

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2115541	(X3) Date Survey Completed 07/19/2019
Name of Provider or Supplier Precision Dermatology Inc	Street Address, City, State 770 Tamalpias Dr Ste 403, Corte Madera, 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 patients test records, the lack of laboratory records, and interview with a laboratory person, it was determined that the laboratory failed to verify the accuracy of its Mohs dermatopathology slides at least twice annually. Findings included: a. The Laboratory failed to provide documents at least twice annually verifying the accuracy of Mohs dermatopathology slides to final stage of clearing for 2017 - 2018. b. The laboratory person affirmed (7/19/19 at 11:30 AM) the aforementioned lack of records and that the written policy and procedure failed to include verifying the accuracy of Mohs dermatopathology slides to final stage of clearing. c. The reliability and quality of Mohs dermatopathology slides in 2017 - 2018 could not be assured in the absence of verifying the procedures' accuracy at least twice annually. The Laboratory reported (7/08/19) to have performed approximately 500 Mohs cases annually. d. This deficiency was previously cited (3/08/2017). .</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 review of 2017 - 2018 laboratory test records and the Laboratory's Plan of Correction (4/10/2017), the lack of laboratory documents, and interview with a laboratory person, it was determined that the Laboratory failed to review and assess the effectiveness of the 2017 plan of correction, revised policy and procedures, and discussions of quality assessments with appropriate staff. Findings included. a. Patients test records for Mohs dermatopathology slides were randomly selected for review from 2017 - 2018. b. The Laboratory failed to provide documents of quality assessment for reviewing the effectiveness of the 2017 Plan of Correction and discussions with the staff for the 2-year timeframe included in this CLIA survey. c. As a consequence, the Laboratory again failed to provide records at least twice annually verifying the accuracy of its Mohs dermatopathology slides. .

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 survey findings and deficiency cited, the Laboratory Director is herein cited for deficient practice in establishing and documenting quality assessment activities to ensure quality and identify failures as they occur. (see D5793).