

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0272695	(X3) Date Survey Completed 08/29/2019
Name of Provider or Supplier Suncoast Skin Solutions Inc	Street Address, City, State 2611-B Se 17th St, Ocala, 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	At the time of the announced, onsite recertification survey, Suncoast Skin Solutions was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493.
D5609	<p>HISTOPATHOLOGY CFR(s): 493.1273(e)(f)</p> <p>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to maintain complete Histopathology quality control documentation for two of two years reviewed (2018-2019). Findings include: The record review of quality control documentation showed there was no record of lot numbers and expiration dates for the Hematoxylin and Eosin (H&E) stains that were used on patient histopathology slides during processing. . The interview with the laboratory manager on 8/29/19 at 10:30am confirmed that the laboratory does not keep any quality control logs that record the lot number and expiration dates for the H&E stains.</p>