

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0686097	<b>(X3) Date Survey Completed</b>  01/05/2024
<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 review of waived testing records and interview with the testing person (TP), the laboratory failed to follow the Osom Rapid Strep A, Alere Afinion Glycated hemoglobin (HgbA1c), and Urinalysis Dipstick manufacturer's quality control (QC) testing instructions from July 2021 through the survey date. FINDINGS: 1. The TP confirmed on January 5, 2024, at approximately 1:00 P.M. that the laboratory failed to perform the required Osom Rapid Strep A, Alere Afinion Glycated hemoglobin (HgbA1c), and Urinalysis Dipstick QC testing from July 2021 through the survey date. This is contrary to the manufacturer's QC performance testing instructions. 2. OSOM Rapid Strep test manufacturer's instructions required QC testing to be performed with each new lot as well as new, untrained operator. a. No documentation of QC performance testing was available from July 2021 through the survey date. b. Approximately two hundred twenty patients were tested each year through the survey date. 3. Alere Afinion Glycated hemoglobin (HgbA1c) manufacturer's instructions required external controls to be tested with each new lot, shipment, and at least every thirty days. a. It was noted that QC performance testing records were available for each new lot received. b. The most recent QC performance testing record available for the external control lot in use was May 2022; No minimum thirty day QC performance testing records were available. c. Approximately one thousand one hundred thirty-one patients were tested each year through the survey date. 4. The urinalysis dipstick manufacturer's instructions required QC testing to be performed for every new lot, shipment, opened bottle, and for strips stored in excess of thirty days. a. No documentation of QC performance testing was available from July 2021</p>

through the survey date. b. Approximately six hundred eighty-four patients were tested each year through the survey date.