

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2184847	<b>(X3) Date Survey Completed</b>  06/09/2021
<b>Name of Provider or Supplier</b>  Pure Pharmacy	<b>Street Address, City, State</b>  959 West Ave #16, Miami Beach, FL	
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>	A remote special focused COVID 19 survey was conducted on 6/9/2021 at PURE PHARMACY, a clinical laboratory. The laboratory was not in compliance with Code of Federal Regulations (CFR), Part 493, requirements of clinical laboratories. The following condition was cited: -D1002 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 lack of records and laboratory director (LD) interview, the laboratory failed to report Severe Acute Respiratory Syndrome Coronavirus 2 (Sars-Cov-2) test results to the Florida Department of Health (DOH) from August 2020 to April 2021 for a total of 5,618 tests. Findings include: -Review of the laboratory Sars-Cov-2 testing information sent by email on 6/9/2021 by the LD, revealed that the laboratory used the test Sofia Flu+ SARS from Quidel from 8/3/2020 to 1/30/2021 and the ID NOW from Abbot since 12/16/2020 to present. -Review of laboratory reporting records to the DOH, revealed that the laboratory failed to report 5,618 Sars-COV-2 tests from 8/3/20 to 4/28/21. During an interview, on 6/9/2021 at 3:30 pm, the LD explained that he assumed the instruments were sending the reports to DOH and when he found out that no automatic report was done, he started reporting to DOH. He confirmed that the laboratory failed to report 5,618 tests.</p>