

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2250699	(X3) Date Survey Completed 03/04/2022
Name of Provider or Supplier Testative	Street Address, City, State 12140 Amos Ln, Fredericksburg, VA	
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
D0000	An announced COVID-19 reporting focused survey for compliance with SARS-CoV-2 test result reporting requirements was conducted virtually for Testative on February 28, 2022 with record review of submitted documents on March 2, 2022 and March 4, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included email correspondence and remote record review with the facility's Sales Operations Manager, Human Resources Director, Information Technology Consultant, and Operations Executive Board Member. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
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 interviews, emails, review of manufacturer's Instructions for Use (IFU), lack of documentation, and patient portal records, the laboratory failed to document temperature monitoring ensuring the Sienna-Clarity COVID-19 COVID-19 Antigen Rapid Test Cassette kits were stored according to the IFU from January 13, 2022 until February 5, 2022. Findings include: 1. During a conference with the Human Resource Director (HRD), on February 28, 2022 at approximately 11:15 AM, the HRD stated the site began testing on approximately January 11, 2022 to February 16, 2022 using the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette. 2. Review of the Sienna-Clarity's IFU (dated 5/19/2021) revealed the following statement: "Storage and Stability-The test kit should be stored as packaged at room temperature or refrigerated at 2C-30C (36F-86F)." The inspector requested to review temperature logs for the laboratory. The laboratory provided no documentation for review. 3. Review of</p>

emailed laboratory responses to the inspector's inquiry from JB GROUP (Testative) on March 2, 2022 at 8:57 AM, revealed a statement "Here are the answers to your inquiry. 4. There are no logs present - but the room temperature was held at 70F." 4. Review of an emailed testing log sheet from Testative on March 2, 2022 at 10:56 AM revealed 516 COVID-19 rapid antigen tests were performed on 24 testing days from January 13, 2022 until February 5, 2022. 5. In an exit interview with the Director of Human Resources on March 4, 2022 at approximately 11:30 AM, the above findings were confirmed.