

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0686097	<b>(X3) Date Survey Completed</b>  06/15/2021
<b>Name of Provider or Supplier</b>  Joseph Slomowits Md	<b>Street Address, City, State</b>  5117 15th Ave, 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>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> 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 surveyor's review of the laboratory's waived testing records and interview with the laboratory testing person, the laboratory failed to follow the manufacturer's instructions for performing the required quality control testing when testing Quidel Quick View in-line Rapid Strep A, Alere Afinion Glycated hemoglobin (HgbA1c) and Contour Next EZ Glucose from September November 2018 through survey date.</p> <p><b>FINDINGS:</b> 1. The laboratory testing person confirmed on June 15, 2021 at approximately 10:00 AM that the laboratory failed to follow the manufacturer's instructions for performing the required quality control testing when testing Quidel Quick View in-line Rapid Strep A, Alere Afinion Glycated hemoglobin (HgbA1c) and Contour Next EZ Glucose from January 1, 2020 through survey date. 2. Quidel Quick View in-line Rapid Strep A requires the external control to be tested with each new lot and/or shipment of test kits. a. The testing did not record the lot numbers and expiration dates for the kits used for patient testing, therefore, the surveyor could not determine the number of test kits were used for patient testing. b. Approximately 327 patients were tested and reported from January 1, 2020 through survey date. 3. Alere Afinion Glycated hemoglobin (HgbA1c) requires the external control to be tested with each new lot and/or shipment of test cassettes. a. The testing did not record the lot numbers and expiration dates for the kits used for patient testing, therefore, the surveyor could not determine the number of test cassettes were used for patient testing. b. Approximately 436 patients were tested and reported from January 1, 2020 through survey date. 3. Contour Next EZ Glucose meter (S/N E251646) requires the external controls to be tested with each new lot of test strips a. The laboratory did not</p>

perform external controls for the current lot for test strips DUOFPEC53A expiration date 6/30/22 b. The testing did not record the lot numbers and expiration dates for the test strips used for patient testing, therefore, the surveyor could not determine the number of test strips were used for patient testing. c. Approximately 50 patients were tested and reported from January 1, 2020 through survey date

**D3009**

**FACILITIES**  
CFR(s): 493.1101(c)

The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

This STANDARD is not met as evidenced by:  
Based on surveyor's review of the Beckman Access 2 control records for Covid 19-Immunoglobulin antibody (IgG) records and an interview with the laboratory testing person, the laboratory failed to maintain their Covid-19 reporting to the NYC Communicable Disease program for reporting both positive and negative Covid 19 test results from March 20, 2020 through survey date. FINDINGS: 1. On September 18, 2020, Executive Order 202.61 was issued requiring the following. All clinical labs and POLs or healthcare providers conducting Covid-19 testing must report Covid 19 test results immediately (within 24 hours of receiving results) through New York State Electronic Clinical Laboratory Reporting System (ECLRS). a. Following up on the recent New York State Executive Order No. 202.61, on September 18, 2020, the New York City Department of Health and Mental Hygiene issued an alert advising providers that perform all point-of-care (POC) Covid 19 testing must report Covid 19 test results electronically via the New York State Electronic Clinical Laboratory Reporting System (ECLRS). 2. The laboratory implemented the Covid testing performed on the Beckman Access 2 analyzer using Covid -19 AB IgG test kit March 20, 2020. 3. The laboratory tested 294 patients from March 20, 2020 through 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 surveyor's review of the calibration verification records and an interview with the laboratory testing person, the laboratory failed to perform calibration verification at least once every six months for T3-uptake performed on the Beckman Access 2 from November 2018 through survey date. FINDINGS: 1. The laboratory testing person confirmed on June 15, 2021 at approximately 11:30 AM , the laboratory failed to perform calibration verification at least once every six months for T3-uptake performed on the Beckman Access 2 from November 2018 through survey date. a. Approximately 439 patients were tested and reported during this time period.

**D5445**

**CONTROL PROCEDURES**

CFR(s): 493.1256(d)(1)(2)(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--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's policies and procedures and an interview with the office manager, the laboratory failed to establish a Risk Assessment (RA) plan as part of the Individualized Quality Control Plan (IQCP) for testing Group A Strep and for performing throat culture testing using Select Strep Agar and 0.04 Bacitracin disk. FINDINGS: The laboratory testing person confirmed on June 15, 2021 at approximately 11:00 AM, that the laboratory failed to a establish a Risk Assessment (RA) plan as part of the Individualized Quality Control Plan (IQCP) for testing Group A Strep and for performing throat culture testing using Select Strep Agar and 0.04 Bacitracin disk. a. Risk Assessment plan to identify and evaluate potential failures and sources of error for testing Group A Strep with Bacitracin disk, to include the five Risk Assessment Components: Specimen, Test System, Reagent, Environment, and Testing Personnel.

**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 findings and interview with the laboratory testing person, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: The QC program was maintained, refer to D6020.

**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 a surveyor's review of bacteriology and endocrinology QC records and confirmed in an interview with the laboratory testing person at the time of this survey, the laboratory director failed to ensure that the QC program for bacteriology and endocrinology was maintained to assure the quality of laboratory services. Refer to: D5439 and D5445.