

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1043833	(X3) Date Survey Completed 09/19/2023
Name of Provider or Supplier Dermatology Associates	Street Address, City, State 1850 Redondo Ave Ste 108, Signal Hill, 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 review of laboratory records for Mohs procedures performed in 2020, the lack of records, and interview with the Laboratory Director/Testing Person, the laboratory failed to at least twice within the 2020 calendar year verify the accuracy of Mohs procedures to clear skin cancer. Findings included: 1. The laboratory Mohs Log recorded more than two Mohs procedures were performed in 2020. 2. Laboratory records documented microscope slides from one of the Mohs procedures performed in 2020 had been sent to a reference laboratory for review, as the means to fulfill the requirement to verify the accuracy of testing. 3. The laboratory failed to provide records that documented at least one additional case of 2020 Mohs slides had been reviewed to verify accuracy. 4. The Laboratory Director/ Testing Person affirmed (9 /18/23 at 11am) the aforementioned findings. 5. And thus, the accuracy, reliability and quality of the Mohs precedures performed in 2020 had not been assured. .</p>
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:
Based on the deficiency cited, review of the laboratory's 2020 plan of correction, and interview with the Laboratory Director, the laboratory failed to review and assess the effectiveness of its corrective action and prevent recurrence of the same deficiency. Findings included: 1. The laboratory failed to at least twice within the 2020 calendar year verify the accuracy of its Mohs procedures. See D5217. 2. This is a repeated deficiency previously cited for the calendar year 2019. a. The laboratory submitted a plan of correction on 2/20/20, stating: "Two cases will be sent annually for QA or one case + one required pathology education (CME)." "We have put into place a systemic change of sending specimens to an outside lab twice per year. We are placing a reminder within our Mohs Log to have the accuracy check performed twice per year and recorded into the Log." 3. The Laboratory Director affirmed (9/19/23 at 11am) the failure to monitor the effectiveness of the plan of correction in 2020 to prevent recurrence of the deficiency. .

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on the serious and cumulative nature of the deficiencies cited at D5217 and D5793, the Laboratory Director is herein cited for not ensuring quality assessment monitoring was established to follow up with the 2020 plan for corrections and prevent recurrence.