

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 03D2051228	<b>(X3) Date Survey Completed</b> 08/20/2024
<b>Name of Provider or Supplier</b> Dermatology & Plastic Surgery Of Arizona	<b>Street Address, City, State</b> 150 S Coronado Dr, Ste 110, Sierra Vista, 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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE 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> <p>This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for Melan-A (MART-1), Cytokeratin (CK5) 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 2022 and 2023. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of Frozen Biopsy, MART-1, and CK5 testing at least twice annually during 2022. 2. No documentation was presented for review to indicate the laboratory verified the accuracy of CK5 testing at least twice annually during 2023. 3. The facility personnel interviewed on 8/20/24 at 11:10 AM confirmed the laboratory failed to verify the accuracy of the testing listed above at least twice annually during 2022 and 2023. 4. The laboratory performs 950 tests annually under the subspecialty of Histopathology.</p>
<b>D5301</b>	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of test requisition documentation for review and interview with the facility personnel, the laboratory failed to have a written or electronic request for</p>

patient testing for three out of three patient records reviewed during the survey. Findings include: 1. The laboratory performs the following special stains: Melan-A (MART-1) and Cytokeratin (CK5). These stains are performed on patient slides as needed and as requested by an authorized person. 2. No written or electronic request for the stains indicated above were presented for review for three out of three patient records reviewed during the survey: MART-1 (patient ID: I22-008 performed on 8/3/22 and patient ID: I23-14 performed on 5/16/23); CK5 (patient ID: I24-007 performed on 3/19/24). 3. The facility personnel interviewed on 8/20/24 at 11:30 AM confirmed the laboratory failed to have an electronic or written test requisition for the special stains performed on the patients indicated above. 4. The laboratory performs approximately 20 special stains annually.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on lack of humidity records for review from 2022, 2023 and 2024, review of the manufacturer's specifications for the Leica CM1520 Cryostat and interview with the facility personnel, the laboratory failed to monitor and document the ambient humidity of the room where the cryostat is utilized. Findings include: 1. The laboratory utilizes the Leica CM1520 Cryostat in conjunction with Mohs testing under the subspecialty of Histopathology with an annual test volume of 950. 2. The manufacturer's specifications for the Leica CM1520 Cryostat reviewed during the survey listed an operating relative humidity range of 0%-60%. 3. On the survey date of 8/20/2024, the laboratory failed to provide documentation demonstrating the ambient humidity of the room where the cryostat is utilized was monitored and recorded on each day of patient testing from 2022 through 2024 through the survey date of 8/20/2024. 4. The facility personnel interviewed on 8/20/2024 at 10:15 AM confirmed the laboratory failed to monitor and document the ambient humidity as indicated above.