

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0188543	<b>(X3) Date Survey Completed</b> 11/07/2019
<b>Name of Provider or Supplier</b> Dermatology Physicians Inc	<b>Street Address, City, State</b> 203 North Lime Street, Lancaster, PA	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with the registered nurse, the laboratory failed to establish a complete competency assessment procedure to assess 1 of 1 clinical consultant for competency in 2019. Findings Include: 1. On the day of survey, 11/07/2019, the laboratory could not provide a complete competency assessment procedure to assess 1 of 1 technical consultant for competency in 2019. 2. The registered nurse confirmed the findings above on 11/07/2019 around 9:20 am.</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 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</p>

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 the review of the histopathology examination procedure and interview with the registered nurse, the laboratory failed to include, step-by-step performance of the procedure, control procedures, pertinent literature references, the laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminent life threatening results in the histopathology examination procedure in 2019. Findings Include: 1. On the date of survey, 11/07/2019, review of the histopathology examination procedure revealed the following areas were not included in the procedure: - Step-by-step performance of the procedure. - Control procedures. - Pertinent literature references. - The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminent life threatening results. - Description of the course of action to take if a test system becomes inoperable. 2. The registered nurse confirmed the finding above on 11/07/2019 around 9:30 am.