Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1054360	10/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Staten Island Pediatric Hematology/Oncology	314 Seaview Avenue, Staten Island, NY	

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 a review of the laboratory's competency assessment policies, competency evaluation records and an interview with the laboratory manager/testing person, the laboratory failed to follow their establish written policies and procedures to assess the competency of the laboratory testing personnel who perform Hematology/CBC testing for the calendar year 2018. FINDINGS: 1. The laboratory manager/testing person confirmed on October 23, 2019 at approximately 2:00 PM, that the laboratory did not follow the established competency evaluation policy. 2. The laboratory did not perform an annual 2018 competency evaluation for three of the four testing personnel who perform moderate complexity testing. 3. The laboratory director failed to perform a six-month competency evaluation during September 9, 2018 for the one new testing person, trained on March 18, 2018.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by:

	Based on a surveyor's review of the laboratory's Quality Assurance (QA) policy and an interview with the laboratory manager/testing person, the laboratory failed to follow their established written QA policy and perform an annual QA review, as required by the laboratory's QA policy, for the calendar year 2018. FINDINGS: The laboratory manger/testing person confirmed on October 23, 2019, at approximately 2: 30 PM, the laboratory failed to follow their established written QA policy and perform an annual QA review, as required by the laboratory's QA policy, for the calendar year 2018. THIS IS S RECITED STANDARD DEFICIENCY FROM THE SURVEY CONDUCTED ON NOVEMBER 10, 2017.
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 a surveyor's review of hematology calibration records and an interview with the laboratory manager/testing person, calibration of the hematology analyzer was not performed at the frequencies required by the manufacturer of the Beckman Coulter ACT Diff hematology analyzer in calendar year 2018. FINDINGS: 1. The manufacturer of the hematology analyzer and the laboratory's calibration policy requires the analyzer to be calibrated every six-months. 2. The laboratory manager /testing person confirmed on October 23, 2019 at approximately 1:30 PM that the laboratory failed to perform the required six-month calibration for the Beckman Coulter ACT Diff therefore, the analyzer was out of calibration from December 7, 2018 through October 10, 2019. Approximately 375 patient specimens were tested and reported for hematology during the above time frame when the Beckman Coulter ACT Diff analyzer was out of calibration. 3. The only calibration documentation for the Beckman Coulter ACT Diff analyzer available for review was for the following dates: November 17, 2017; June 7, 2018 and October 10, 2019. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEYS CONDUCTED ON NOVEMBER 10, 2017 AND SEPTEMBER 24, 2015.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's a review of plan of correction from the previous survey,

	laboratory records and interview with the laboratory manager/testing person, the laboratory director failed to provide overall management and direction for the laboratory. The laboratory director failed to ensure that: 1. The plan of correction from the surveys conducted on November 10, 2019 and September 24, 2015 was implemented and maintained; 2. The QC procedures are maintained for hematology testing; Refer D6020; 3. The QA policies are maintained; Refer to D6021; 4. The six-month and annual competency was not performed in the calendar year 2018; Refer to D6053 and D6054. THIS IS RECITED CONDITION DEFICIENCY FROM THE SURVEYS CONDUCTED ON NOVEMBER 10, 2017 AND SEPTEMBER 24, 2015.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory Quality Assessment (QA) policy and confirmed in an interview with the laboratory manager/testing person, the laboratory director failed to follow their QA procedure for having an effective and on going mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system for hematology. Refer to:D5209, D5291 and D5437. THIS IS A RECITED STANDARD DEFICIENCY FROM THE SURVEYS CONDUCTED ON NOVEMBER 10, 2017.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on surveyor's review of the personnel records and confirmed in an interview with the laboratory manager/testing person, the laboratory director, acting as the technical consultant, failed to perform the semi-annual evaluation due September 2018 for the one of three testing personnel during the first year of patient testing. Refer to D5209.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on a surveyor's review of the personnel files and confirmed in an interview with the laboratory manager/testing person, the laboratory director, acting as the technical consultant, failed to perform annual competency evaluation for three of four testing personnel in calendar year 2018. Refer to D5209.