

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2054758	(X3) Date Survey Completed 10/18/2019
Name of Provider or Supplier Mohs Micrographic Surgery Laboratory	Street Address, City, State 3140 Kearney St, Bldg 2, 2nd Fl, Fremont, 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 review of patients test records, the Laboratory Personnel Report (CLIA)[10/15/19], and the laboratory policy for quality assessment of histopathology testing; and interview with laboratory personnel, it was determined that the laboratory failed to establish a policy and process for assessing quality and at least twice annually verify the accuracy of Mohs procedures performed by additional testing personnel. Findings included: a. Review of Mohs records and the CLIA Personnel Report revealed procedures were performed by additional Mohs surgeons, as follows: Mohs surgeon Dates ----- Testing Person - 5 2019: July Testing Person - 6 2019: August, September, October b. Laboratory personnel affirmed (10/18/19 at 12:00pm) that the policy and practice of "peer review" of Mohs slides had been specific to Testing Person-1; and that no policy or process had been established to verify the accuracy of Mohs procedures performed by the additional Mohs surgeons, Testing Persons 5 & 6. c. The reliability, quality, and accuracy of Mohs procedures performed by Testing Persons 5 & 6 had not been assured.</p>