

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2263981	(X3) Date Survey Completed 10/23/2025
Name of Provider or Supplier Kayla Pediatrics, Pc	Street Address, City, State 930 N Wood Avenue, Linden, NJ	
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
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) Proficiently Testing (PT) records and interview with the Technical Consultant (TC) the Laboratory Director (LD) failed to ensure that the laboratory participated in an accurate split sample assessment for Hematology testing. from 7/3/24 to 10/23/25. The findings include: 1. A review of AAB-MLE PT events 3-2024, and 1,2,3-2025 revealed that the laboratory did not verify accuracy of the following analytes. a) Mean Corpuscular Volume (MCV) b) Mean Corpuscular Hemoglobin (MCH) c) Mean Corpuscular Hemoglobin Concentration (MCHC) d) Red Cell Distribution Width (RDW) e) Mean Platelet Volume (MPV) f) Granulocytes absolute (GRA#) g) Monocytes absolute (MON#) h) Lymphocytes Absolute (LYM#) 2. The TC confirmed on 10/23/25 at 1:00 pm that the LD did not ensure the laboratory participated in an accurate split sample assessment for the above mentioned tests.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) 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>

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM), Quality Control (QC) and interview with the Technical consultant (TC) the laboratory failed to follow the procedure "Corrective actions for failed QC" for the Horiba ABX Micros 60 analyzer used to perform Hematology testing from 7/3/24 to 10/23/25. The findings include: 1. The PM stated "When QC results in a failure the following should be done:" a) "Repeat the control" b) "If the control fails follow the Horiba Cleaning procedure as per the manual" c) "If the QC continues to fail after following the clearing procedure, switch out the QC samples to a new set." d) "If the failure continues contact Horiba support and DO NOT use the machine until direction is provided." 2. QC was run as follows: a) Level 1 QC was run five times on 10/9/25. b) Level 2 QC was run four times on 10/9/25 c) Level 2 QC was run eleven times on 9/28/25 d) Level 3 QC was run six times on 10/22/25. f) Level 3 QC was run four times on 10/9/25. g) Level 3 QC was run four times on 10/3/25. 3. There was no documented evidence that the PM was followed for the above QC failures. 4. The TC confirmed on 10/10/25 at 10:55 am the laboratory failed to follow the above mentioned procedure for failed QC.