Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0886119	(X3) Date Survey Completed 05/01/2018
Name of Provider or Supplier Pediatric Center, The	Street Address, City, State 556 Central Ave, New Providence, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform CA correctly on nine out of nine TP in the calendar years 2016 and 2017. The finding include: 1. The laboratory did not document what records were reviewed and when they were reviewed. 2. The laboratory used tools incorrectly as follows: a. Direct observation of maintenance was used as a CA tool for specimen collection, following test procedure, recording and resulting of test results, documentation of quality control and Proficiency Test (PT) records, test performance, and reporting results. b. Assessment of test performance through PT testing and blind sampling tool was as a CA tool for the following test procedure, recording and resulting of test results, documentation of quality control, recognizes system failures, instrument maintenance and function checks, test performance, and reporting results 2. The TP #4 listed on CMS form 209 confirmed on 5/1/18 at 12:50 pm that CA was not performed correctly.
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 PM policy for flagging of Hematology results run on the Cell Dyn Emerald from 3/21/16 to the date of the survey. The finding includes: 1. The PM stated flagged results will be re-run, the re-run documented and reviewed with the Physician for acceptance or denial but a review of seven out of seven samples with flagged results revealed the above procedure was not followed. 2. The TP #4 listed on CMS form 209 confirmed on 5/2 /18 at 1:20 pm the PM was not followed.