

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0298917	<b>(X3) Date Survey Completed</b>  11/12/2025
<b>Name of Provider or Supplier</b>  Suncoast Skin Solutions Inc	<b>Street Address, City, State</b>  608 S 9th St Ste C, Leesburg, 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 on November 12, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiency cited is as follows:
<b>D3011</b>	<p><b>FACILITIES</b> 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, interview, review of the laboratory procedure manual and safety data sheets, the laboratory failed to ensure protection from chemical hazards used in their Hematoxylin and Eosin stain from 08/28/2023 to 11/12/2025. Findings: A. 1. During a tour of the laboratory on 11/12/2025 at 9:20 AM, the flammable reagents were seen under the sink cabinet. 2. Review of the Safety Data Sheets for the 100% Reagent Alcohol stain noted, "Store locked up." Review of the Safety Data Sheets for the Eosin - Y - Alcohol 0.25% and the XS-3 Xylene Substitute noted "Keep in fireproof place." 3. During interview on 11/12/2025 at 9:25 AM, the Laboratory Manager acknowledged there was no fireproof cabinet. B. 1. During a tour of the laboratory on 11/12/2025 at 9:20 AM, there was no fume hood over the staining work station and there were no respirators seen. 2. Review of the Safety Data Sheets showed following chemicals included the respiratory hazard symbol: 100% Reagent Alcohol, Gill 3 Hematoxylin, and XS-3 Xylene Substitute. 3. Review of the Safety Data Sheets for 100% Reagent Alcohol noted, 100% Reagent Alcohol - "Inhalation: May cause drowsiness or dizziness." The Safety Data Sheets for Gill 3 Hematoxylin noted, "May cause respiratory irritation." Review of the Safety Data Sheets for XS-3 Xylene Substitute noted, "Inhalation: High concentrations may cause central nervous system depression such as dizziness, vomiting, numbness, drowsiness, headaches, and</p>

similar narcotic symptoms." 4. Review of the Safety Data Sheets for 100% Reagent Alcohol and Gill 3 Hematoxylin noted, "Use NIOSH (National Institute for Occupational Safety and Health) approved full faced piece negative pressure respirators equipped with appropriate cartridges or canisters within the use limitations of these devices." The Safety Data Sheets for Eosin - Y - Alcohol 0.25% noted, "If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn." 5. During interview on 11/12/2025 at 9:25 AM, the Laboratory Manager acknowledged there was no fume hood.