

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D2092598	<b>(X3) Date Survey Completed</b>  09/15/2025
<b>Name of Provider or Supplier</b>  Omni Dermatology, Inc	<b>Street Address, City, State</b>  11851 N 51st Ave Ste E130, Glendale, 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 the microscopic interpretation of Frozen Biopsy specimens 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 2024. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of the microscopic interpretation of Frozen Biopsy specimens at least twice annually during 2024. 2. The facility personnel interviewed on 9/15/25 at 11:40 AM confirmed the laboratory failed to verify the accuracy of Histopathology testing at least twice annually during 2024. 3. The laboratory performed four frozen biopsies in 2024.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of test procedures for testing performed under the subspecialty of Histopathology and interview with the facility personnel, the laboratory failed to</p>

establish a written test procedure for Frozen Section Biopsy testing. Findings include:

1. The laboratory performs testing under the subspecialty of Histopathology with a reported annual test volume of 540.
2. No documentation was presented for review during the survey conducted on 9/15/25 to indicate the laboratory established a written test procedure for Frozen Section Biopsy testing.
3. The facility personnel interviewed on 9/15/25 at 11:40 AM confirmed the laboratory failed to establish a written test procedure for Frozen Biopsy testing.