

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0296330	(X3) Date Survey Completed 02/26/2020
Name of Provider or Supplier Shorepoint Health Venice	Street Address, City, State 420 S Tamiami Trail, Venice, 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	An unannounced complaint survey, #2020000625, was conducted on 02/26/2020 at Venice Regional Bayfront Health Laboratory. The facility was not in compliance with 42 CFR 493, Requirement for clinical laboratories. The following Conditions were cited: D6168 Testing Personnel 493.1487
D6168	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on observation, record review, and staff interview the laboratory failed to have 1 out of 1 Lab Assistant performing testing without a State of Florida Clinical Laboratory Personnel license from 11/2019 to 01/15/2020 (See D6170).</p>
D6170	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a)</p> <p>Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview the laboratory failed to have 1 out of 1 Lab Assistant performing testing without a State of Florida Clinical Laboratory Personnel license from 11/2019 to 01/15/2020. Findings Included: Review of Chapter 483, Florida Statutes, Rule 64B3-2.003(19), Florida Administrative Code "Placement of specimens onto an automated instrument or system is considered a</p>

manual pretesting duty, provided it does not include any activity that initiates the analytic process." Observation in the laboratory on 02/26/2020 at 2:26 PM revealed Testing Person #C putting a rack with patient samples on the chemistry analyzer. Once the rack was on the machine, it automatically fed into the analyzer for testing (initiating the analytic process). On 02/26/2020 at 3:30 PM, Testing Personnel #A and #B confirmed that the Hematology and Chemistry analyzers automatically feed the rack into the machine as soon as it was placed on the analyzer. They also revealed that if the Coagulation analyzer was running when the rack goes on the machine, it would self feed into the analyzer as well. On 02/26/2020 at 4:00 PM, the Laboratory Manager confirmed that a Lab Assistant, with a high school diploma and no clinical laboratory licence, was hired in 11/2019. The Laboratory Manager reported that the Lab Assistant was loading the racks with patient samples and placing them on the analyzers that self feed (initiating the analytic process) until 01/15/2020. She stated that the Lab Assistant was pulled to Customer Service due to a staffing need, and she thought it was acceptable for the Lab Assistant to perform this task because he was not pushing the start button.