

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0272561	<b>(X3) Date Survey Completed</b>  04/16/2020
<b>Name of Provider or Supplier</b>  Suncoast Skin Solutions Inc	<b>Street Address, City, State</b>  525 North Dacie Point, Lecanto, 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 Dermatology and Skin Surgery Center PA on 04/16/2020. 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>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Medical Assistant, the laboratory failed to evaluate the accuracy of the subspecialty of Parasitology testing for Wet Mount testing for Scabies and the subspecialty of Mycology Potassium Hydroxide (KOH) testing for fungi at least twice a year for 2 (2018 and 2019) out of 2 years reviewed for 7 (B, C, D, E, F, G, and H) out of 7 testing personnel. Findings Included: Review of the CMS 209, Laboratory Personnel Report, signed by the Laboratory Director on 3/14/20, revealed 7 Testing Personnel (B, C, D, E, F, G, and H) for moderate complexity. Record review of the "Proficiency Testing" form for Wet Mount and KOH testing revealed that the Proficiency Testing would be performed every 6 months . The following results were found: Testing Personnel B had performed one (10/17/19) Wet mount proficiency testing out of the every 6 months proficiency testing for 2019. Testing Personnel C had not performed Wet Mount or KOH proficiency testing every 6 months for 2 out of 2 years (2018 and 2019). Testing Personnel D had not performed Wet Mount proficiency testing every 6 month for 2 out of 2 years (2018 and 2019) and had performed KOH proficiency testing every 6 month for 1 (11/13/2018) out of 2 years (2018 and 2019). Testing Personnel E had performed KOH proficiency testing every 6 months for 1 (2018) out of 2 years (2018 and 2019). Testing Personnel F had not performed Wet Mount proficiency testing</p>

every 6 months for 2 out of 2 years (2018 and 2019). Testing Personnel G had not performed KOH proficiency testing every 6 months for 2018 and had performed one (1/17/2019) KOH proficiency testing out of the every 6 months for 2019. Additionally, Testing Personnel G had not performed Wet Mount proficiency testing every 6 months for 1 (2019) out of 2 years (2018 and 2019). Testing Personnel H had not performed Wet Mount proficiency testing every 6 months for 1 of 1 year (2019). Interview on 04/16/20 at 12:20 PM with the Medical Assistant/Moh's Technician confirmed that no other peer reviews were available for review. She also stated the laboratory did not know how to perform the proficiency testing without patient samples.