

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0159935	(X3) Date Survey Completed 05/06/2019
Name of Provider or Supplier Rajesh Mariwalla Physician Pc	Street Address, City, State 1111 Montauk Highway, Suite 104, West Islip, 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 manufacturer's packet insert for OSOM Genzyme Influenza A&B and interview with the testing person, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new kit of Influenza A&B opened. FINDINGS: 1. The laboratory is using the OSOM Genzyme Influenza A&B kit. The manufacturer of the OSOM Genzyme requires that external positive and negative controls (provided in the kits) be performed with each new lot number/shipment. 2. On May 6, 2019 at approximately 1:00 PM the laboratory supervisor confirmed surveyor's findings that documentation for the required external control testing was not available at survey for calendar year 2018 and up to survey date. 3. Approximately 300 patient specimens were tested and reported for Influenza A&B testing during the above time frames.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of American Academy of Family Physicians (AAFP) Proficiency Testing (PT) reports and an interview with the testing person, the</p>

laboratory failed to evaluate, perform and document remedial action for the PT score of less than 100% for the following subspecialty: 2019 first event: Bacteriology = 80%