

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2208022	(X3) Date Survey Completed 05/02/2022
Name of Provider or Supplier Coastline Medical Inc	Street Address, City, State 509 Viking Dr Suite E, Virginia Beach, 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 focused survey for compliance with SARS-CoV-2 test result reporting requirements was conducted virtually for Coastline Medical INC on May 2, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as the following: 42 CFR part 493 CLIA Regulation: D1002- 42 CFR. 493.1100 Condition Reporting of SARS-CoV-2 test results.
D1002	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</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 a review of procedures and test logs, lack of documentation, and an interview, the laboratory failed to report four hundred sixty-three (463) SARS-Co-V-2 negative test results as required for two hundred seventy-one (271) of 271 testing days reviewed from January 29, 2021 through March 1, 2022. Findings include: 1. Review of the laboratory's SARS-CoV-2 testing procedure documentation revealed that the office utilized AccessBio CareStart and Salofa Oy Sienna-Clarity COVID-19 Rapid Antigen test kits during the timeframe of 01/29/21 up to the date of the inquiry on 05/02/22. 2. SARS-CoV-2 patient test result logs/documentation was reviewed for timeframe of 01/29/21 through 03/01/22. 3. Review of test records revealed that negative SARS-CoV-2 test results were not reported to the state agency for 271 testing days during the review timeframe outlined above. The inspector requested to review evidence of reporting negative COVID-19 test results for the 271 test dates. The director of operations stated on 5/02/22 at approximately 3:00 PM "We submitted positive results online but did not submit any negative SARS-CoV-2 test results to the</p>

state agency. I do not have evidence of reporting negatives. We were not aware to report negatives." 4. The laboratory performed five hundred thirty-two (532) SARS-CoV-2 tests on the 271 testing days of the period outlined above: 69 positive, 463 negative. 5. An exit interview with the director of operations on 5/02/22 at approximately 5:00 PM confirmed the above findings.