Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0886119	01/19/2023
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
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 patient work records, review of the Manufacture Operator Manual (OM) and interview with the General Supervior (GS), the laboratory failed to follow the OM for Hematology testing performed on the Cell-Dyn Emerald from 6/8/21 to the date of survey. The findings include: 1. The OM stated patient results with S flags ""Check the specimen for clots or agglutination. Follow your laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required." 2. 3 out of 5 patient work records had "S" flags. But the laboratory did not follow the OM. 3. The GS confirmed on 1/19/23 at 1:40 pm the laboratory failed to follow the OM.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as

	acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of Calibration (CAL) records, Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Abbott Cell-Dyn Emerald analyzer from November 2020 to the date of survey. The findings include: 1. A review of Cal records revealed that the laboratory performed Cal once in the calendar year 2020 and 2022. 2. A review of Cal records revealed that the laboratory did not perform Cal in the calendar year 2021. 3. The GS confirmed on 1/19/23 at 1:32 pm that the laboratory failed to perform and document Cal once every six months.