

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2255101	(X3) Date Survey Completed 08/09/2022
Name of Provider or Supplier North Shore Medical Labs Inc	Street Address, City, State 8021 Citrus Park Town Suite 7810, Tampa, FL	
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 onsite special focused COVID-19 reporting survey was conducted on August 3, 2022 to August 9, 2022 at North Shore Medical Labs Inc, a clinical laboratory in Tampa, FL. North Shore Medical Labs Inc was not in compliance with Code of Federal Regulations (CFR), Part 493, requirements of clinical laboratories.
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 observation and interview, the laboratory failed to report Corona Virus Disease 2019 (COVID-19) test results as required by the Florida Department of Health (FDOH) from 04/16/2022 to 08/03/2022. Findings Included: On 03/10/2022, the laboratory was informed by an email from the Agency for Health Care Administration Lab Unit that "You have been authorized to perform COVID-19 testing. Please remember that if a laboratory performs COVID-19 testing, the test results must be reported to the Department of Health (DOH)." The mandatory reporting requirements outlined by FDOH Executive Order 20-013, section 381.0031, Florida Statutes, and Florida Administrative Code Chapter 64D-3, noted laboratories must report both negative and positive COVID-19 test results. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated on 08/09/2022 by the Chief Executive Officer, the laboratory listed they performed COVID-19 testing using the iHealth COVID-19 Antigen Rapid Test and the annual test volume was 100 tests. A tour of the laboratory on 08/03/2022 at 12:30 PM, revealed the laboratory had three iHealth COVID-19 Antigen Rapid Test kits. Review of random Daily Specimen Log that were available for review showed the</p>

earliest date the COVID-19 rapid tests were performed was on 04/16/2022. On 08/05/2022 at 9:30 AM, the Chief Executive Officer stated they did not know they needed to report the COVID-19 test results to the Florida Department of Health.