Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0934797	05/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
Patrick J Dipaolo Md	781 Bloomfield Avenue, Montclair, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. 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 maintain the Work Records (WR) and Attestation Statements (AS) signed by the analyst and Laboratory Director for Hematology tests performed with the American Proficiency Institute for events in the calendar years 2018 and 2019. The findings include: 1. The WR and AS were not maintained for the 1-2018, 3-2018 and 1-2019 events. 2. The TP confirmed on 5/9/19 at 10:00 am that AS and WR were not maintained.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: a. Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate competency accurately on one of one TP on 5/4/19. The findings include: 1. The laboratory failed to use the CA evaluation tools accurately as follows: a. Monitoring the recording and reporting of test results, Quality Control (QC), Proficiency Test (PT) performance and preventative maintenance logs was used to assess: 1. Specimens processed and stored in a timely manner. 2. Testing material stored and handled correctly. 3. Observation of all phases of testing. 4. Instrument maintenance and function checks. 5. The TP contacts appropriate person when questions arise b. Direct observation of performance of instrument maintenance and function checks was used to assess: 1. Specimens processed and stored in a timely manner. 2. Testing material stored and handled correctly. 3. Observation of all phases of testing. 4. Patient tests reported according to protocol. 5. The TP recognizes all system failures, unacceptable QC and calibrations and erroneous test results. 6. The TP contacts appropriate person when questions arise. c. Assessment of test performance through blind patient samples or PT was used to assess: 1. When problems arise the TP knows how to assess the problem and does what is required. 2. The TP documents all corrective plan of actions associated with QC, instrument maintenance and PT. 3. The TP contacts appropriate person when questions arise 2. The TP stated on 5/9/19 at 10: 30 am the laboratory did not uses the CA evaluation tools accurately. b. Based on review of the CA records, review of the personnel files and interview with the TP, the laboratory failed to perform a CA on one of one TP in the calendar years 2017 and 2018. The TP confirmed on 5/9/19 at 10:20 am that CA was not performed annually. Note: These citations were cited on previous survey performed 2/2/17 Plan of correction stated "All future assessments will use the listed designation"
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 Proficiency Testing (PT) results and interview with the Testing Personnel (TP), the laboratory failed to evaluate results when the laboratory received an unacceptable score for Hematology Testing performed with the American Proficiency Institute (API) from 2/2/17 to the date of the survey. The findings include: 1. The laboratory received unacceptable grades as follows: a. 2-2017 sample HEM-07 Red Blood Cells (RBC) b. 3-2017 sample HEM-11 Monocytes c. 2-2018 - Hemoglobin, Mean Corpuscular Hemoglobin Concentration (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Mean Corpuscular Volume (MCV) d. 3-2018 sample HEM-14 MCV e. 1-2019 sample HEM-02 MCV 2. No evaluation was documented for the unacceptable PT score. 3. The TP confirmed on 5/9/19 at 10: 55 am that the laboratory did not perform and document an evaluation of unacceptable PT results. Note: This was cited on the previous survey performed 2/2/17 Plan of correction stated "The medical director shall review and evaluate all PT results.
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 surveyor review of the Procedure Manual, review of Quality Control (QC) data and interview with the Testing Personnel (TP), the laboratory failed to follow the Hematology QC lot to lot verification procedure from 2/2/17 to the date of the survey. The findings include: 1. The PM stated to run the new lot of QC five times with the current lot before the old lot expires. 2. A review of documentation revealed QC was not run five times before putting in use. 2. The laboratory did not run new QC before the old lot expired as below: a. Lot 079100 expired 5/6/19 - New Lot 67500 was verified 5/6/19 b. Lot 077100 expired 2/11/19 - New Lot 079100 was verified 2/11/19 3. The TP confirmed on 5/9/19 at 11:40 am that the QC procedure above was not followed.
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 (PM) and interview with the Testing Personnel (TP) the laboratory failed to have all applicable procedures for Hematology Tests from 2/2/17 to the date of the survey. The findings include: 1. The laboratory did not have a procedure for: a. Specimen Rejection b. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. c. Critical Values d. The course of action to be taken if the test system becomes inoperable. 2. The TP confirmed on 5/9/19 at 11:50 am that the PM did not have all applicable procedures.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the

	current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have an approved, signed and dated PM by the Laboratory Director from 2/2/17 to the time of the survey. The TP confirmed 5/9/19 at 11:15 am a PM signed by the LD was not available.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on the surveyor review of the Work Records (WR) for Hematology Tests and interview with the Testing Personnel (TP), the laboratory failed to maintain a record system that included the identity of the TP performing the test from 2/2/17 to the date of survey. The TP confirmed on 5/9/19 at 12:35 pm that the laboratory failed to include the identity of the TP on WR.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR from 2/2/17 to the date of survey. The TP confirmed on 5/9/19 at 12:20 pm that the TRD was not on the FR.
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 lack of a Quality Assessment (QA) program and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA program for laboratory testing from 2/2/17 to the date of survey. The TP confirmed on 5/9/19 at 12: 15 pm that a QA program was not established. Note: This was cited on previous survey performed 2/2/17 Plan of correction stated "The Laboratory Director has established and maintained a QA program which has been implemented and used."
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director failed to have appropriate education records for one out of one TP on file from 2/8/17 to the date of the survey. The TP confirmed on 5/9/19 at 10:00 am that education records were not in the PF. Note: This was cited on previous survey performed 2/2/17 Plan of correction stated "TP employed in the laboratory have current education and experience documentation on file in the personal / HR records.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, Competency Assessment (CA) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a CA procedure with all the required elements to ensure TP are

	competent to perform tests from 2/2/17 to the date of the survey. The findings include: 1. The laboratory had a CA form but did not have a written procedure stating when CA must be performed. 2. The TP confirmed on 5/9/19 at 12:30 pm that a CA procedure was not adequately 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 Personal (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 Beckman Coulter AcT diff 2 analyzer from 2/2/17 to the date of the survey. The TP confirmed on 5/9/19 at 12:25 pm that trends and shifts were not reviewed.