

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2100417	(X3) Date Survey Completed 07/02/2025
Name of Provider or Supplier Dermatology Clinic, The	Street Address, City, State 901 West Main Street, Suite 201, Freehold, 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 Onsite Dermatologist (OD), the laboratory failed to verify the accuracy and reliability of Histopathology testing twice a year from 1/13/24 to 5/7/25. The finding includes: 1. The last documented evidence that a BA was performed was 2/10/24. 2. The OD confirmed 7/2/25 at 1:10 pm, the laboratory did not verify the accuracy of Histopathology testing twice a year.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: A) Based on surveyor observation of Histopathology reagents and interview with the Onsite Dermatologist (OD), the laboratory used expired Histopathology reagents from 3/26/24 to 7/2/25. The findings include: 1. Adventek Tissue marking dyes were expired as follows: a) Blue marking day lot # 083812 expired 6/1/2021 b) Black marking dye lot #092020 expired 12/31/2021 c) Red marking day lot # 083863 expired 6/1/2021 2. Approximately 330 patients were tested with expired reagent. 3. The OD confirmed on 7/2/25 at 1:30 pm that the laboratory used expired reagents.</p>

Note: These are the same Marking Dyes cited for being expired 3/26/24. Same lot #'s and expiration dates. B) Based on surveyor observation of Histopathology reagents and interview with the OD, the laboratory used expired Histopathology reagents from 10/31/24 to the 7/2/25. The findings include: 1. High Def 1% Lot # 133297 Expired 10/31/2024. 2. Gill 3 Hematoxylin Lot #180061 Expired 2/28/25. 3. Vintage Bluing Lot # 144960 Expired 3/31/25. 4. Approximately 330 patients were tested with expired reagent. 5. The OD confirmed on 7/2/25 at 1:30 pm that the laboratory used expired reagents.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on survey review of the Biannual assessment (BA) records, Laboratory Reagents and interview with the Onsite Dermatologist (OD) the Laboratory Director (LD) failed to ensure the Quality Assurance (QA) program was maintained to assure the quality of laboratory services from 3/26/24 to 7/2/25. The finding includes: 1. The laboratory used expired marking dye which was cited on the previous survey 3/26/24. Cross refer D5417 2. The laboratory used expired Bluing agent, Hematoxylin, and High Diff 1%. Cross refer 5417 3. The Laboratory failed to perform BA in 2024 and 2025. D5217 4. The OD confirmed on 7/2/25 at 1:40 pm, the QA program was not maintained,.