Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2108993	12/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
California Dermatology Specialists	11645 Wilshire Blvd Ste 1080, Los Angeles, 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 review of patient biopsy slides, patient final electronic testing report (medical record (EMR), slide labeling and interview with a laboratory personnel and laboratory director, it was determined that from 02/01/2017 through 09/24/2018 for one (1) out of ten (10) patients testing records reviewed, the laboratory failed to establish and follow written policies and procedures for specimen collection and labeling for each biopsy specimen source. The findings included: a. Review of one (1) patient's unique identifier(s) (accession #) found on the histopathology biopsy slide was incorrectly transcribed in the final patient biopsy pathology report (EMR). Biopsy Date Slide # EMR # 04/17/2017 P17-002761 A1 P17-002760 b. On 12/19/2018, 11: 45 AM (survey date), the laboratory director affirmed that the unique identifier(s) (Accession #) on biopsy slides and the patient final testing report (EMR) did not match. c. Based on the laboratory's annual test volume declaration (12/19/2018) the laboratory performed 85 patient initial biopsies annually.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, random review of patients test reports 02/01/2017 through 09/24/2018, and an interview with the laboratory director, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic quality assessment systems for 2017 and 2018 to the date of the survey. The Findings include: a. The surveyor requested on 12/19/108 (survey date) documentation of ongoing quality assessment (QA) for the postanalytic system includes assessing practices/issues related to test report monitoring and evaluating the accuracy and completeness of the laboratory's test reports and the laboratory's turn-around times and procedures for notification of test results. b. The laboratory director conffirmed 12/19/2018 11:45 AM (survey date) that the laboratory did not have a written policy and procedure to assess monitor and correct problem in the postanalytical systems. c. No documentation could be retrieved at the time of the survey to indicate that the postanalytic review was conducted by a designated person for an ongoing mechanism to monitor, assess and, when indicted, correct problems when identified. (See D5203)