

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1097142	(X3) Date Survey Completed 03/03/2020
Name of Provider or Supplier R Makala Anders Md Medical Corp	Street Address, City, State 864 2nd St Ste B, Santa Rosa, 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 Surveyor review of laboratory's policy & procedure, patient, quality control and proficiency testing records, and interview with the Laboratory testing personnel, the laboratory failed to verify, at least twice annually, the accuracy of its Mohs testing for the year of 2018 and 2019. The findings include: a. The laboratory performs Mohs procedure which includes onsite tissue processing, slide preparation and reading. The laboratory did not have any documentation showing that it had verified its test accuracy. b. The laboratory testing person, on 3/3/2020 at 11:30 am, affirmed that the laboratory did not verify its Mohs test accuracy, yearly. c. The laboratory's testing declaration form, signed by the laboratory Director on 3/3/2020, stated that the laboratory performs 700 tests, annually.</p>
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are</p>

properly performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, patient, quality control and proficiency testing records, and interview with the laboratory testing personnel, it was determined that the laboratory Director failed to assure compliance with the applicable regulation. See D5217.