

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0687900	(X3) Date Survey Completed 09/05/2025
Name of Provider or Supplier Arizona Dermatology - Paradise Valley	Street Address, City, State 4835 E Cactus Rd, Ste 155, 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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's humidity logs, lack of corrective action documentation and interview with the facility personnel, the laboratory failed to document corrective action taken for humidity measurements that were outside the laboratory's established range for 88 out of 88 testing dates from July 2024 through January 2025. Findings include: 1. The laboratory's established humidity range as indicated on the Daily Maintenance Log is "less than 60%." 2. Review of the Daily Maintenance Logs from July 24, 2024 through January 14, 2025 revealed the documented humidity measurement exceeded the laboratory's established humidity range on 88 out of 88 testing dates. 3. The laboratory failed to document corrective action taken for the humidity measurements that were outside the laboratory's established humidity range on the 88 testing dates indicated above. 4. The facility personnel interviewed on 9/05/25 at 12:55 PM confirmed the laboratory failed to document corrective action for the humidity measurements that were outside the laboratory's established humidity range for the 88 testing dates indicated above. 5. The laboratory performs testing in the subspecialty of Histopathology with a reported annual test volume of 1,600.</p>

D5801**TEST REPORT**

CFR(s): 493.1291(a)

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of final test results for Mohs maintained in the Electronic Health Record (EHR) and interview with the facility personnel on September 5, 2025 at 12:40 PM, the laboratory failed to accurately transcribe Mohs test result information into the patient's EHR for one out of four patient records reviewed during the survey. Findings include: 1. Patient-specific data and the final test result information for Mohs is manually transcribed by laboratory personnel into the patient's EHR. 2. One out of four Mohs cases reviewed (# 23652) failed to include the correct number of Mohs stages in the patient's EHR. The Mohs map, patient's slides, and the laboratory's Mohs log indicated the number of Mohs stages as 4. The Mohs test information maintained in the EHR indicated the number of Mohs stages as 3. 3. No documentation was presented for review during the survey conducted on 9/05/25 to indicate the laboratory has a system in place to ensure the accuracy of patient-specific data and patient test results that are manually entered by laboratory staff into the patient's EHR. 4. The facility personnel interviewed on 9/05/25 at 12:40 PM acknowledged the test result error for Mohs case# 23652 and confirmed the laboratory failed to have a system in place to verify the accuracy of patient-specific data and patient test results that are manually entered into the EHR. 5. The laboratory performs testing in the subspecialty of Histopathology with a reported annual test volume of 1,600.