

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2214750	(X3) Date Survey Completed 12/15/2022
Name of Provider or Supplier Advanced Dermatology & Skin Cancer Specialists	Street Address, City, State 47647 Caleo Bay Ste 120, La Quinta, 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
D3013	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory's stored tissue slides and interview with the laboratory staff, it was determined that the laboratory failed to maintain and stored under conditions that ensure proper preservation. The findings included: a. The laboratory performed Mohs surgery onsite and stored the tissue slides in the Ziploc plastic bags. b. The slides clumped together and an oil like wetting showed inside the storage bags. c. The laboratory failed to maintain and store the tissue slides properly and failed to ensure proper preservation of the quality of the slides.</p>
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of lack of the documents for evaluation of proficiency testing performance of histopathology testing, and interview with the laboratory staff, it was determined that the laboratory failed to perform at least twice annually for examining Mohs tissue slides and to ensure the accuracy and reliability of patient test results. The findings included: a. The laboratory performed Mohs surgery onsite to examine the tissue histopathology. b. At the time of survey (12/15/2022 @ 10:50 am) the</p>

laboratory staff failed to provide the documents of evaluation of proficiency testing performance. c. The laboratory failed to verify the accuracy of histopathology testing at least twice annually for the year of 2021 and 2022.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on lack of the documents for evaluation of proficiency testing performance of histopathology testing and verification activities to ensure accuracy and reliability of patient test results, and interview with the laboratory staff, it was determined that the laboratory failed to document evaluation of proficiency testing performance and verification activities. The findings included: a. The laboratory performed Mohs surgery onsite and examined histopathology tissue slides. b. At the time of survey (12/15/2022 @ 10:50 am) the laboratory failed to provide documents of evaluation of proficiency testing performance activities to ensure the accuracy and reliability of the test results

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on review of lack of the laboratory's policies and procedures (P&P) and interview with the laboratory staff, it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess in the general laboratory systems requirements. The findings included: a. The laboratory performed Mohs surgery onsite and perform histopathology tissues. b. The laboratory staff failed to provide written policies and procedures (P&P) and documentations at the time of survey (12/15/2022 @ 10:55 am) for histology procedures including evaluation of proficiency testing performance to ensure accuracy of the testing results at least twice annually. c. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirement (see D-5219, and D-5221).

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on lack of the laboratory's procedure manual for histopathology testing including Mohs surgery's histology procedures, and interview with the laboratory staff, it was determined that the laboratory failed to provide written procedure manual for histopathology testing. The findings included: a. The laboratory performed histopathology while performing Mohs surgery onsite. b. The laboratory staff at the time of survey (12/15/2022@ 10 55 am) failed to provide written procedures manual. c. The laboratory failed to establish written procedure manual for histopathology services.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on review of the Cryostat temperature records, and interview with the laboratory staff, it was determined that the laboratory failed to define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. These conditions must be monitored and documented and include the temperature. The findings include: a. The laboratory performed Mohs surgery onsite and outsource the histology service. b. Review of the "EQUIPMENT QUALITY CONTROL FORM 18: ROOM AND TEMPERATURE LOG SHEET" Month ____ (not indicated) and Year was 2021, under the column of "Room Temperature" and Cryostat", there were temperature recorded as follow: RT = room temperature in Fahrenheit, CT = cryostat temperature in Celsius Date RT CT 1/27 74 F -26 C 3/17 76 F -22 C 5/19 77 F -20 C 7/18 75 F -24 C 5.5.22 (?) 73 F -23 C 7.27.22 73 F -21 C 9.28.22 73 F -19 C 11.21.22 (?) 72 F -19 C c. The laboratory failed to indicate the acceptable temperature ranges for both room and cryostat temperature so one can understand the operation activity was perform within acceptable temperature.

D6095

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:
Based on observation, review of lack of laboratory manual, records, and documents, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. The findings included: a. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. b. The laboratory performed Mohs surgery onsite

and examined histopathology testing. c. The laboratory failed to store and maintain the slides under conditions that ensure proper preservation (D-3013). d. The laboratory failed to establish the laboratory procedure manual (D-5401), e. The laboratory failed to perform evaluation of proficiency testing performance and verify accuracy of the patient test results (D-5219, D-5221 and D-5291), f. The laboratory failed to establish and indicate the acceptable temperature ranges for room and cryostat temperatures (D-5413).