

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2097262	<b>(X3) Date Survey Completed</b>  05/02/2019
<b>Name of Provider or Supplier</b>  Suncoast Skin Solutions Inc-Mobile Unit	<b>Street Address, City, State</b>  500 Vonderburg Drive Suite 115w, Brandon, 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 CLIA recertification survey was conducted at Suncoast Skin Solutions Inc - Mobile Unit on 05/02/19. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D6102</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Histopathology Supervisor, the laboratory director failed to document training and competency for one (Testing Personnel #C) of two testing personnel. Findings included: A review of CMS Form 209 titled Laboratory Personnel Report signed by the laboratory director on 05/01/19 revealed Testing Person #C performed high complexity histopathology testing. A review of Testing Person #C's personnel file revealed training records and competency had not been documented. Testing Person #C was hired August 8th, 2017 and discontinued testing on the mobile unit on May 1st, 2018 Interview on 05/02/19 at 10:00 AM with the Histopathology Supervisor, confirmed there were no training or competency records for Testing Person #C for histopathology testing.</p>
<b>D6103</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for</p>

monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director failed to ensure documented policies and procedures were established to ensure that individuals performing testing are competent and maintain their competency. Findings included: Review of the histopathology laboratory's procedure manual showed that the laboratory failed to have a procedure on training and competency assessments for employees working in the histopathology laboratory. On 05/02/19 at 10:00 AM, the Histopathology Supervisor stated that they did not have a procedure for training and competency.