

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2250699	<b>(X3) Date Survey Completed</b> 03/02/2022
<b>Name of Provider or Supplier</b> Testative	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	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 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: 42 CFR. 493.1100 Condition Reporting of SARS-CoV-2 test results.
<b>D1002</b>	<p><b>REPORTING OF SARS-CoV-2 TEST RESULTS</b></p> <p>During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on interviews, testing record review, and lack of documentation, the facility failed to report positive and negative COVID-19 results to the state public health department on twenty-four (24) testing days from January 13, 2022 until February 6, 2022 while performing five-hundred sixteen (516) patient COVID-19 tests. Findings include: 1. During a conference on February 28, 2022 at approximately 11:15 AM, the Human Resource Director (HRD) stated the site began COVID testing on around January 11, 2022 and halted testing on February 16, 2022. The HRD stated the site performed on-site COVID-19 testing using the Sienna-Clarity COVID-19 Antigen Rapid Test Cassette and collection of Polymerase Chain Reaction (PCR) SARS CoV-2 (COVID-19) specimens to be sent out. 2. At approximately 11:25 AM on February 28, 2022, an Information Technology (IT) Consultant stated they realized last week</p>

they were not reporting COVID-19 antigen testing to the Virginia Department of Health (VDH). The IT consultant stated "We were only entering PCR results into the "Simple Reporting" website and were not entering COVID-19 Antigen results into the website." 3. At approximately 11:35 AM on February 28, 2022, the investigator requested to review the policy related to COVID-19 testing and documentation of reporting of all positive and negative COVID-19 tests performed by the laboratory to VDH. An Executive Board Member in charge of Operations (EBMO) stated "We will provide the requested documents." The laboratory provided no documentation to review. 4. In a conference with the HRD, IT consultant and EBMO on February 28, 2022 at approximately 11:55 AM, the above findings were confirmed. 5. 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.