

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2097959	(X3) Date Survey Completed 12/03/2020
Name of Provider or Supplier California Dermatology Care	Street Address, City, State 500 Alfred Nobel Dr Ste 185, Hercules, 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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on an audit of 5 patient reports as part of the quality assessment review (in the date range of 1/1/2019-12/1/2020) and the associated tissue slides, the laboratory failed to establish/monitor an ongoing mechanism to detect mistakes of slide labeling (analytic process). The diagnostic abbreviation on one patient slide did not match that on the procedure report. Findings include: 1. On 12/3/2020, an audit was conducted from 10 a.m. to 11:30 a.m. with a review of 5 randomly selected MOHS patients 2. One of the audit cases demonstrated an inconsistency in the slide labelling vs. the diagnosis indicated on the procedure report. The patient under review indicated a procedure logbook diagnosis of SCC, and the slide also indicated SCC. The associated procedure report indicated skin cancer type of BCC. The internal patient ID number, procedure date and name were consistent. 3. A representative of the laboratory (LP) confirmed on (12/3/2020 at 10:45 a.m. that the above descriptions were inconsistent. No corrective action was documented.</p>