Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1038446	11/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Institute	2001 Santa Monica Blvd Ste 1160w, Santa Monica, CA	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory's policy and procedure, 5 patient reports, the associated daily biopsy log book sheets, and an interview with the laboratory staff, the pathology laboratory reports reviewed failed to indicate evidence assuring tissue and patient identification integrity. The findings include: a.The daily biopsy log book sheet indicated specimen size, such as 3 mm (millimeter) for a given patient. The pathology report indicated a microscopic description and specimen type, but not a gross tissue description, number of sections submitted nor tissue size. The tissue slide returned to the laboratory in each of the 5 cases reviewed had multiple tissue sections stained. The patient/tissue integrity could therefore not be assured given the single tissue being sent for biopsy, and the fact that multiple sections were returned. b. The laboratory staff on 11/22/2019 at 12:30 pm affirmed that a gross description, along with any description of the number of tissue sections prepared, was not on the pathology report. c. The laboratory's testing declaration signed by the laboratory Director on 11/20/2019, stated that the laboratory performs 746 Histology tests annually.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary

	to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory's policy and procedure, QC records, and an interview with the laboratory staff, the laboratory failed to demonstrate a procedure for corrective action. The findings include: a.The laboratory had documentation for procedure testing, but there was not a procedure in the event corrective action was needed if there was a discrepancy (for example, a discrepancy in peer review or slide /patient identification). b. The laboratory staff on 11/22/2019 at 12:30 pm affirmed that a corrective action procedure in the event of discrepancy did not exist. c. The laboratory's testing declaration signed by the laboratory Director on 11/20/2019, stated that the laboratory performs 746 Histology tests annually.