| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 03D0666037 | 01/16/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Associates In Dermatology Care Dba | 11000 N Scottsdale Rd, Ste 120, Scottsdale, 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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| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of cryostat and room temperature records from one testing date in October 2024 and interview with the facility personnel, the laboratory failed to monitor and document the temperature of the cryostat and the room temperature where dermatopathology reagents are utilized and stored on each day of patient testing. Findings include: 1. The laboratory processes specimens and interprets dermatopathology slides in conjunction with Mohs surgery, with an approximate annual test volume of 122. 2. The laboratory failed to monitor and document the temperature of the room where dermatopathology reagents are utilized on 10/18/2024. 3. The laboratory failed to monitor and document the temperature of the cryostat which is used to process patient specimens on 10/18/2024. 4. The laboratory tested 9 patients on 10/18/24. 5. The facility personnel interviewed on 1/16/2025 at 1:25 PM confirmed that the laboratory failed to monitor and document the room temperature of the laboratory and the temperature of the cryostat on 10/18/2024. |
| **D5473** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(2)(g) |

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| | (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.<br><br>This STANDARD is not met as evidenced by:<br>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 1 out of 3 testing dates reviewed during the survey, for intended reactivity and to ensure predictable staining characteristics. Findings include: 1. The laboratory performs Mohs under the subspecialty of Histopathology with a reported annual test volume of 122. 2. The laboratory failed to document the acceptability of the H&E stain on 1 out of 3 testing dates (10/18/2024) reviewed during the survey. 3. The laboratory tested 9 patient's specimens using the H&E stain on 10/18/24. 4. The facility personnel interviewed on 1/16/2025 at 1:20 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 on the testing date indicated above. |