Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0875736	06/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Shetra Sivamurthy, Md	89-34 134th Street, Jamaica, 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
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 lack of procedures and an interview with the laboratory director, the laboratory failed to establish and follow a written policy and procedure for an ongoing mechanism to monitor, assess, and when indicated correct problem that may occur in the laboratory testing. This is a repeat deficiency from the last survey of August 4, 2016.
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 a lack of a procedure manual and an interview with the laboratory director, the laboratory did not have a procedure manual available for review. Finding: It was confirmed with the laboratory director on June 28, 2018 at approximately 1:45 pm, that the laboratory director failed to have a signed and dated procedure manual available for review.

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 laboratory director, the laboratory failed to calibrate the Coulter AcT Diff 2 hematology analyzer every six months. Calibration was last performed on August 6, 2017. The manufacturer of the Coulter AcT Diff hematology analyzer requires the instrument to be calibrated every six months. Findings Include: 1. It was confirmed with the laboratory director at on June 28, 2018 at approximately 12:45 pm that the Coulter AcT Diff 2 has not been calibrated since August 6, 2017. 2. The Coulter AcT Diff 2 analyzer has been out of calibration since February 6, 2018 to the date of this survey. 3. Approximately 250 patient specimens were tested and reported for hematology testing when the laboratory was out of calibration. This is a repeat deficiency from the survey of September 25, 2014 and August 4, 2016 .
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 findings and confirmed in an interview with the laboratory director at the time of the survey, the director failed to provide overall management and direction for the laboratory. Findings Include: The director failed to ensure that: 1. Plan of correction from the survey conducted on September 25, 2014 and August 4, 2016 was implemented and maintained. 2. The QC program for hematology was maintained. Refer to D6020 3. The QA program for hematology was maintained for QA . Refer to D6021 This is a repeat deficiency from the survey of August 4, 2016 .
D6020	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 program is established and

	maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory records and an interview with the laboratory director, the laboratory director failed to ensure that the QC program was maintained for hematology testing. Refer to D5437 This is a repeat deficiency from the survey of September 25, 2014 and August 4, 2016.
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 a lack of policies, procedures and confirmed in an interview with the laboratory director, the director failed to ensure that a QA program was established and maintained to assure the quality of laboratory testing. Refer to D5401 and D5291 This is a repeat deficiency from the survey of August 4, 2016 for D5291.