

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2035585	(X3) Date Survey Completed 09/28/2021
Name of Provider or Supplier Dermatology Consultants Of Short Hills	Street Address, City, State 636 Morris Tpk, Short Hills, NJ	
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
D5413	<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 temperature charts, observation of the room where Mohs testing was performed and interview with the Office Manager (OM), the laboratory failed to monitor and document the temperature where Mohs testing was performed from 5/2/18 to the date of the survey. The OM confirmed on 9/28/21 at 12:45 pm that the temperature was not monitored.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of Mohs reagents and interview with the Office Manager (OM), the laboratory failed to discard an expired Mohs reagent from 5/2/18 to the date of survey. The findings include: 1. On the date of the survey the laboratory</p>

had an expired reagent as follows: Avantik Eosin Y Stain Solution, 1 % (w/v) in Alcohol. Lot number J168-06, Expiration 6/25/21 2. Approximately 60 patients were tested with the expired reagent. 3. The OM confirmed on 9/28/21 at 12:15 pm that the laboratory used an expired reagent.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on surveyor review of Personnel Files (PF) and interview with the Office Manager (OM), the Laboratory Director failed to have appropriate training documented for one out of two TP on the date of the survey. The OM confirmed on 9/28/21 at 12:30 pm that training records were not available.