

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0934797	(X3) Date Survey Completed 06/29/2021
Name of Provider or Supplier Patrick J Dipaolo Md	Street Address, City, State 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Competency Assessment (CA) records and interview with the Office Manager (OM), the laboratory failed to follow the CA procedure on one of one Testing Personnel for the calendar years 2019 and 2020. The OM confirmed on 6/29/21 at 9:40 am that the CA procedure was not followed as stated above.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Office Manager (OM), the laboratory failed to review and evaluate results when they received an unacceptable score in Hematology tests performed with the American Proficiency Institute (API) for the third event in the calendar year 2019. The findings include: 1. The laboratory received a 40% Grade for Mean Corpuscular Hemoglobin (MCH) 2. The laboratory received a 60% Grade for Mean Corpuscular Volume (MCV) 3. There was no documented evidence that the laboratory investigated the failures. 4. The OM confirmed on 6/29/21 at 10:45 am that the laboratory did not review and document an evaluation of unacceptable PT results.</p>

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 Office Manager, (OM) the laboratory failed to have all applicable procedures for Hematology Tests from 5/9/19 to the date of the survey. The findings include: 1. The PM did not have the Reportable Range (RR) for tests performed on the Beckman Coulter AcT diff 2 analyzer. (see # 6 above) 2. The PM did not have a procedure to report results that did not fall within the RR (see # 6 above) 3. The OM confirmed on 6/29/21 at 10:00 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 review of the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to ensure that an approved PM was available to all testing personnel from 5/9/19 to the date of the survey. The finding includes: 1. The laboratory could not provide a PM that was approved and signed by the current laboratory director. 2. The OM confirmed on 6/29/21 at 10:00 am that the PM was not approved and signed by the Laboratory Director.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM), the Laboratory Director failed to have an approved PM available for Hematology testing from 5/19/21 to the date of the survey. The OM confirmed on 6/29/21 at 10:00 am an approved PM was not available.