

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D0703618	<b>(X3) Date Survey Completed</b>  12/15/2023
<b>Name of Provider or Supplier</b>  Little Rock Pediatric Clinic	<b>Street Address, City, State</b>  500 South University, Suite 615, Little Rock, AR	
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>D5783</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Through review of the laboratory's " Quality Control (QC) Protocol", the "Control Summary Report" for the Medonic Hematology analyzer serial number 47578, The "Data Log" from the same Medonic Hematology analyzer , the laboratory's Corrective Action Log, lack of documentation, and interview with laboratory staff members it was determined that the laboratory failed to document corrective action on one of one occasion when quality control results failed to meet the laboratory's criteria for acceptability. Findings follow: A) Review of the laboratory's "Quality Control Protocol" revealed that test runs are to be rejected when any control is "out of range" for two consecutive runs; and, under the heading "Procedure for Corrective Action", "document all corrective action on the remedial action worksheet". B) Review of the QC Summary Report revealed that on 3/24/23 Hematology low control lot # 2221201 with an acceptable range for Red Blood Cell Counts of (2.14 to 3.38 ) was resulted as 2.08 at 7:56 a.m., 2.13 at 7:58 a.m., and 2.05 at 8:15 a.m, three consecutive results outside of the laboratory's acceptable range. C) Review of the laboratory's "Corrective Action Log" revealed no entry for corrective action taken on 3/24/23. D) Upon request, the laboratory could not provide documentation of the corrective action taken</p>

on 3/24/23. E) In an interview on 12/15/23 at 10:45 a.m. the laboratory staff member (# 4 on the CMS 116 form) confirmed that corrective action was not documented on the occasion identified above.