

|  |  |   |
|--|--|---|
| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>03D2160360       | <b>(X3) Date Survey Completed</b><br><br>01/10/2024 |
| <b>Name of Provider or Supplier</b><br><br>A To Z Dermatology  | <b>Street Address, City, State</b><br><br>13650 N 99th Ave Ste 100, Sun City, AZ |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
|---------------------------|---|
| <b>D5203</b>              | <p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b><br/>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:<br/>Based on review of Mohs test records and interview with the facility personnel, the laboratory failed to ensure positive identification on one out of five dermatopathology specimens from the time of collection of the specimen through completion of testing and reporting of test results. Findings include: 1. The laboratory performed Mohs and Frozen biopsy testing under the subspecialty of Histopathology from 1/25/21 through 11/22/22. The laboratory performed 189 tests between 1/25/21 and 11/22/22. 2. One out of five Mohs test records reviewed during the survey (Case# SC65-2022 from 7/5/22) failed to ensure positive patient identification throughout the entire testing process. The patient's slides, Mohs log, and Mohs map were labeled with the patient's last name listed as "Bobstick," while the operative report maintained in the patient's EMR listed the last name as "Bostick". 3. The facility personnel interviewed on 1/10/24 at 10:55 AM acknowledged that the laboratory failed to ensure positive identification of the patient's specimens from the time of collection through completion of testing and reporting of results as indicated above.</p> |
| <b>D5217</b>              | <p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b><br/>CFR(s): 493.1236(c)(1)</p> <p>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.</p>   |

This STANDARD is not met as evidenced by:  
Based on lack of accuracy verification documentation for Mohs testing and Frozen Biopsy testing and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the subspecialty of Histopathology at least twice annually during 2021 and 2022. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of Mohs testing at least twice annually during 2021 and 2022. 2. No documentation was presented for review to indicate the laboratory verified the accuracy of Frozen Biopsy testing at least twice annually during 2021 and 2022. 3. The facility personnel interviewed on 1/10/24 at 10:40 AM confirmed the laboratory failed to verify the accuracy of Mohs testing and Frozen Biopsy testing at least twice annually during 2021 and 2022. 4. The laboratory performed 189 patient tests from 1/25/21 through 11/22/22.

**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 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. Findings include: 1. The laboratory performed Mohs and Frozen biopsy testing under the subspecialty of Histopathology from 1/25/21 through 11/22/22. The laboratory performed 189 patient tests during that timeframe. 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 to read patient slides. 4. The facility personnel interviewed on 1/10/24 at 10:45 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.

**D5473**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to test and document the acceptability of the

Hematoxylin & Eosin (H&E) staining materials each day of use for intended reactivity and to ensure predictable staining characteristics. Findings include: 1. The laboratory performed Mohs and Frozen biopsy testing on patients under the subspecialty of Histopathology from 1/25/21 through 11/22/22. The laboratory tested 189 patients during that time frame. 2. No documentation of the H & E stain acceptability was presented for review for Mohs testing that occurred on 9/27/22. Ten patients were tested on 9/27/22. 3. The facility personnel interviewed on 1/10/24 at 10:30 AM confirmed the laboratory failed to test and document the H&E stain acceptability on 9/27/22.

**D5787**

**TEST RECORDS**  
CFR(s): 493.1283(a)

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 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 and interview with the facility personnel, the laboratory failed to maintain a copy of the the Mohs map for one of out five patients. Findings include: 1. The laboratory performed Mohs and Frozen biopsy testing on patients under the subspecialty of Histopathology from 1/25/21 through 11/22/22. The laboratory performed 189 patient tests during that timeframe. 2. One out of five patient test records reviewed during the survey (SC09-2022 from 1/24/22) 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 1/10/24 at 10:10 AM confirmed that the Mohs map indicated above was not presented for review during 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 and Frozen biopsy testing on patients under the subspecialty of Histopathology from 1/25/21 through 11/22/22. The laboratory

performed 189 patient tests during that timeframe. 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 five operative Mohs reports reviewed during the survey in the EHR (Case# SC65-2022 on 7/05/22) failed to include the unique case number. 4. The facility personnel interviewed on 1/10/24 at 11:05 AM confirmed the Mohs operative report maintained in the EHR for the patient indicated above failed to include the unique Mohs case number.