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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>03D1002763      | <b>(X3) Date Survey Completed</b><br><br>01/10/2024 |
| <b>Name of Provider or Supplier</b><br><br>All Dermatology   | <b>Street Address, City, State</b><br><br>14239 W Bell Rd Ste 101, Surprise, 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>   |
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| <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 the laboratory's Mohs logs, Mohs maps, patient slides and final test reports maintained in the patient's Electronic Medical Record (EMR), and interview with the facility personnel, the laboratory failed to ensure positive identification of a patient's dermatopathology specimens from the time of collection through completion of testing and reporting of test results. Findings include: 1. The laboratory performs testing in conjunction with the Mohs procedure under the subspecialty of Histopathology with an annual test volume of 1,017. 2. It is the practice of the laboratory to label each Mohs slide with two patient identifiers, Date of Birth (DOB) and patient name, to ensure positive patient identification throughout the testing process. 3. Seven out of seventeen Mohs slides (all Stage II slides) for patient B.W. from 10/10/23 were labeled with the incorrect DOB. 4. The facility personnel interviewed on 1/10/24 at 1:05 PM confirmed the patient's slides indicated above were labeled with the incorrect DOB.</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 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 2023. Findings include: 1. The laboratory performs testing in conjunction with the Mohs procedure under the subspecialty of Histopathology with an annual test volume of 1,017. 2. No documentation was presented for review to indicate the laboratory verified the accuracy of the microscopic interpretation (for Mohs) at least twice annually during 2023. 3. The facility personnel interviewed on 1/10/24 at 1:33 PM confirmed that the laboratory failed to verify the accuracy of dermatopathology testing at least twice annually during 2023.

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:  
Based on review of established quality assessment (QA) policies and procedures and interview with the facility personnel, the laboratory failed to follow established QA policies to monitor, assess and correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. The laboratory performs testing under the subspecialty of Histopathology, with an annual test volume of 1,017. The laboratory performs the microscopic interpretation (reading/diagnosis) of histopathology specimens which are read during the Mohs procedure. 2. The laboratory's established QA policy presented for review during the survey states, "Two cases, annually, per physician, per location, per testing category, are sent to ClinPath Diagnostics to be reviewed by a local qualified provider. Documentation and review of these tests are maintained in the Slide Review Book and retained for a minimum of two years as required by CLIA Regulations." 3. The laboratory failed to follow the established QA policy indicated above as evidenced by the laboratory's failure to verify the accuracy of at least two Mohs cases in 2023. See D5217 for findings. 4. The facility personnel interviewed on 1/10/24 at 1:40 PM confirmed the laboratory failed to follow their established QA policy and procedure regarding accuracy verification for Mohs testing.

**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 document the acceptability of the Hematoxylin &

Eosin (H&E) staining materials on 90 out of 116 testing days, for intended reactivity and to ensure predictable staining characteristics. Findings include: 1. The laboratory performs testing in conjunction with the Mohs procedure under the subspecialty of Histopathology with an annual test volume of 1,017. 2. The laboratory performs the Hematoxylin and Eosin (H&E) stain on patient specimens prior to the microscopic interpretation. 3. The laboratory failed to document the acceptability of the H&E stain on 90 out of 116 testing days during the timeframe of 8/31/21 through 1/09/24. 4. 402 patients were tested from 8/31/21 through 1/09/24. 5. The facility personnel interviewed on 1/10/24 at 1:45 PM confirmed the laboratory failed to document the H&E stain acceptability each day of use for intended reactivity and to ensure predictable staining characteristics during the timeframe indicated above.