

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 29D2129860	(X3) Date Survey Completed 06/22/2021
Name of Provider or Supplier Mohave Dermatology-Pahrump	Street Address, City, State 1420 E Calvada Blvd Ste 100, Pahrump, NV	
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
D0000	<p>This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on June 22, 2021. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.</p>
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on a random patient audit between the dates of March 14, 2019 and April 1, 2021, a review of the director approved policy and procedure entitled "Quality Assurance Policy," and an interview with the Office Manager, the laboratory failed to ensure that positive patient identification was maintained throughout the testing process for one of ten patient records reviewed. Findings include: 1. A random patient audit between the dates of March 14, 2019 and April 1, 2021 revealed that for the April 1, 2021 Mohs case number P21-62, the labels on two of two slides did not include the date of birth in accordance with the director approved policy entitled "Quality Assurance Policy." 2. The director approved policy entitled "Quality Assurance Policy," in the section entitled "Analytic" stated, "A log will be created by the Mohs Technician so that he/she can maintain an accurate record of specimens he /she has been processing on each Mohs day. This log will include the following information; Patient (Last, First) name, Date of Birth (DOB), Unique Identifier (DOB), Mohs date, and site being performed. The same information that is presented</p>

on the log will also need to be on the patient Mohs map and slides." 3. The Office Manager confirmed the findings during an interview conducted on June 22, 2021 at approximately 10:00 AM. The laboratory performs approximately 96 Histopathology tests annually.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory records of the annual preventative maintenance for the microscope, and an interview with the Office manager, the laboratory failed to retain records of the annual preventative maintenance for the microscope for the years of 2018, 2019 and 2020. Findings include: 1. There were no records for the annual preventative maintenance for the laboratory microscope between the dates of August 7, 2017 and March 1, 2021. 2. The Office Manager confirmed the findings during an interview conducted on June 22, 2021 at approximately 9:30 AM. The laboratory performs approximately 96 Histopathology tests annually.

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 a random patient audit between the dates of March 14, 2019 and April 1, 2021, a review of the laboratory quality assessment daily checklist records, a review of the director approved policy entitled "Quality Assurance Policy" and an interview with the Office manager, the director failed to ensure that the established quality assessment program was maintained to detect and correct failures in quality when they occur. Findings include: 1. A random patient audit between the dates of March 14, 2019 and April 1, 2021 revealed that for the April 1, 2021 Mohs case number P21-62, the quality assessment review conducted did not detect the failure to include the patient Date of Birth (DOB) on the labels of two of two patient slides as the unique patient identifier in accordance with the director approved policy entitled "Quality Assurance Policy." 2. The director approved policy entitled "Quality Assurance Policy," in the section entitled "Analytic" stated, "A log will be created by the Mohs Technician so that he/she can maintain an accurate record of specimens he/she has been processing on each Mohs day. This log will include the following information; Patient (Last, First) name, Date of Birth (DOB), Unique Identifier (DOB), Mohs date, and site being performed. The same information that is presented on the log will also need to be on the patient Mohs map and slides." 3. The director approved policy

entitled "Quality Assurance Policy," in the section entitled "Post-Analytic" stated, "After Mohs has been completed for the day, Medical Assistant and Office Manager will review all documents and patient charts to assure that everything is input correctly. A check-list will be created every Mohs day to ensure that all patient information has been checked thoroughly." 4. The Quality Assurance checklist created on April 2, 2021 for the Mohs procedure date of April 1, 2021, in the section entitled "Slides," the failure to include the patient DOB on the slides was not detected and corrected. 5. The Office Manager confirmed the findings during an interview conducted on June 22, 2021 at approximately 10:00 AM. The laboratory performs approximately 96 Histopathology tests annually.