

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0986124	(X3) Date Survey Completed 02/01/2019
Name of Provider or Supplier Allied Physicians Group, Pllc	Street Address, City, State 2 Teleport Drive, Suite 107, Staten Island, 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 surveyor's review of the laboratory's procedure manual, lack of waived testing records and an interview with the testing person, the laboratory failed to record the quality control results, lot numbers and expiration dates for the Sekisui OSOM Ultra Rapid Strep A and Influenza A & B tests kits, and Roche Chemstrip 10SG urine test strips. FINDINGS INCLUDED: 1. The testing person confirmed at approximately 10:30 AM on February 1, 2019 that the laboratory failed to record the lot numbers, expiration dates and quality control results for Sekisui OSOM Ultra Rapid Strep A and Influenza A & B tests kits. 2. Sekisui OSOM Ultra Rapid Strep A and Influenza A & B manufacturer requires external positive and negative controls (provided in the test kits) be performed and documented with each new lot number/shipment of test kits. Approximately 200 patient specimens were tested and reported for Rapid Strep A and 40 patients for Influenza A & B from October 2018 through the survey date. 3. The laboratory failed to retain a copy of the Roche Chemstrip 10SG packet insert, therefore, the surveyor was not able to determine the quality control requires of urine test strips. The laboratory did not record the lot numbers and expiration dates for the urine test vials. Approximately 250 patient specimens were tested and reported from October 2018 through the survey date.</p>