Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0932982	04/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Niculae Ciobanu, Physician, Pc	945 5th Avenue - Office 6 Right Side Area, New York, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the laboratory director, the laboratory failed to have a complete procedure manual. Findings Include: On April 10, 2019, 12:30 PM it was confirmed by the laboratory director, that the laboratory failed to have procedures in place for: 1) Control procedures (number/level of controls tested), acceptability of controls, number of

	times control are tested before acceptance; 2) Lot to lot verification of new controls; 3) Calibration procedures; 4) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
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 observation of the laboratory's testing area and an interview with the laboratory director/testing person, the laboratory failed to discontinue the use of the expired reagent used to stain peripheral smears. Findings Include: On April 30, 2019, at approximately 11:45 AM, the laboratory director/testing person confirmed that the laboratory continued to use lot # 8154, Giemsa hematology stain past its expiration date of January 11, 2017, through the date of this survey. Approximately 3 patients were tested and reported for manual differentials.
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 a review of hematology quality control (QC) records and an interview with the laboratory director/testing person, the laboratory failed to ensure that hematology QC results performed on the Boucl Medonic hematology analyzer was within an acceptable range prior to testing patient specimens. Findings Include: On April 30, 2019, at approximately 12:00 pm, it was confirmed with the laboratory director, that the laboratory tests three levels of QC material and their policy is to have all three level of QC material within acceptable range prior to patient testing. On the following days, these controls were not within acceptable range. A total of 178 patient specimens were tested and results reported on these days. Low control February 1, 2019 - WBC & RBC February 6, 2019 - RBC February 13, 2019 - WBC & RBC February 14, 2019 - WBC February 20, 2019 - WBC, RBC, Hgb, Hct & Platelets March 13, 2019 - Platelets March 18, 2019 - WBC, RBC, Hgb, Hct March 20, 2019 - Hgb & Platelets March 25, 27, & 28, 2019 - WBC & RBC April 4, & 11, 2019 - Platelet April 22 - RBC & WBC Normal Control February 7, 2019 - RBC February 18, 2019 - Platelets February 20, 2019 - WBC, RBC, Hgb, Hct & Platelets March 11, 2019 - Platelets March 13, 2019 - WBC & RBC March 18, 2019 - Platelets March 20, 2019 - Platelets April 29, 2019 - RBC High Control February 1, 2019 - RBC February 4, 2019 - RBC & Hgb February 8, 2019 - RBC, HCT & Hgb February 11, 2019 - RBC, Hgb & Hct February 13, 2019 - RBC & Hgb February 14, 2019 - RBC & Hgb February 15, 2019 - RBC & Hgb February 20, 2019 - WBC, RBC, Hgb, Hct & Platelets March 18, 2019 - Platelets March 20, 2019 - Platelets
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 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 and determine if patient test results were adversely affected.
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 findings and an interview with the laboratory director/testing person, the director failed to provide overall management and direction for the laboratory. The director failed to ensure that: 1. The QC program for hematology was maintained. Refer to D6020 2. The quality assessment (QA) program for hematology was maintained. Refer to D6021
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 a review of QC records and an interview with the laboratory director/testing person, the director failed ensure that the QC program for hematology testing was maintained to assure quality laboratory services. Refer to D5417, D5481 & D5783.
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 the surveyor's review of the laboratory's policy/procedure manual and an interview with the laboratory director/testing person, the laboratory director failed to ensure that the laboratory's quality assessment (QA) policy/procedure was followed. Refer to D5403, D5481 and D5783.