

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2129703	(X3) Date Survey Completed 06/21/2023
Name of Provider or Supplier Simon Barkagan Md	Street Address, City, State 2964 Brighton 6th Street, Brooklyn, 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 direct observation, lack of Quality Control (QC) records, and an interview with the laboratory director, the laboratory failed to follow the Siemens Multistix 10SG reagent strip manufacturer's instructions for testing and documenting QC material when new lots were received. FINDINGS: 1. No Siemens urine Multistix 10SG test strip QC records were available from June 2021 through the survey date. 2. The laboratory director confirmed on June 21, 2023, at approximately 11:00 A.M. that the laboratory performed QC but did not document the results.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Individual Quality Control Policy (IQCP) direct observation, and an interview with the laboratory director, the laboratory failed to retain the Clinical Laboratory Standard Institute (CLSI) packet insert. FINDINGS: 1. The laboratory's IQCP and urine bacteriology policy required retention of the CLSI statements. 2. The QC records did not include the required CLSI statements for the</p>

following lots: a. #3319722 expiration date 02-10-2022 received in lab 7-8-2021. b. #3748539 expiration date 09-14-2022 received in lab 2-3-2022. c. #4211352 expiration date 04-06-2023 received in lab 9-12-2022. 3. The laboratory director confirmed on June 21, 2023, at 11:30 A.M. that the laboratory failed to retain the CLSI statements from 7/1/2022 through the survey date.