Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0936395	10/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Gregory P Manzullo Md	100 Commons Way Bldg A 100, Toms River, NJ	

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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to retain all Performance Report (PR) received from the Oneworld Accuracy Accutest (OAA) for events Q1,2,3 in 2018 and Q1in 2019. The TP #1 listed on CMS form 209 confirmed on 10/30/19 at 12:45 am that PR were not retained.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate results when they received an unacceptable score in Hematology tests performed on the Cell Dyn Emerald series analyzer with the One World Accuracy AccuTest (OWAA) in the 2019 Cycle 2 event. The findings include: 1. The laboratory received "UNACC" unacceptable in 2019 cycle 2 on samples D - for Red Blood Cell Count, B and D - for Platelets. 2. The laboratory received "*ACC" ungradable results in 2019 cycle 2 on samples A trhough D for Granulocytes, Lymphocytes, and Monocytes. 3. There was no documented evidence that the laboratory evaluated and verified the failures. 4. The TP #1 listed on CMS form 209 confirmed on 10/3019 at 12:42 pm that the laboratory did not perform and document an evaluation of unacceptable PT results.

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 review of the Laboratory Records and interview with the Testing Personnel (TP), the laboratory failed to meet the analytic system requirements for Hematology tests. The findings include: 1. The laboratory failed to establish a Corrective Action (CA) procedure 2. The laboratory failed to follow Manufacturer Operator manual. Cross refer to D5411. 3. The laboratory failed to perform Calibration Verification every six months. Cross refer to 5439 4. The laboratory did not perform two levels of QC before testing patients for Hematology Tests. Cross refer to D5447. 5. The laboratory did not perform corrective action on failed Hematology QC. Cross refer to D5783. 6. The laboratory failed to establish a procedure to verify new QC. Cross refer to D5791.
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 surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the laboratory failed to have a Corrective Action (CA) procedure when Quality Control values fails from 10/31/17 to the date of the survey. The TP #1 listed on CMS from 209 confirmed at 1:45 pm on 10/30/19 the laboratory did not have a CA procedure.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of patient work records, review of the Manufacture Operator Manual (OM) and interview with the Testing Personnel (TP), the laboratory failed to follow the OM for Hematology testing performed on the Cell-Dyn Emerald from 12/20/18 to the date of survey. The findings include: 1. The OM stated patient results with L2 flags "May indicate the presence of myelocytes, lymphoblasts, or basophils. Check the specimen for clots or agglutination. Follow you laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required" 2. The OM stated patient results with L3 flags "May indicate the presence of eosinophils, or myelocytes. Check the specimen for clots or agglutination. Follow you laboratory's review criteria or review a stained smear to confirm the differential results. Redraw and retest the specimen as required" 3. 5 out of 10 patient work records reviewed had L2 or L3 flags. But the laboratory did not follow the OM. 4. The TP #1 listed on CMS from 209 confirmed on 10/30/19 at 1:40 pm the laboratory failed to follow the OM.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of Calibration Verification (CV) records and interview with the Testing Personnel (TP), the laboratory failed to perform and document CV procedures at least

	once every six months for Hematology Tests performed on the Cell-Dyn Emerald analyzer from October 2018 to the date of the surveyor. The TP #1 listed on CMS from 209 confirmed on 10/30/19 at 1:10 pm CV was not performed every six months.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to perform and document two level of controls on each day of patient testing for Hematology testing performed on the Cell-Dyn Emerald analyzer. The findings include: 1. Controls were not run on 1/14/19 and, 7/1/19. 2. Approximately one hundred patients were run and reported each day QC was not done. 3. The TP #1 listed on CMS form 209 confirmed on 10/30/19 at 1:00 pm that two levels of QC were not performed every day of patient testing.
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 surveyor review of the Quality Control (QC) records and interview with Testing Personnel (TP), the laboratory failed to take corrective action when controls were out of range for Hematology Testing on the Cell-Dyn Emerald from July 2019 to the date of survey. The findings include: 1. A review of the QC records revealed: a. Red Blood Cell (RBC), Hematocrit (HCT), Mean Corpuscular Hemoglobin (MCH), and Mean Corpuscular Hemoglobin Concentration (MCHC) were out of range for all three levels of controls run from July 2019 to the date of survey. 2. Approximately 850 patients were run during the above mentioned time frame. 3. The TP #1 listed on CMS form 209 confirmed on 10/30/19 at 12:50 pm that corrective action on failure of QC was not performed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The

	laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), review of previous plan of corrections, and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for verification of Quality Control material from 9/28/15 until the date of survey. The TP#1 listed on CMS form 209 confirmed on 10/30/19 at 1:30 pm that the laboratory did not have a procedure for QC verification. Note: The deficiency was previously cited on 10/31/17 The Plan of corrections stated " Policy will be written and applied to manual on quality control procedure material. In-service with lab personal on documentation verification. If quality control is not verifying properly,the lab personnel will report to the lab supervisor"
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 an surveyors review of the laboratory's records, procedures and interview with the testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 3/5/19 to the date of the survey. 1. The LD failed to establish a Quality Control program. Cross Refer to D6020. 2. The LD failed to establish a Quality Assurance plan. Cross 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 surveyor review of the Procedure Manual (PM), Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure a Quality Control (QC) program was established for Hematology Testing from 10/31/17 to the date of survey. The finding includes: 1. The was no documented evidence of QC review from July 2019 through October 2019. 2. The TP #1 listed on CMS from 209 confirmed on 10/30/19 at 12:30 pm that a QC program was not maintained.
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 a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from 10/31/17 to the date of the survey. The TP #1 listed on CMS from 209 confirmed 10/30/19 at 12:00 pm that a QA plan had not been established.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Cell Dyne Emerald analyzer from 10/31/17 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 10/30/19 at 12:45 pm that trends and shifts were not reviewed.