Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2208117	10/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Phytogenics Specialty Pharmacy	4501 Nw 31st Ave, Oakland Park, 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	A remote special focused COVID 19 survey was conducted on 10/13/2021 at PHYTOGENICS SPECIALTY 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-Co-V-2 TEST RESULTS.
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS 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. This CONDITION is not met as evidenced by: Based on a lack of reporting records and pharmacy office manager (POM) 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 02/23 /2021 to 10/13/2021 for a total of 114 tests. Findings include: Review of the laboratory SARS-CoV-2 testing information sent by email on 10/01/2021 by the POM, revealed that the laboratory performed 42 tests with Biohit SARS-CoV-2 ANTIGEN RAPID TEST KIT and 72 tests with Biohit SARS-CoV-2 IgG/IgM ANTIBODY TEST KIT for a total of 114 tests. During an interview on 10/13/2021 at 2:00 PM, the POM explained that the pharmacy started testing on 02/23/2021 and that the laboratory hired a consultant for the SARS-CoV-2 testing, this consultant was fired in August 2021 and no testing was done after that date. The POM confirmed that the laboratory had no records of reporting to the DOH for the tests performed.