

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2104214	<b>(X3) Date Survey Completed</b> 03/21/2024
<b>Name of Provider or Supplier</b> Dermatology Institute & Laser Center	<b>Street Address, City, State</b> 35 Green Pond Rd, Rockaway, 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>D5217</b>	<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 the lack of Biannual Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to verify the accuracy of Histopathology testing in the calendar years 2022. The OM confirmed on 3/21/24 at 11:30 am that the laboratory did not perform BA for Histopathology.</p>
<b>D5401</b>	<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: A) Based on surveyor review of the Procedure Manual (PM), and interview with the Office Manager (OM), the laboratory failed to follow the procedure for "Proficiency Testing" for histopathology testing. The findings include: 1. The PM states "List of board certified dermatologists for this office" as "Dr Armin Bijal" and "Dr Marc Jacobson" 2. There was no documented evidence that the aforementioned doctors participated in the "Proficiency testing" procedure. 3. The OM confirmed on 3/21/24 at 11:00 am, the laboratory failed to follow the PM. B) Based on surveyor review of the Procedure Manual (PM), observation of Staining Station (SS) and interview with</p>

the Office Manager (OM), the laboratory failed to follow the PM for Hematoxylin-Eosin (HE) staining from 9/15/22 to the date of the survey. The findings include: 1. The PM stated two dips of "95% Alcohol" after Eosin dip., the SS had one 2. The PM stated for steps fourteen, fifteen and sixteen as three changes of "100% Alcohol" the SS had two. 3. The OM confirmed on 3/21/24 at 1:30 pm that the laboratory did not follow the PM.

**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 10/16/19 to the date of survey. The findings include: 1. Adventek Tissue marking dyes were expired as follows: a) Blue marking day lot # 115434 expired 1-31-2023 b) Yellow marking dye lot # 121748 expired 5-31-2023 c) Red marking day lot # 123231 expired 5-31-2023 2. Approximately 200 patients were tested with expired reagent. 3. The OM confirmed on 3/21/24 at 12:30 pm that the laboratory used expired reagents.