

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2080392	(X3) Date Survey Completed 03/09/2021
Name of Provider or Supplier Advanced Dermatology	Street Address, City, State 31150 S Temecula Pkwy Ste 104, Temecula, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Mohs surgery's policies and procedures (P&P) manual, Cryostat temperature records, and interview with the office manager, it was determined that the laboratory failed to follow its written policies and procedures manual in a manner that provides test results within the laboratory's stated performance specifications for histopathology test. The findings included: a. The laboratory performed Mohs surgery and examine the tissue slides prepared immediately onsite. b. A Cryostat equipment was used to cut the tissue for histopathology testing. c. The Mohs P&P manual was reviewed and approved by the current laboratory director on 2/27/2019. 4. Section II. Tissue Collection & Preparation, under I. Cryostat: a. Cryostat temperature is set at an optimum cutting temperature between -20 oC to - 31 oC. e. In a record seen the Advanced Dermatology & Skin Cancer Specialists, Policies and Procedures Manual, page 7, a "DAILY MAINTENANCE LOG" indicated: 2) Log temperature (acceptable range -18 oC to -30oC), recorded and dated Cryostat Temp each day of use. started on 1/5/20 thru 12/2/20 (total of 13) for the year of 2020. f. In a record seen "Temecula" "EQUIPMENT QUALITY CONTROL" "FORMS 18: ROOM AND TEMPERATURE LOG SHEET" Year 2021 had indicated a column of "Range Cryostat" -20 oC to - 30 oC recorded and dated from 1/6 thru 3/3 (2021). g. The laboratory failed to follow its Cryostat optimum temperature setting in the P&P</p>

Manual setting of -20 oC to -30 oC, instead in the year of 2020, using -18 oC to -30 oC, while in the year of 2021 using -20 oC to -30 oC. h. Not following its written P&P manual is not in compliance with the CLIA rules and regulations.

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 review of the laboratory's Mohs surgery's policies and procedures (P&P) manual, Cryostat temperature records, and interview with the office manager, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided. The findings included: a. the laboratory performed Mohs surgery and examine the tissue slides prepared immediately onsite. b. A Cryostat equipment was used to cut the tissue for histopathology testing. c. The optimum/acceptable temperature range written in the Mohs surgery P&P manual is different from the daily operation settings, see D-5411.