Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2192990	05/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Rapidlab Llc	1401 Route 70 East Suite 27, Cherry Hill, NJ	

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	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the BD veritor and interview with the Office Manager (OM), the laboratory failed to follow the Information for Use (IFU) when performing Covid tests from September 2020 to the date of the survey. The findings include: The laboratory did not follow the IFU as below: 1. The IFU states "Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets." 2. The fact sheet states "This test is not yet approved or cleared by the United States FDA" 3. The OM confirmed at 12:00 pm on 5/20/21 that the laboratory did not follow the IFU.