

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2057459	<b>(X3) Date Survey Completed</b> 02/21/2024
<b>Name of Provider or Supplier</b> Dermatology Specialists, The	<b>Street Address, City, State</b> 176 Mountain Avenue, Hackettstown, NJ	
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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Temperature Logs (TL), the Procedure Manual (PM), the User Manual for the Olympus CX41 microscope and interview with the Office Manager (OM), the laboratory failed to monitor and document room temperature and humidity where the Professional component (PC) for Histopathology tests are performed in the calendar year 2022. The findings include: 1. There was no record of temperature or humidity in the office where the PC for Histopathology tests was being performed in calendar year 2022. 2. The PM states "temperature logs will be maintained for ambient room air and refrigerator temperatures when necessary." 3. The OM confirmed on 2/21/24 at 11:35 am, temperature and humidity records for calendar year 2022 where the PC were being performed were not available for review.</p>
<b>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system</p>

performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to establish a maintenance protocol for the Olympus CX41 microscope used for Histopathology tests from 10/12/21 to 2/21/24. The findings include: 1. The PM did not have a maintenance protocol for the Olympus CX41 microscope used for Histopathology tests. 2. The OM confirmed on 2/21/24 at 11:00 am the laboratory did not have a maintenance protocol for the Olympus CX41 microscope.

**D5601**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on the lack of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to record the reaction of the control slide for Hematoxylin-Eosin (HE) stain on each day of Mohs testing from 10/12/21 to 2/21/24. The finding includes: 1. The laboratory failed to document HE QC slide reactions for Histopathology tests performed at this location. 2. The laboratory read approximately 10,000 patients annually. 3. The OM confirmed on 2/21/24 at 11:45 am that the HE QC slide reaction was not recorded on each day the Professional Component (PC) was performed. Note: This deficiency was previously cited on 10/12/21.