Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2135998	06/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
All Island Dermatology	100 Village Square Suite 170, Glen Cove, NY	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the Mohs laboratory's procedure manual and interview with the office manager, the laboratory failed to establish written procedures for twice per year verification and remediation of any discrepant results found during the twice yearly verification of histopathology testing.
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: Based on a lack of humidity records and an interview with the office manager, the laboratory failed to follow the manufacturer's instructions to monitor and document the room humidity where testing is performed. Findings Include: It was confirmed by the office manager, on June 7, 2019 at approximately 11:00 AM that the laboratory failed to follow the manufacturer's criteria to monitor and document the humidity of the room where Mohs testing is performed from April 2018 through the date of this survey.
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's observation of the laboratory's testing area and an interview with the office manager, the laboratory used testing materials beyond manufacturer's expiration date. FINDINGS: Surveyor observed one bottle of 1% Eosin lot # 62877 expired October 2018 and one bottle of Hematoxylin lot # 420353 expired January 2019. Indate container of Eosin and an indate container of Hematoxylin were not available for use. Approximately 30 Moh's patient biopsy specimens were processed and test results released using the expired stain reagents.