

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0663269	<b>(X3) Date Survey Completed</b>  04/09/2018
<b>Name of Provider or Supplier</b>  Select Skin Md Llc	<b>Street Address, City, State</b>  1600 36th St Ste B, Vero Beach, 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>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the facility failed to establish and follow a written quality assessment policy, and the procedure for proficiency testing was incomplete. Findings included: Record review of the laboratory procedure manual showed that their was no quality assessment policy. During an interview on 4/9/18 at 3:07 PM, General Supervisor stated that they did not have a quality assessment policy for the laboratory. Record review of the laboratory procedure on proficiency testing showed that the procedure was incomplete. The procedure failed to include what the laboratory would do if there was a discrepancy in the diagnosis between the Laboratory Director who made the initial diagnosis and the Clinical Consultant who performed the blind review. The procedure also failed to mention what corrective action would be taken if a diagnosis need to be corrected on the patients laboratory reports. During an interview on 4/9/18 at 3:17 PM, General Supervisor acknowledged that the procedure was incomplete.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic</p>

examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory procedure manual was incomplete and did not include instructions for making the 95% alcohol solution. Findings include: Review of the procedure manual for the laboratory showed that there were no instructions for making the 95% alcohol solution. The procedure titled "H&E Staining Procedure states that the "95% alcohol must be made". During an interview on 4/9/18 at 3:25 PM, General Supervisor acknowledged that the procedure manual did not include instructions for making the 95% alcohol solution.