Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2104214	09/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Institute & Laser Center	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Practice Owner (PO) the laboratory failed to follow its policies and procedures for assessing the competency of TP who perform Histopathology testing at the date of survey. The findings include: 1. The CA was not performed on one out of one TP in the calendar years, 2020, and 2021. 2. The laboratory CA policy stated that testing personnel are evaluated annually. 3. The PO confirmed on 9/15/22 at 1:20 pm the laboratory did not follow the CA procedure.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Practice Owner (PO), the laboratory failed to follow all procedures written for Moh's tests from July 2020 to the date of the survey. The findings include: 1. There was no documented evidence the below mentioned procedure were followed: a. "C. Annually:

	Have preventative maintenance services performed on the MOHS pathologist Microscope". 2. The PO confirmed on 9/15/22 at 1:30 pm that the laboratory did not follow the PM.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: a. Based on the lack of Temperature Logs (TL) and interview with the Practice Owner (PO), the laboratory failed to monitor and document Room Temperature (RT) and Humidity where Histopathology tests were performed from 8/2/19 to the date of survey. The PO confirmed on 9/15/22 at 1:30 pm that the laboratory did not document RT and Humidity. b. Based on the lack of Temperature Logs (TL) and interview with the Practice Owner (PO), the laboratory failed to to monitor and document temperature range for the Cryostat used in Histopathology tests from 8/2/19 to the date of the survey. The PO confirmed on 9/15/22 at 1:40 pm that the laboratory did not document temperature range for the Cryostat.
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 surveyor review of Quality Control (QC) records and interview with the Practice Owner (PO), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reaction from 8/2/19 to the date of survey. The findings include: 1. The laboratory did not document H&E QC reaction for reading of Histopathology slides. 2. The laboratory read and reported approximately 450 patients. 3. The OM confirmed on 9/13522 at 1:20 pm that the laboratory did not document H&E QC stain reaction.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

	This STANDARD is not met as evidenced by: Based on the lack of the Biannual Assessment (BA) records and interview with the Practice Owner (PO), the Laboratory Director failed to ensure BA was performed to evaluate the laboratory's performance accurately 8/2/19 to the date of survey. The PO confirmed on 9/15/22 at 1:00 pm the BA was not performed to evaluate the laboratory's performance accurately.