

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0674937	<b>(X3) Date Survey Completed</b> 11/16/2023
<b>Name of Provider or Supplier</b> Kids Care Pediatric Associates Pc	<b>Street Address, City, State</b> 2266 Dutch Broadway, Elmont, NY	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on lack of annual competency records for testing person (TP) #7, the laboratory failed to perform the 2022 annual competency for TP #7. Confirmed findings by interview with laboratory director (LD) on November 16, 2023, about 11:00 A.M.</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of CAP PT reports, the laboratory failed to evaluate and document corrective action for PT scores less than 100% for the following analytes: 2023 first event, HCT 80%. 2023 second event, RBC 80%. 2023 third event, HCT 60%. Confirmed findings by interview with LD on November 16, 2023, about 10:30 A.M.</p>
<b>D5469</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(10)(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--</p>

Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Quality Control (QC) records, the laboratory failed to perform verification of Medonic M Series hematology analyzer QC reagents current lot numbers to new lot numbers. FINDINGS: 1. No documentation of hematology analyzer QC reagent lot to lot validation was available from the date of instrument implementation to the date of the survey. 2. The LD confirmed by interview on November 16, 2023, about 11:30 A.M., current lot to new lot validation of hematology analyzer QC reagents was not performed.