

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0858630	<b>(X3) Date Survey Completed</b>  03/28/2019
<b>Name of Provider or Supplier</b>  Lev J Paukman Md	<b>Street Address, City, State</b>  396 Ave X, Brooklyn, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the American Proficiency Institute (API) Proficiency testing (PT) records, plan of correction document for failure to enroll in 2018 API program and an interview with the laboratory testing person, the laboratory failed to enroll in PT that meets the criteria in Subpart I and is approved by HHS for the speciality Chemistry and sub-specialty Endocrinology testing in the calendar year 2018. FINDINGS: 1. The laboratory testing person confirmed on March 28, 2018 at approximately 4:30 PM, that the laboratory failed to enroll in the 2018 API PT program. Approximately 1500 patient specimens were tested and results reported for chemistry and the subspecialty Endocrinology testing. 2. The laboratory director did not implement the plan of correction from the PT Desk Review on 08/14/2018 stating, that the laboratory had emailed the last event of 2018 and also enrolled in two remedial events for 2018. And that results will be forward to the PT coordinator." a. The laboratory failed to enroll in the 2018 API PT program. b. The laboratory failed to perform the 2018 3rd event for chemistry and sub-specialty endocrinology and did not perform the two remedial events.</p>
<b>D5293</b>	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on surveyor's review of the laboratory's Quality Assessment (QA) policies and procedures, the plan of correction documentation from the August 14, 2018 PT Desk Review survey and an interview with the laboratory testing person, the laboratory failed to follow their established QA policy after identifying PT issues. FINDINGS: The laboratory testing person confirmed on March 28, 2019 at approximately 4:30 PM, that the laboratory did not implement the plan of correction for failure to enroll in the 2018 PT program and perform two PT test events as stated in their response to the deficiency statement. a. the laboratory did not perform a review of the effectiveness of corrective actions taken to prevent failure to enroll in a PT program b. the laboratory failed to revise the PT enrollment policy to prevent recurrence for failure to enroll in a PT program

**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 records for the Abbott Architect 1000 analyzer, Quality control (QC) records and an interview with the laboratory testing person, the laboratory failed to perform calibration verification at least once every six months for the analytes: Thyroid Stimulating Hormone (TSH), Total Triiodothyronine (TT3), Carcinoembryonic Antigen (CEA), Follicle Stimulating Hormone (FSH), Total Prostate Specific Antigen (T. PSA), Progesterone, Prolactin,

and Ferritin on the Abbott Architect 1000 analyzer. FINDINGS: The laboratory testing person confirmed on March 28, 2019 at approximately 5:00 PM, the surveyor's findings that the laboratory did not perform a required calibration verification from April 4, 2017 through March 28, 2019 for the eight analytes noted above. a. The laboratory's QC policy requires calibration verification for those analytes with less than three point calibrators; TSH, TT3, CEA, FSH, T. PSA, Progesterone, Prolactin, and Ferritin have two point calibrators. b. The laboratory did not retain calibration verification records for 2016, therefore, the surveyor could not determine when the last date for calibration/verification was performed for these analytes. c. The analyzer was out of calibration for 24 months. Approximately 1,500 patient samples were tested and reported during this time-period.

**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 surveyor's review of the laboratory's established policies & procedures, laboratory records and interview with the laboratory testing person, the laboratory director failed to provide overall management of the laboratory. FINDINGS: The laboratory director failed to ensure that the: 1. laboratory implemented the plan of correction from the PT Desk Review survey PT conducted on August 14, 2018. 2. laboratory was enrolled in the API PT program, refer to D6015; 3. laboratory follow their established QA program for all phases of laboratory testing, refer to D6021; 4. laboratory followed their established QC procedures for chemistry and sub-specialty endocrinology testing, refer to D6024.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)

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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of laboratory API PT records and an interview with the laboratory testing person, the laboratory failed to enroll in Proficiency Testing (PT) for chemistry and sub-specialty endocrinology for the calendar year 2018. Refer to D2000.

**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 testing person, the laboratory director failed to ensure that the laboratory's quality assessment (QA) policy/procedure was followed. Refer to: D5293

**D6024**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(7)

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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the chemistry & endocrinology calibration records, QC records, the laboratory's QA policy/records and 2017 API PT records and confirmed in an interview with the laboratory testing person, the laboratory director failed to ensure that remedial action was taken and documented when problems were identified. Refer to: D2000, D5293, and D5439.