

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2045055	<b>(X3) Date Survey Completed</b>  04/11/2024
<b>Name of Provider or Supplier</b>  Arizona Dermatology Specialists, Pllc	<b>Street Address, City, State</b>  14800 W Mountain View Blvd, Ste 160, 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>
<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 review of policies and procedures, lack of test requisition documentation for review and interview with the facility personnel, the laboratory failed to have a written or electronic request for patient testing for two out of two patient records reviewed during the survey. Findings include: 1. The laboratory performs Frozen Biopsies (Sections) in conjunction with the Mohs procedure under the subspecialty of Histopathology. 2. The laboratory's "Frozen Section Procedure" reviewed during the survey states: "All specimens will be accompanied with a pathology requisition completed in the patient room." 3. No written or electronic request for Frozen Biopsy testing was presented for review for two out of two patient records reviewed during the survey (patient ID: FSS22-06 performed on 4/14/22, and patient ID: FSS23-12 performed on 6/15/23). 4. The facility personnel interviewed on 4/11/24 at 10:45 AM confirmed the laboratory failed to have an electronic or written test requisition for the Frozen Biopsies performed on the patients indicated above. 5. The laboratory performs approximately 20 Frozen Biopsies annually.</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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</p>

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 Linistat Linear Stainer and interview with the facility personnel, the laboratory failed to monitor and document the humidity of the room where the above instrumentation is utilized. Findings include: 1. The laboratory utilizes the Linistat Linear Stainer in conjunction with Mohs testing under the subspecialty of Histopathology with a reported annual test volume of 2,784. 2. The manufacturer's specifications for the Linistat Linear Stainer reviewed during the survey listed an operating relative humidity range of 0% - 80%. 3. On the survey date of 4/11/2024, no documentation was provided for review to indicate the laboratory monitored and documented the humidity of the room where the above instrumentation is utilized on each day of patient testing during 2022, 2023 and 2024 through the date of the survey. 4. The facility personnel interviewed on 4/11/2024 at 11:10 AM confirmed the laboratory failed to monitor and document the ambient humidity as indicated above.