

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1021032	(X3) Date Survey Completed 10/21/2024
Name of Provider or Supplier James T Wang Md	Street Address, City, State 29833 Santa Margarita Pkwy, Ste 100, Rancho Santa Margarita, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on interview with Laboratory director (LD) and review of laboratory's Proficiency Testing (PT) records on October 21, 2024, it was determined that the Laboratory failed to ensure that the accuracy of the Mohs test was verified at least twice annually for the years 2022, 2023 and 2024. The findings include: 1. It was the practice of the laboratory to perform Mohs Micrographic Surgery, which is not listed in the subpart I of the 42 CFR part 493. For the test procedure not listed in subpart I the laboratory must verify the accuracy of the test procedure twice annually. 2. On October 21, 2024, at approximately 12:30 pm, the laboratory director affirmed that the laboratory maintained no documentation to show it verified the accuracy of Mohs procedure at least twice annually for the years 2022, 2023 and 2024. 3. The laboratory's testing declaration form, signed by the laboratory director on October 15, 2024, stated that the laboratory had performed 200 Mohs procedures annually.</p>
D6082	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1)</p> <p>The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.</p>

This STANDARD is not met as evidenced by:

Based on interview with Laboratory director (LD) and review of laboratory's Proficiency Testing (PT) records on October 21, 2024, it was determined that the Laboratory director failed to ensure that testing systems developed and used for Mohs procedure provides quality laboratory services for all aspects of test performance. See D5217