

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2079844	<b>(X3) Date Survey Completed</b>  02/19/2018
<b>Name of Provider or Supplier</b>  Suncoast Skin Solutions Inc	<b>Street Address, City, State</b>  429 2nd St Nw, Winter Haven, 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>D5791</b>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager, the laboratory failed to have documentation that a quality assurance program was being followed for 2 out of 2 (2016-2017) years reviewed. Findings Included: Review of the policy and procedures (signed and dated by the Lab Director on 01/07/17) stated "The Quality Management Program is overseen by the Quality Management Committee (QMC) which meets quarterly." Also, "An annual appraisal of the effectiveness of the QM program will be made and documented." Documentation of the quality assurance program was requested and no documentation was provided. During an interview on 02/19/18 at 10:27 AM the Laboratory Manager confirmed that there was no documentation of the quality assurance program.</p>