

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1039559	(X3) Date Survey Completed 04/04/2018
Name of Provider or Supplier Suncoast Skin Solutions Inc	Street Address, City, State 2001 Siesta Dr Ste 201, Sarasota, 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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on observation of reagent labels and interview with the Licensed Practical Nurse (LPN), the laboratory failed to dispose chemical reagents according to manufacturer's instructions. Findings included: During the 2nd laboratory tour on 4/4/18 at 11:40 AM, the Hematoxylin Stain Solution, GILL III, and the 100% Reagent Alcohol label were observed. The labels stated "Dispose of contents/container to an approved waste disposal plant." (Photographic evidence was obtained). During an interview at 11: 30 AM on 04/04/18, the LPN stated chemicals were flushed down the sink with lots of water.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on competency records for two out of two years and interview with the Licensed Practical Nurse (LPN), the laboratory failed to evaluate the competency of the Mid-Level Practitioner. Findings included: During competency record review it was discovered that the Mid-Level Practitioner who started July 2016 had not had an</p>

competency evaluations for two out of two years (2016 and 2017). During an interview on 04/04/18 at 11:25 AM, the LPN confirmed that the competency evaluations had not been performed for the Mid-Level Practitioner.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on record review of virology (Tzanck) and parasitology (scabies) peer review for two out of two years (2016-2017) and interview with the Licensed Practical Nurse (LPN), the laboratory failed to perform peer review twice a year. Findings included: During record review of peer review, it was found that the Tzanck peer review was only performed 09/08/16, and the scabies was performed 09/08/16. During an interview on 04/04/18 at 11:45 AM, the LPN confirmed the laboratory did not have any other peer reviews.