

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0679478	<b>(X3) Date Survey Completed</b>  11/28/2022
<b>Name of Provider or Supplier</b>  Island Coast Pediatrics Pa	<b>Street Address, City, State</b>  13650 Metropolis Ave Ste 101, Fort Myers, 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>	<p>An onsite special focused COVID-19 reporting survey was conducted on 11/28/22 at Island Coast Pediatrics PA, a clinical Laboratory in Fort Myers, Florida. This survey was conducted in conjunction with a recertification survey. Island Coast Pediatrics PA is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is description of the noncompliance.</p>
<b>D3000</b>	<p><b>FACILITY ADMINISTRATION</b> CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) 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.</p> <p>This CONDITION is not met as evidenced by: Based on observation, and interview, the laboratory failed to report SARS - COV - 2 antigen test results as required by the Florida Department of Health (FDOH) from 6/25 /22 to 11/28/22. The laboratory SARS - COV - 2 antigen test volume from 6/25/22 to 11/28/22 was 1224. The findings included: A tour of the laboratory on 11/28/22 at 10: 30 a.m., revealed the laboratory was performing SARS - COV - 2 antigens tests with the Quidel Quickvue (Lot#708180 - expiration date 11/12/23). In an email on 12/01 /22 at 4:04 p.m., the Clinical Manager stated "We stopped reporting in June as we were told to. I am unsure of who the exact person was. My COVID nurse was unable to recall whoever had advised that she was instructed it was no longer needed."</p>