

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D2263981	<b>(X3) Date Survey Completed</b>  07/03/2024
<b>Name of Provider or Supplier</b>  Kayla Pediatrics, Pc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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 surveyor review of the Procedure Manual (PM), and interview with the Testing Personnel (TP), the laboratory failed to have a procedures for Performance Verification (PS) for Hematology testing from July 2022 to the date of survey. The TP confirmed on 7/3/24 at 12:30 pm that the laboratory failed to have the above mentioned procedure.</p>
<b>D5411</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Operators Manual (OM), Procedure Manual (PM), and interview with the Testing Personnel (TP), the laboratory failed to follow the OM for "2.1.1. Preliminaries" from 7/8/22 to the date of survey. The findings include: 1. The OM states to "Check the repeatability of the instrument by running a fresh normal whole blood sample 11 times with no alarms. Discard the first result and calculate the</p>

	<p>CV on the remaining 10 runs." 2. There was no documented evidence that the above mentioned procedure was performed prior to Calibration. 3. The TP confirmed on 7/3 /24 at 11:45 AM that the laboratory did not follow the OM.</p>
<p><b>D5469</b></p>	<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-- 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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercial QC material with each new lot and/or shipment of QC used for Hematology tests performed on ABX Micro 60 analyzer on the date of survey. The finding includes: 1. There was no documented evidence that QC lot #MX447 was verified before being put into use. 2. The TP confirmed on 7/3/24 at 10:20 am that the QC material was not verified before putting in use.</p>
<p><b>D5471</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Bacitracin discs in use and interview with the Testing Personnel (TP) the laboratory failed to check each lot number and shipment of Bacitracin Discs for positive and negative reactivity from 6 /24/24 to the date of the survey. The finding includes: 1. There was no record of Bacitracin QC for Lot # 3180394 currently in use. 2. Approximately 25 patients run and reported. 3. The TP confirmed on 7/4/24 at 1:00 pm that the laboratory did not perform QC on Bacitracin disc as stated above.</p>
<p><b>D5779</b></p>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(a)</p>

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Procedure Manual (PM), and interview with the Testing Personnel (TP) the laboratory failed to have available Corrective Action (CA) procedures to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports on the date of survey. The finding includes: 1) There were no CA procedures for Failed Quality Control (QC) results. 2) The TP confirmed on 7/3/2024 at 1:00 pm that the laboratory failed to have available CA procedures.

**D6013**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP)), the Laboratory Director (LD) failed to ensure that PS procedures performed on Horiba ABX micro 60 analyzer were adequate from July 2022 to the date of survey. The findings include: 1. The LD did not review and sign the PS results. 2. There was no documented evidence that Accuracy was performed. 3. There was no documented evidence that precision was performed. 4. There was no raw data for linearity. 5. The TP confirmed on 7/3/24 at 10:35 am that PS records were not adequate.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Quality Control (QC) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that the QC program was maintained for laboratory services provided from July 2022 to the date of survey.. The findings include: 1. The PM states "check

your instruments precision on the levy Jennings charts detailed reports". a) There was no documented evidence that the above mentioned procedure was performed. b) The PM did not specify the frequency in which this procedure is performed. c) The PM did not specify whose responsibility it is to review the Levy Jennings graph. d) The PM did not specify statistic parameters for acceptable precision parameters. 3 The TP confirmed on 7/3/24 at 11:30 am the LD did not ensure the QC plan was maintained. .