

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1066021	(X3) Date Survey Completed 03/28/2019
Name of Provider or Supplier Rocky Mountain Dermatology	Street Address, City, State 5748 S Adams Ave Parkway, Suite B, Washington Terrace, UT	
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
D5403	<p>PROCEDURE MANUAL 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 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.</p> <p>This STANDARD is not met as evidenced by: Based on Mohs map records review, procedure manual review, lack of documentation and confirmation by staff, the laboratory procedure manual lacked a legend to identify the marking ink color codes to the ink color or the "-" code for 11 of 11 maps reviewed for testing performed from 03/29/2017 to 03/26/2019. The laboratory performed approximately 300 Mohs micrographic surgical sample analysis per year. Findings include: 1. The laboratory procedure manual step by step procedure for Mohs maps, (used to record and document consecutive horizontal surgical specimen</p>

analysis for the presence or absence of dermatological tumors) failed to include a legend to identify the specimen margin's ink colors used for orientation of the specimen. 2. The laboratory procedure manual failed to include in the step by step procedure for Moh's map recording the explanation for the code"(-)" on the map. 3. In an interview with staff on 03/26/2029 at approximately 5:45 P.M. staff confirmed the lab's procedure manual did not include a color legend to correlate ink colors to the symbols on the map or for the "(-)" interpretation.