

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0971951	(X3) Date Survey Completed 03/19/2019
Name of Provider or Supplier Family Medical Practice Of Long Island, Pc	Street Address, City, State 253 Broadway, Amityville, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the manufacturer's packet inserts for the Imco Rapid Strep A and an interview with the technical consultant, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls for waived testing from November 2017 through the survey date. FINDINGS: 1. The laboratory performs Rapid Strep A. The manufacturer of the Imco Rapid Strep A requires that external positive and negative controls, included in each test kit, be performed for each kit opened prior to use for patient test. 2. On March 19, 2019 at approximately 11:30 AM, the technical consultant confirmed surveyor's findings that the required external positive and negative quality controls were not performed for the Imco Rapid Strep A with each new kit opened from November 2017 through the survey date. 3. Approximately 100 patients specimens were tested and reported for Rapid Strep testing from November 2017 through the survey date. PLEASE NOTE: THIS IS A RECITED DEFICIENCY FROM THE SURVEY CONDUCTED ON NOVEMBER 27, 2017.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:
Based on the surveyor's review of American Proficiency Institute (API) Proficiency Testing (PT) reports and an interview with the technical consultant, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2018 second event: Cholesterol = 80% Thyroid Stimulating Hormone (TSH) = 80% 2018 third event: TSH = 80% Red Blood Cells (RBC) = 80% Mean Corpuscular Hemoglobin Concentration (MCHC) = 80% 2019 first event: Cholesterol = 80% Sodium (Na) = 80% TSH = 80%

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory records and interview and confirmed by the technical consultant, the laboratory failed to verify twice annually the accuracy of test results for Sex Hormone-Binding Globulin (SHBG) test from November 2017 when testing was initiated through the survey date. Approximately 100 patients samples were tested and reported for above tests from November 2017 through the survey date.

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 the surveyor's review of the laboratory's calibration verification records and an interview with the laboratory technical consultant, the laboratory failed to perform calibration verification at least once every six months for chemistry testing on the Liasys 450 analyzer from June 21, 2018 to September 25, 2018. FINDINGS: 1. The

	<p>calibrators for the analytes, tested on the Liasys 450 analyzer have fewer than three points, therefore, the laboratory is required to perform calibration verification every six months. 2. At approximately 11:30 AM on March 19, 2019, the technical consultant confirmed that the documentation of the calibration verification available for review was for calibration verification performed on 12/20/17 and 9/26/18. 3. The Liasys 450 analyzer was out of calibration from 6/21/18 through 9/25/18. 4. Approximately 150 patient specimens were tested and reported for chemistry analytes when the Liasys 450 analyzer was out of calibration verification.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor findings and interview with the technical consultant, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the survey conducted on 11/27/2017, refer to D1001; 2. Reviewed, approved and signed validation studies, D6007; 3. Maintained the laboratory's established QA program for all phases of laboratory testing, refer to D6021.</p>
<p>D6007</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)</p> <p>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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of validation records and an interview with the technical consultant, the laboratory director failed to review, sign and approve the completed validation studies for the Liasys 450 analyzer prior to patient testing on December 20, 2017. FINDINGS: On March 19, 2019 at approximately 11:30 AM the laboratory technical consultant confirmed surveyor findings that although the verification of performance specifications for the Liasys 450 analyzer was completed on 12/20/17, the laboratory director failed to review, approve and sign the completed validation studies prior to initiating patient's chemistry testing.</p>
<p>D6021</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

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 review of the laboratory quality assessment records (QA), and interview with the technical consultant, the laboratory director failed to follow the laboratory's QA procedures. Findings Include: At approximately 11:30 AM on March 19, 2019, the technical consultant confirmed that although the QA reviews were performed by the laboratory's technical consultant, the laboratory failed to ensure that actions taken to prevent recurrence of the original problem. Refer to D1001, D5211, D5217, D5439