Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0711000	05/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Barry A Baker Md	3665 East Tremont Ave, Bronx, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of proficiency test (PT) records and an interview with the technical consultant and testing person, the laboratory failed to perform PT testing in the same manner as patient specimen testing. Findings Include: It was confirmed by the technical consultant, on May 23, 2019 at approximately 2:30 pm, that PT specimens are always performed by one of two testing personnel, whereas, patient specimens are performed by both testing personnel.
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 a review of the laboratory record and an interview with the technical

	consultant, the laboratory failed to retain the background check printouts for the of the hematology analyzer. Findings Include: On May 23, 2019, at approximately 2:30 pm, the technical consultant confirmed that the laboratory failed to retain the background check reports for the hematology analyzer, Cell Dyn 1700, from July 20, 2017, through the date of this survey.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) reports and an interview with the technical consultant, the laboratory did not evaluate, perform and document remedial action for the PT scores less than 100%. Findings Include: It was confirmed by the technical consultant on May 23, 2019, at approximately 3:00 pm, that the laboratory failed to evaluate the following PT results: Hematology - 2018 1st event Platelets = 80%
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 review of calibration records and an interview with the technical consultant, the laboratory failed to calibrate the hematology analyzer every six months. Findings Include: It was confirmed by the technical consultant on May 23, 2019, at approximately 2:15 pm that: 1. The manufacturer requires that calibration be performed every six months; 2. Calibration was performed on June 21, 2017, and November 8, 2018; 3. Calibration was due December 21, 2017; 4. The Cell Dynn 1700 was out of calibration from December 21, 2017, to November 8, 2018 (11 months); Approximately 486 patient specimens were tested and reported for hematology testing when calibration was not performed.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of quality assessment (QA) procedures, calibration records, and confirmed in an interview with the technical consultant, the laboratory director failed to ensure that the laboratory's QA and QC programs for hematology testing were maintained to assure the quality of laboratory services. Refer to: Refer to D5211, D5411, and D5437