

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2211133	(X3) Date Survey Completed 04/30/2021
Name of Provider or Supplier Niranjan K Mittal Physician Pllc	Street Address, City, State 4509 5th Avenue, 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 surveyor's review of Beckman Dickinson (BD) Veritor Rapid Detection SARS-CoV-2 packet insert and an interview with the testing person, the laboratory failed to perform and document the required external controls for each new lot or shipment of BD Veritor SARS-CoV 2 test cassettes, prior to patient testing from 3/21/21 through survey date. FINDINGS: 1. The testing person confirmed on April 30, 2021 at approximately 11:30 the surveyor's findings, that the laboratory failed to perform and document the required external controls for each new lot or shipment of BD Veritor SARS-CoV 2 test cassettes, prior to patient testing from 3/21/21 through survey date. a. The packet insert for the BD Veritor Rapid Detection of SARS-CoV-2 requires external controls be performed with for each new lot or shipment or at periodic intervals required by your facility for the SARA-CoV-2 test cassettes. b. Swab controls are supplied with each kit. These swab controls are used to ensure that the test reagents work properly and that the test procedure is performed correctly. c. The surveyor could not determine if the controls were tested for the current lot in use lot# 1046836 with expiration date of 7-15-21., and prior test kits due to the lack of Quality Control (QC) records. 2. Approximately 200 patient samples were tested and reported for SARS-CoV-2 from 3/21/21 through survey date.</p>