Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2104214	03/23/2018
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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to establish a written procedure for Biannual Assessment (BA) from June 2017 to the date of survey. The LD confirmed on 3/23/18 at 12:00 pm that a BA procedure was not established.
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), observation of the Automated Staining Station (ASS) and interview with the Laboratory Director (LD), the laboratory failed to follow Mohs Staining Procedure from June 2017 to the date of the survey. The findings include: 1. The ASS in the laboratory did not correspond with the staining procedure in the PM. a) The PM stated Staining Container (SC) # 7 was for Scott's Bluing reagent but it was not on the ASS. b) The ASS had SC # 9 for

	95% alcohol but it was not in the PM. c) The PM had SC # 10 and 11 for 95% alcohol but there was no alchol in # 10 and 11 on ASS. d) The ASS had four 100% alcohol in SC # 10, 11, 12 and 13 but the PM stated three SC. e) The PM had Histoclear in SC # 15 but there no SC label for histoclear on ASS. 2. The LD confirmed on 3/23/18 at 12: 45 pm that PM procedure did not match with ASS.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the Staining Station and interview with the Laboratory Director (LD), the laboratory failed to label all staining jars used for Mohs testing from June 2017 to the date of the survey. The LD confirmed on 3/23/18 at 12: 35 pm that the staining jars were not labeled.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory records and interview with the Laboratory Staff (LS), the laboratory failed to establish a maintenance protocol for automated stainer and Fume Hood when protocols were not provided by the manufacturer from June 2017 to the date of survey. The LS confirmed on 3/23/18 at 12:20 pm that the laboratory did not establish maintenance protocol.
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 surveyor review of the Biannual Assessment (BA) records and interview

	with the Laboratory Director (LD), the LD failed to review and evaluate the results of Histopathology tests received from the reviewer for the calender year 2017. The LD confirmed on 3/23/18 at 12:15 pm that the LD did not review the BA records.