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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 03D2184889 | (X3) Date Survey Completed 08/12/2022 |
| Name of Provider or Supplier Arizona Mohs Surgery, Pllc | Street Address, City, State 7530 N Oracle Rd, Suite 102, Tucson, AZ | |
| 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 |
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| D3043 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with the laboratory manager on August 12, 2022, the laboratory policies and procedures lacked the requirements for retention of histopathology micrographically oriented hsitographic surgery (Mohs) slides. The findings include: 1. Review of the laboratory's Policies and procedures revealed the lack of retention requirements for the Mohs slides created for patient Dermatopathology testing. 2. The laboratory manager confirmed by interview on August 12, 2022 at 3:00 pm the lack of a policy or procedure for retention of Dermatopathology Mohs slides. 3. The laboratory reports performing 1193 Mohs Dermatopathology patients annually.</p> |
| D3045 | <p>RETENTION REQUIREMENTS CFR(s): 493.1105(b)</p> <p>If the laboratory ceases operation, the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are retained and available for the time frames specified in this section.</p> <p>This STANDARD is not met as evidenced by:</p> |

Based on review of the laboratory's policy and procedure manual, and interview with the laboratory manager, the laboratory failed to have a policy or procedure providing provisions if the laboratory should cease operation for Dermatopathology micrographically oriented histographic surgery (Mohs) testing regarding retention of patient records and slides. Findings include: 1. The laboratory is a privately owned entity performing Dermatopathology Mohs testing since May of 2020. 2. Review of the laboratory's policy's and procedure's revealed the lack of reference to the retention and storage of patient testing records and slides if the laboratory ceased operations. 3. The laboratory manager confirmed by interview on August 12, 2022 at 3:30 pm, the lack of a policy or procedure for retention of patient records and dermatopathology slides if the lab ceased operations. 4. The laboratory reports performing 1193 dermatopathology slide reviews annually.

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on review of laboratory policy's and procedure's, laboratory maintenance records, observations during laboratory tour, and interview with the laboratory manager on August 12, 2022, the laboratory failed to perform and document annual function checks as outlined in their policy. Findings include: 1. The laboratory performs micrographically oriented histographic surgery (Mohs) Dermatopathology staining under a fume hood in the cryostat and nurse computer station area. 2. The laboratory policy "Air Vent/Fume Hood Policy" states the fume hood function check would be performed and documented annually. 3. Review of maintenance records reviewed revealed the lack of documentation of annual fume hood function check being performed for 2021 and 2022 post installation in 2020. 4. Tour of the laboratory revealed the lack of a function check sticker of the laboratory fume hood. 5. The laboratory manager confirmed by interview on August 12, 2022 at 3:30 pm the lack of following their policy for performing and documenting fume hood function checks. 6. The laboratory reports performing 1193 Mohs slides annually.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
Based on personnel record review and the laboratory's policy's and procedure's on August 12, 2022, the laboratory director failed to establish a policy and procedure for monitoring the competency of the micrographically oriented histographic surgery

(Mohs) technician. Findings include: 1. The laboratory has one (1) Mohs technician who is responsible for the operation and maintenance of the laboratory's Cryostat and Dermatopathology Mohs slide stain processing. 2. The laboratory lacked documentation of the competency for the (1) Mohs technician for 2021 and 2022. 3. The laboratory manager confirmed by interview the lack of policy or procedure for performing and documenting competency for the Mohs technician on August 12, 2022 at 4:00 pm. 4. The laboratory performs 1193 Mohs dermatopathology testing annually.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on personnel record review and interview with the laboratory manager on August 12, 2022, the laboratory director failed to specify, in writing, the responsibilities and duties of the micrographically oriented histographic surgery (Mohs) Technician and identify which examinations and procedures the Mohs Technician is authorized to perform. Findings include: 1. The laboratory personnel Job description for the Mohs Technician lacks the specification of the responsibilities for the Mohs technician for staining, quality control, retention of Dermatopathology slides and to perform as the Quality Assessment coordinator for the laboratory. 2. The laboratory manager confirmed by interview the lack of delegation of authority, and specifications of responsibilities as cited above. 3. The laboratory reports performing 1193 Dermatopathology patient tests annually.