

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2188301	(X3) Date Survey Completed 11/10/2021
Name of Provider or Supplier Bioreference Health, Llc	Street Address, City, State Quest Diagnostics Training Center, East Rutherford, 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	<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 review of the Accula SARS-CoV-2 Test, Manufactures Package Insert (MPI), observation of Testing Personnel (TP) and interview with the Site Supervisor (SS), the laboratory failed to follow the MPI when performing Covid tests from July 2020 to the date of the survey. The findings include: The laboratory did not follow the MPI as below: 1. The MPI states "Follow standard BSL-2 guidelines when working with patient samples" 2. There was no evidence that the laboratory was following BSL-2 guidelines. 3. The MPI states "Due to the high sensitivity of the Accula SARS-CoV-2 Test, contamination of the work area with previous samples may cause false positive results. Clean the Accula Dock". 4. Observation of TP revealed that TP was decontaminating the work area only. 5. The SS confirmed at 10:00 am on 11/10/21 that the laboratory did not follow the MPI.</p>