

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0605685	(X3) Date Survey Completed 10/20/2020
Name of Provider or Supplier Csi Medical Group	Street Address, City, State 9460 No Name Uno Ste 210, Gilroy, 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 1/1/2019-9/1/2020) and the associated tissue slides, the laboratory failed to establish/monitor an ongoing mechanism to detect mistakes of slide labeling (analytic process). Findings include: 1. On 10/20/2020, an audit was conducted from 3:00 p.m. to 4:30 p.m. with a review of 5 randomly selected MOHS patients 2. One of the audit cases demonstrated an inconsistency in the procedure anatomic patient location in the patient logbook vs. the patient report. The patient under review indicated a procedure logbook location of left nose on 9/13/19, and the associated laboratory report indicated a clinical location of left ear. 3. A representative of the laboratory (LP) confirmed on (10/20/2020 at 3:45 p.m. that the above descriptions were inconsistent. No corrective action was documented.</p>