

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2018804	(X3) Date Survey Completed 10/21/2020
Name of Provider or Supplier Jennifer Baron Md, A Medical Corporation	Street Address, City, State 123 Di Salvo Ave, Ste A, San Jose, 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 1/1/2019-10/20/2020) and the associated tissue slides, the laboratory failed to establish/monitor an ongoing mechanism to detect mistakes of the internal documentation process (analytic process) as it relates to correlation with the dates in the patient log book and the actual procedure date. Findings include: 1. On 10/21/2020, 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 date in the patient logbook vs. the patient report. The patient under review indicated a procedure logbook date of 9/25/2019 and the patient report indicated a procedure date of 9/26/2019 (correct date). 3. Upon further review, it was determined that the MOHS service had mis-dated the internal log book for all the cases on that date (indicating a date of 9/25/2019 instead of 9/26/2019). 4. A representative of the laboratory (LP) confirmed on 10/21/2020 at 3:45 p.m. that the above dates in the logbook were indeed inconsistent with the patient reports for that day. No corrective action was documented</p>