Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0698051	10/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Romeo D Balagot Md	4277 Hempstead Turnpike, Suite 107, Bethpage, 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
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 surveyor's review of the laboratory's available quality control records and confirmed in an interview with the laboratory director, the laboratory failed to have complete quality control (QC) records available for the Coulter AcT Diff hematology analyzer. Findings: The Laboratory Director confirmed, on October 30, 2018 at approximately 9:30 AM, the surveyor findings that QC records for the Coulter AcT Diff were not available from January 2017 through December 2017. Approximately 50 patient specimens were tested and reported for hematology during the above time frame. PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON DECEMBER 29, 2016.
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 the surveyor's review of American Academy of Family Physicians (AAFP) Proficiency Testing (PT) reports and an interview with the laboratory director/testing person, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2017 second event: Red

	blood cells (RBC) = 60% Hematocrit (HCT) = 80% White Blood Cells (WBC) = 80% 2017 third event: RBC = 80% Cell ID = 93% HCT = 80% Hemoglobin (HGB) = 60% WBC = 20% Monocytes = 80% 2018 first event: Cell ID = 93% Lymphocytes = 80% 2018 second event: HGB = 80% PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON DECEMBER 29, 2016.
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 policies and procedures and confirmed in an interview with the laboratory director/testing person at the time of this survey, the laboratory failed to establish and follow a written Quality Assessment (QA) policy and procedure for an ongoing mechanism to monitor, assess, and when indicated correct problems that may occur in the laboratory testing.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor's review of records and an interview with the technical consultant, the laboratory failed to: 1. Ensure that the laboratory discontinued the use of expired QC materials. Refer to D5417; 2. Perform and document calibration for hematology. Refer to D5437; 3. Ensure that hematology QC test results were within acceptable range prior to testing patient specimens. Refer to D5481; 4. Ensure that corrective actions were taken when quality controls were out of range. Refer to D5783
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor's review of the hematology quality Control (QC) records and an interview with the laboratory director/testing person, the laboratory failed to discontinue the use of expired hematology quality control materials. FINDINGS: 1.

	The laboratory used 3 levels of expired QC for hematology testing lot numbers: 770422, 770423 and 770424 expired 4/10/2017 for Quality controls low, normal and high respectively from 1/31/2018 through 6/3/2018. 2. The laboratory used 3 levels of expired QC for hematology testing lot numbers: 733422, 733423 and 733424 expired 6 /4/2018 for Quality controls low, normal and high respectively from 6/5/2018 through 9/4/2018. 3. Approximately 50 patients were tested for hematology using the expired quality control materials during the above time frames. PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON DECEMBER 29, 2016.
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 hematology calibration records and an interview with the laboratory director/testing person, calibration of the hematology analyzer was not performed at the frequencies required by the manufacturer of the Coulter AcT Diff hematology analyzer. FINDINGS: 1. The manufacturer of the Coulter AcT Diff hematology analyzer requires analyzer calibration every six months. 2. On October 30, 2018 at approximately 9:30 AM the laboratory director confirmed surveyor findings that the documentation of the hematology analyzer calibration available for review was for calibrations performed on 8/23/17 and 2/2/18. The analyzer was therefore out of calibration from 12/1/2016 through 8/22/17 and was out of calibration from August 3, 2018 through the survey date. 3. Approximately 35 patient specimens were tested and reported for hematology during the above time frames when the analyzer was out of calibration. PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON DECEMBER 29, 2016.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor's review of the hematology available quality control records and an interview with the laboratory director/testing person, the laboratory failed to ensure that hematology QC results performed on the Coulter AcT Diff were within acceptable range prior to testing patient specimens. Findings Include: 1. Review of QC records found and it was confirmed with the laboratory director on October 30,

	2018 at approximately 9:30 AM during review of QC data that the following levels of control material were out of acceptable range and remediation was not performed: On 1/31/18 and on 7/31/18 three out of three QC were out of range for multiple analytes, On 5/16/18, 6/18/18, 7/2/18, 7/31/18 and 9/17/18 two out of three QC were out of range. 2. Approximately 35 patients' specimens were tested and reported for hematology testing during the above dates. PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON DECEMBER 29, 2016.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a surveyor's review of the hematology QC records and an interview with the laboratory director/testing person, the laboratory failed to perform and document corrective action when QC results were out of acceptable range and failed to evaluate all patient test results obtained for each unacceptable test run through the last acceptable test run to determine if patient test results were adversely affected. Refer to: D5481
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 the surveyor's review of laboratory records, the laboratory director failed to provide overall management and direction of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the survey conducted on 12/29/16; 2. QC program for hematology testing was maintained, refer to D6020; and, 3. General laboratory systems QA review was performed and documented, refer to D6021 PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON DECEMBER 29, 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 the surveyor's review of Quality Control (QC) records and confirmed, during this onsite survey with the laboratory director/testing person, the laboratory director failed to ensure that the QC program for hematology testing was maintained to assure quality of laboratory services. Refer to: D3031, D5417, D5437, D5481, D5783 PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON DECEMBER 29, 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 lack of quality assessment (QA) policy and confirmed in an interview with the laboratory director/testing person at the time of the survey, the laboratory director failed to ensure that the laboratory established and maintained a QA program as part of the laboratory's overall quality systems program. Refer to D3031, D5211, D5291, D5417, D5437, D5783 PLEASE NOTE: THIS IS A RECITE FROM THE SURVEY CONDUCTED ON DECEMBER 29, 2016.