Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2060295	02/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
San Diego Family Dermatology	15725 Pomerado Rd Ste 102, Poway, 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 laboratory documents for Mohs procedures, histopathology slides, and patients test records; and interview with laboratory personnel, the laboratory failed to follow written policies and procedures to ensure accurate specimen identification from the time of collection through completion of testing and reporting of results. Findings include: a. The laboratory log book of Mohs procedures performed included the following records: Date Patient Site M16# ---------- 9/22/16 H, J R mid Helix 133 " W, B L med Shin 134 b. M16-133 1) The Mohs Flow Sheet documented the Location as R mid helix. 2) 3 out of 7 slides for patient H, J were mislabeled as "M16-134, L med Shin" c. M16-134 1) The Mohs Flow Sheet documented the Location as L medial shin, but was crossed out and re-stated as "Temple". 2) The Mohs Micrographic Operative Report documented that the procedure was performed on "L Temple". 3) 2 out of 2 slides for patient W, B were mislabeled as "L Med Shin". d. Laboratory personnel affirmed (2/15/18) the aforementioned discrepancies in the Mohs records and slides; and thus, the failure to ensure accurate identifications from time of collection through completion of testing and reporting of Mohs procedures. e. The accuracy and quality of Mohs records and slides could not be assured. The laboratory stated the estimated volume of Mohs procedures performed annually as 252. .
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on survey findings and deficiency cited (D5203), the laboratory failed to establish a written policy and maintain the practice to monitor and assess all Mohs records and histopathology slides from time of specimen collection through completion of testing and reporting of results to ensure accuracy and correct problems as they occur. Findings include: a. Errors occurring on 9/22/2016 were not identified in the laboratory's routine random reviews for quality assessment. The errors were identified 17 months later during this CLIA onsite survey/inspection. See D5203. b. The accuracy and quality of Mohs records and slides could not be assured. The laboratory stated the estimated volume of 252 Mohs procedures performed annually for 2016 and 2017.