

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2138289	(X3) Date Survey Completed 03/09/2023
Name of Provider or Supplier Mccray Dermatology	Street Address, City, State 623 West Ave Q Ste E, Palmdale, 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 proficiency testing records, and interview with the laboratory staff, the laboratory failed to verify, at least twice annually, the accuracy of its histopathology slide reading for the year of 2021 and 2022. The findings include: 1. The laboratory reads skin biopsy slides (histopathology) that are prepared by USC pathology lab. Histopathology slide reading is not listed in subpart I (not regulated), so the laboratory must verify the accuracy of the test or procedure twice annually. The laboratory did not have any documentation showing that it had verified the test accuracy. Therefore, the accuracy of the results provided by the laboratory can not be assured and may have harmed patients. 2. The laboratory staff, on 3/9/2023 at 2:16 pm, affirmed that the laboratory did not verify its biopsy slide reading accuracy. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/23/2023, stated that the laboratory performs 1,354 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</p>

to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's proficiency testing records, and interview with the laboratory staff on 3/9/2023 at 2:16 pm, it was determined that the laboratory director failed to assure compliance with the applicable regulation. See D5217.