

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D0214310	<b>(X3) Date Survey Completed</b>  12/06/2018
<b>Name of Provider or Supplier</b>  Davidsonville Pediatrics	<b>Street Address, City, State</b>  2772 Rutland Road, Davidsonville, MD	
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>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory procedure manual and hematology quality control (QC) record review and interview with the laboratory manager, the laboratory failed to document corrective action when hematology QC was out of range. Findings: 1. The laboratory utilizes a Medonic M-Series hematology analyzer to perform hematology testing. The procedure manual states that, "A corrective action form will be filled out whenever a problem arises in calibration or when an out of control situation occurs not resolved by simple repeat analysis." 2. A review of hematology QC from 3/27/17 to 4/30/17 of lot #21702-31 (low control), #21702-32 (normal control), and #21702-33 (high control) showed that on 3/31/17 the RBC was out low on the low control and run 3 times; the RBC, Hgb, and Hct were out low on the normal control and run 4 times; and the WBC, RBC, Hgb, Hct, Plt, and Lymph (Abs) were out low on the high control and run 3 times. Corrective action was not documented; and 3. On 4/3/17 the WBC had an error code, "TB." The low control was run 3 times, the normal control was run 4 times, and the high control was run 6 times. Corrective action was not documented; and 4. On 4/7/17 the RBC was out low on the high control and run 3 times. Corrective action was not documented; and 5. On 4/21/17 the RBC was out low on the low</p>

control and run 3 times. Corrective action was not documented; and 6. On 4/24/17 the RBC was out low on the low control and run 4 times; the RBC, Hgb, and Hct were out low on the normal control and run 5 times; and the RBC and Hgb were out low on the high control and run 4 times. Corrective action was not documented; 7. On 4/27/17 the RBC, Hgb, and Hct were out low on the normal control and run 3 times; the RBC was out low on the high control and run 3 times. Corrective action was not documented. 8. A review of hematology QC in June, 2018 of lot #21805-21 (low control), #21805-22 (normal control), and #21805-23 (high control) showed that on 6/19/18 the MCV was out low on all three levels of control. The low control was run 5 times, the normal control was run 6 times, and the high control was run 2 times. During an interview at 12:30 PM, the laboratory manager stated that the service rep and the QC manufacturer had been called and they were told that this lot number of QC had had trouble with low MCV. Corrective action was not documented. 9. During an interview on 12/6/18 at 1:00 PM, the laboratory manager confirmed that corrective actions were not documented when hematology QC was out of range on the Medonic M-Series hematology analyzer.