviewed by the laboratory director on December 2018 and March 2019 with no corrective action documented for the incorrect ranges. 2) Review of patient number one final test report revealed white blood cell count reported on December 10, 2018 when the incorrect ranges were in use. 3) Interview with the lead testing personnel on January 22, 2020 at 11:50 a.m. confirmed the laboratory's quality assessment process was ineffective when it failed to correct problems with incorrect quality control ranges for lot 068800 in 2018 and 2019.