

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0878979	<b>(X3) Date Survey Completed</b>  09/13/2021
<b>Name of Provider or Supplier</b>  Lakeland Facility Operations Llc	<b>Street Address, City, State</b>  5245 N Socrum Loop Road, Lakeland, 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 complaint special focused COVID-19 reporting survey for complaint number 2021011422 was conducted 08/26/21 to 09/13/21 for Lakeland Facility Operations LLC, a clinical laboratory in Lakeland Florida. Lakeland Facility Operations LLC was not in compliance with Code of Federal Regulations (CFR), Part 493, requirements of clinical laboratories. The following Condition was not met: D1002- Reporting of Sars-Cov-2 Test Results 493.41
<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 record review and interview the laboratory failed to report negative COVID-19 test results to the Department of Health since testing began in April of 2021. Findings Included: Review of testing documentation revealed that the laboratory was using BinaxNOW COVID-19 Antigen Card from Abbott. Review of results sent to the Department of Health from 08/12/21 and 08/13/21 revealed only positive results were reported. Interview on 09/07/21 at 4:49 PM the Administrator confirmed that only positive results were reported to the Department of Health instead of all tests performed whether positive, negative, or indeterminate.</p>