

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2157981	<b>(X3) Date Survey Completed</b>  03/03/2021
<b>Name of Provider or Supplier</b>  Lee Health Coconut Point Clinical Laboratory	<b>Street Address, City, State</b>  23450 Via Coconut Point, Estero, 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>	An announced recertification survey was conducted from 03/2/21 through 03/03/21 at Lee Health Coconut Point Clinical Laboratory, a clinical laboratory in Estero, Florida. Lee Health Coconut Point Clinical Laboratory is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the noncompliance. 42 CFR 493.1101 Standard: Facilities
<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 record review and interview with the Laboratory Compliance Officer, the laboratory failed to follow the State of Florida Statute 483 regarding independent clinical laboratories and requirements for persons performing testing in the independent clinical laboratory since 07/18/2019. (See D3009)</p>
<b>D3009</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview with the Laboratory Compliance Officer, the laboratory failed to be in compliance with Florida Statute 483 regarding independent clinical laboratories and requirements for persons performing testing in the independent clinical laboratory since 7/18/19. The finding included: Review of CMS 209 Laboratory Personnel Report dated 3/2/21 and signed by the Laboratory Director revealed that 28 testing personnel (#TP M - NN) out of 41 testing personnel (#TP A - NN) were performing moderately complexity testing (iStat testing). Review of personnel files for 7/28/19 - 3/2/21 for Testing Personnel (#M - NN) revealed that the Testing Personnel did not have a Florida Clinical Laboratory Technologist or Technician license. Review of the State of Florida Hospital license 9/29/19 - 9/28/21 revealed the facility was licensed as an Off-Site Emergency Department. Review of the "Point of Care Testing Program" showed that Point of Care Testing was performed at "Alternate Site Testing" (which is an exception for hospital lab testing) and the personnel requirements were "Personnel performing moderate complexity testing, including non - laboratory personnel, must have a minimum of one of the following: 1. Associate degree in chemical, physical, or biological science or medical laboratory technology from an accredited institution: or 2. High School graduate or equivalent and have successfully completed an official military medical laboratory procedures course and have held the military enlisted occupational specialty of Medical Laboratory Specialists; or 3. High School diploma or equivalent and have a record of training defined in the CLIA regulation 42 CFR493.1423". Review of the "Test Orders and Requisitions" revealed "Laboratory tests must be ordered by the physician or a non - physician provider (not a Lee Health organization provider)". Interview on 3/3/21 at 5:00 p.m., with the Laboratory Compliance Officer, she stated she did not know the laboratory should have been certified as an independent lab according to CLIA regulations due to acceptance of non-physician client specimens. The iStat testing personnel must be Florida licensed clinical laboratory personnel under Florida Statutes Chapter 483.