

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2070785	(X3) Date Survey Completed 08/27/2024
Name of Provider or Supplier New Jersey Pediatric And Adolescent Care Llc	Street Address, City, State 1680 Route 23 North, Wayne, 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
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to document the evaluation of all incorrect scores and corrective action taken for the 3rd Hematology event of 2022 with the American Association of Bioanalysts (AAB). The findings include: 1. The laboratory received a 80% score for Hemoglobin and Leukocytes for specimen #14 for the 3rd Hematology event of 2022. 2. There was no documented evidence for evaluation or corrective action performed for the aforementioned PT event. 3. The LD confirmed on 8/27/24 at 11:15 am, the laboratory failed to evaluate and perform corrective action for the 3rd Hematology event of 2022.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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 ABX Micros 60 Operators Manual (OM), Procedure Manual (PM), Test Records (TR) and interview with the Laboratory Director (LD), the laboratory failed to follow the OM for the ABX Micros 60 from 1/25/24 to 8/27/24. The findings include: 1. The OM stated "Failure to perform any of these</p>

recommended cleaning procedures can result in decreased reliability of your system. It is important that you monitor your analyzer for the types of specimens that may cause pre-mature cleaning other than routine. At the beginning of each business day, a Startup cycle must be performed. This can be done either automatically or manually whichever the system has been set up for." 2. Two out of five TR reviewed from 1/25/24 had the message "Startup cycle not initiated." 3. There was no documented evidence that the aforementioned procedure was followed 4. The LD confirmed on 8/27/24 at 10:45 am that the laboratory did not follow the OM.