Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0886119	06/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Center, The	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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Nurse Manager (NM), the laboratory failed to review and evaluate results when they received an unacceptable score in Hematology tests performed with the American Proficiency Institute for the first event in the calendar year 2020. The findings include: 1. The laboratory received an 80% for Platelet Count 2. There was no documented evidence that the laboratory investigated the failure. 3. The NM confirmed on 6/8/21 at 10:10 am that the laboratory did not review and document an evaluation of unacceptable PT results.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Nurse Manager (NM), the laboratory failed to ensure that all PS

	procedures were performed for Hematology testing on the Cell-Dyn Emerald from March 2021 to the date of survey. The finding includes: 1. There was no documented evidence that a Method Comparison was performed. 2. The NM confirmed on 6/8/21 at 11:15 am that not all PS were performed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of Calibration Verification (CV) records and interview with the Nurse Manager (NM), the laboratory failed to perform and document CV procedures at least once every six months for Hematology Testing on the Cell-Dyn analyzer in the calendar year 2020. The finding includes: 1. A review of 2020 CV records revealed that CV was performed once on 11/9/2020. 2. The NM confirmed on 6/8/21 at 10:30 am CV was not performed every six months.