

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2035585	(X3) Date Survey Completed 04/19/2023
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), lack of Biannual Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to verify the accuracy and reliability of Histopathology testing twice a year in the calendar year 2022. The finding includes: 1. There was no evidence that a BA was performed in 2022. 2. The OM confirmed on 4/19/23 at 1:00 pm that the laboratory did not verify the accuracy of Histopathology testing twice a year.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), observation of Staining Station (SS) and interview with the Office Manager (OM), the laboratory failed to follow the PM for Hematoxylin-Eosin (HE) staining from 9/28/21 to the date of the survey. The findings include: 1. The PM stated step nine "100% Alcohol 10 seconds (3 Changes)" 2. The SS had two changes of 100% Alcohol at step 9. 3. The OM confirmed on 4/19/23 at 1:30 pm that the laboratory did not follow the PM.</p>

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:

Based on surveyor observation of Histology reagents and interview with the Office Manager (OM), the laboratory failed to discard expired Histopathology reagent from 6/30/22 to the date of survey. The finding include: 1. Gill 3 Hematoxylin reagent Lot 112907 expired 6/30/22. 2. Approximately 200 patients were tested with expired reagent. 4. The OM confirmed on 4/19/23 at 2:30 pm that the laboratory used expired reagents.