

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2087829	(X3) Date Survey Completed 02/13/2020
Name of Provider or Supplier Advanced Dermatology & Skin Cancer Specialists	Street Address, City, State 1180 N Indian Cyn Dr Ste E315, Palm Springs, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the facility, review of lack of the laboratory records, and phone conversations with the testing personnel and Mohs histotech manager, it was determined that the laboratory failed to retain the laboratory records and documents related to the tissue slides prepared while performing Mohs surgery by the histology laboratory technicians. The findings included: a. The laboratory failed to retain and continue to retain documents for all tissue slides preparation activities. b. No documents were available to ensure the evaluation of proficiency testing performances for 2018 and 2019 (see D-5217). c. The laboratory failed to retain and document the quality controls activities for negative/positive slides in 2018 and 2019 as of 02/13 /2020 on site. d. The laboratory failed to retain, if any, the Mohs Tech Annual Personnel Competency Evaluation (see D-5209).</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel competency evaluation records, and</p>

phone conversations with the testing personnel and Mohs histotech manager, it was determined that the laboratory failed to follow its written policies and procedures (P&P) to assess the competency of the employees. The findings included: a. Review of previous "Mohs Tech Annual Personnel Competence Evaluation" records, it was noted that the evaluation records stopped at the end of year of 2017. b. There were missing documents of competency evaluation for the Mohs Tech after 2018 thru 2019.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of lack of evaluation of proficiency testing performance for histopathology for the year of 2018 and 2019, and phone contacts with the testing personnel and the Mohs Histotech Manager, it was determined that the laboratory failed, at least twice annually, to verify the accuracy of the histopathology testing the laboratory performed. The findings included: a. The laboratory performed histopathology while Mohs surgery procedures been performed, which is not listed in the subpart I of 42 CFR part 493. b. The laboratory failed to, at least twice annually, verify the accuracy of the histology testing procedures by either enrolling in a proficiency testing program or using split sample with a qualified testing personnel. c. There were missing documents for the evaluation of proficiency testing performance of the testing personnel for 2018, and 2019.

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 laboratory's "Daily Maintenance Record", and phone contacts with the testing personnel and Mohs tech Manager, it was determined that the laboratory Mohs Tech failed to monitor and document the temperature conditions of the Cryostat equipment which is essential for accurate and reliable test system operation, and test result reporting when performing Mohs procedures. The findings included: a. Review a "Daily Maintenance Record" established for Advance Dermatology & Skin Cancer Specialists - Mohs Laboratory Manual, no Cryostat temperature been monitored and documented after 6/12/18, i.e. last part of 2018 and the entire year of 2019 and up to current date of 2/13/2020. b. Each histotech was reminded by the policies and procedures and must address in the record, to follow 4 procedures to complete the identified items listed while doing the slide preparations including, but are not limited to the followings: "Temp", "Isopropyl alcohol as needed", "Eosin as needed", "Reagent Alcohol", etc. c. The histotech used a "check"

	<p>mark to indicate that something has been done, but no explanations what are the check mark mean? c. No explanations were available what a check mark indicates?</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory supply stored, and interview with the office personnel, it was determined that the laboratory failed to indicate and to label the open date with the expiration date of the reagents or supplies used to prepare/stain Mohs tissue slides. The findings included: a. The laboratory performed Mohs surgery tissue slides preparation onsite. b. The laboratory stores the reagents and supplies for preparing the tissue slides. c. Among them are Hematoxyline 2 and Reagent Alcohol 200 proof. d. No dates marked or identified for open date with a expiration date for each reagent once it was opened to assure the strength and the stability of the reagents used.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory facility, review of the laboratory records, and phone interview with the laboratory testing person and the Mohs histotech Manager, it was determined that the laboratory director failed to ensure that the quality control programs were established and maintained to assure the quality of laboratory services provided. The findings included: a. The laboratory failed to retain its laboratory operation activity records, see D-3031 b. The laboratory failed to perform competency evaluation of the histotech's, see D-5209</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory facility, review of the laboratory records, and phone interview with the laboratory testing person and the Mohs histotech Manager, it was determined that the laboratory director failed to ensure that the quality assessment</p>

programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included: a. The laboratory failed to retain its laboratory operation activity records for years, see D-3031 b. The laboratory failed to perform competency evaluation of the histotech's for years, see D-5209 c. The laboratory failed to perform, at least twice annually, to verify the accuracy of the proficiency testing performance, see D-5217.

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 of the laboratory facility, review of the laboratory records, and phone interview with the laboratory testing person and the Mohs histotech Manager, 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 failed to retain and continue to document its laboratory operation activity records, see D-3031 b. The laboratory failed to perform competency evaluation of the histotech's, see D-5209 c. The laboratory failed to perform, at least twice annually, to verify the accuracy of the proficiency testing performance, see D-5217. d. The laboratory failed to maintain and to assure the testing systems, equipment or reagents in optimal conditions and to provide accurate, reliable and timely results, see D-5413 and D-5415.