Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2070785	(X3) Date Survey Completed 02/01/2022
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to retain all QC records for tests performed on the Horiba ABX Micros 60 from January 11/12/19 to the date of survey. The finding includes: 1. All hematology QC that was repeated due to a failed QC run were not retained. 2. The TP # 1 listed on the CMS form 209 confirmed on 2/1/22 at 11:00 am that the all QC records were not retained.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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. 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 follow their procedure for "Monthly Quality Control Review" (MQCR)log from 11/12/19 to the date of survey. The

	finding include: 1. There was no documented evidence that the MQCR log was completed. 2. The The TP#1 listed on CMS from 209 confirmed on 2/1/22 at 10:21 am the MQCR log was not being completed.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Operators Manual (OM), and interview with the Testing Personnel (TP), the laboratory failed to follow the OM for "2. Calibration", "2.1.1. Preliminaries" procedures from 11/12/19 to the date of survey. The findings include: 1. The OM stated as follows: 1- Carry out a Concentrated cleaning procedure (See Section 6, 1.3.6. Concentrated Cleaning, page 6-11). 2- Perform two blank cycles to check the cleanliness of the instrument. 3- 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 CV on the remaining 10 runs. 4- Check that the CV calculated using the remaining 10 runs meets or exceeds the specifications in "3.2. Precision Claims*, page 9" 2. There was no documented evidence that the above mentioned procedures were performed. 3. The TP#1 listed on CMS from 209 confirmed on 2/1/2021 at 10:32 am that the laboratory did not follow the OM.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to document all corrective action when High, Normal, or Low controls were out of range and had to be rerun for hematology tests performed on the Horiba ABX Micros 60 analyzer from 11/12/19 to the date of survey. The findings include: 1. There was no corrective action log for QC. 2. The TP stated "They do not keep work records or documentation for failed QC runs", and "do not document corrective action when QC is out of range and has to be rerun". 3. The TP #1 on CMS form 209 confirmed on 12/17/21 at 1:00 pm that the laboratory failed to document all corrective action.
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 and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the QC program was maintained for laboratory services provided from January 2020 to the date of the survey. The findings include: 1. There was no evidence of monthly QC review by the LD. 2. The monthly levy Jennings charts did not have date ranges. 3. The TP#1 listed on CMS from 209 confirmed on 2/1/22 the LD did not ensure the QC plan was maintained. .