

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2160722	(X3) Date Survey Completed 01/17/2024
Name of Provider or Supplier A To Z Dermatology	Street Address, City, State 1821 N Trezell Rd Suite 2, Casa Grande, 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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's microscope maintenance policy and interview with the facility personnel, the laboratory failed to perform and document the annual preventative maintenance of the microscope used for patient testing under the subspecialty of Histopathology. Findings include: 1. The laboratory began testing on March 13, 2021 in the subspecialty of Histopathology with an annual test volume of 100. 2. The laboratory's established microscope maintenance policy reviewed during the survey states: "Grounding check is monitored yearly." 3. The laboratory failed to provide evidence of annual preventative maintenance from 2021 and 2022 for the microscope used for reading patient's Mohs slides. 4. The facility personnel interviewed on 1/17/24 at 11:40 AM confirmed the laboratory failed to provide documentation of annual preventative maintenance from 2021 and 2022 for the microscope used by the laboratory to read patient slides.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time</p>

of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on review of patient test records for Mohs testing, review of the Mohs log and interview with the facility personnel, the laboratory failed to maintain a copy of the Mohs map for one out of three patient records. Findings include: 1. The laboratory began Mohs testing on patients on 3/13/21 under the subspecialty of Histopathology with an annual test volume of 100. 2. One out of three patient test records reviewed during the survey (63-2021 from 12/7/21) was missing the Mohs map. The map was not scanned into the patient's electronic records and the facility personnel could not produce evidence of the map during the survey. 3. The facility personnel interviewed on 1/17/24 at 11:25 AM confirmed the Mohs map indicated above could not be located at the time of the survey.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of Mohs test reports maintained in the Electronic Health Record (EHR) and interview with the facility personnel, one out of five Mohs test reports reviewed in the EHR failed to include the case number. Findings include: 1. The laboratory performed Mohs testing on patients under the subspecialty of Histopathology with an annual test volume of 100. 2. It is the practice of the laboratory to assign a unique case number to each Mohs case, and the unique case number is manually transcribed into the operative test report maintained in the EHR. 3. One out of three operative Mohs reports reviewed during the survey in the EHR (Case# 02-2023 on 12/8/23) failed to include the unique case number. 4. The facility personnel interviewed on 1/17/24 at 11:30 AM confirmed the Mohs operative report maintained in the EHR for the patient indicated above failed to include the unique Mohs case number.