

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0940907	(X3) Date Survey Completed 03/06/2025
Name of Provider or Supplier Alliance Dermatology & Mohs Center	Street Address, City, State 14506 W Granite Valley Dr, Ste 220, Sun City West, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's established policy and procedure for the accuracy verification process for Mohs testing and interview with the facility personnel, the laboratory failed to follow the established policy and procedure for one out of one discrepancies found during the accuracy verification process performed in 2024 for Mohs testing. Findings include: 1. The laboratory's established policy titled, "Protocol for Accuracy Check Discrepancies" states, "If there is a discrepancy between our diagnosis and the secondary diagnosis, we will send the case to a third lab for verification. Upon receipt of the third verification, the Laboratory Director will assess further and treat the patient accordingly. Any discrepancy must be recorded on Form 23: Request for Corrective Action and kept in the Mohs Book. This will be reviewed with lab personnel." 2. Review of the accuracy verification records from 2024 indicated a diagnosis discrepancy was identified on one out of one Mohs cases reviewed, patient J.S. from 5/03/2024. See D5821 for specific findings. 3. No evidence was presented for review during the survey conducted on 3/06/25 to indicate the laboratory sent the case referenced above to a third lab for verification, resulting in the laboratory's failure to follow the established policy stated above. 4. No evidence was presented for review during the survey conducted on 3/06/25 to indicate the laboratory documented the diagnosis discrepancy on "Form 23: Request for Corrective Action", resulting in the laboratory's failure to follow the established policy stated above. 5. The facility personnel interviewed on 3/06/25 at 1:40 PM</p>

confirmed the laboratory failed to follow the established policy and procedure stated above for one diagnosis discrepancy identified during the accuracy verification process performed in 2024. 6. The laboratory performs the microscopic interpretation of Mohs specimens in the sub-specialty of Histopathology, with an approximate annual test volume of 529.

D5821

TEST REPORT
CFR(s): 493.1291(k)

(k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on review of test verification records from 2024, lack of a corrected test report for testing performed in conjunction with the Mohs procedure and interview with the facility personnel, the laboratory failed to issue a corrected test report for one out of one patients tested in the sub-specialty of Histopathology. Findings include: 1. The laboratory performs Mohs on patient specimens in the sub-specialty of Histopathology, with an approximate annual test volume of 529. It is the practice of the laboratory to maintain the Mohs test report (operative note) and the Mohs map in the patient's Electronic Medical Record (EMR). 2. It is the practice of the laboratory to send at least two previously diagnosed Mohs cases to a board-certified Dermatopathologist twice annually for review to verify the accuracy of the original diagnosis. 3. The accuracy verification records reviewed for 2024 indicated a discrepancy for one Mohs case, patient J.S. from May 3, 2024. The test report from 5/03/24 containing the original diagnosis indicated the malignant cells (squamous cell carcinoma) were removed at Stage 1 with the operative note stating, "No residual tumor seen. There were no malignant cells seen in the sections examined." The accuracy verification records for this case noted a checkmark for "Disagree with original diagnosis" with the reviewing physician noting "Squamous Cell Carcinoma in situ (Bowen Disease), No invasive carcinoma." 4. No documentation was presented for review during the survey to indicate the laboratory issued an amended/corrected test report as a result of the diagnosis discrepancy identified for the Mohs case referenced above. 5. The facility personnel interviewed on 3/06/25 at 1:35 PM confirmed the laboratory failed to issue an amended test report for the discrepancy identified in the case stated above.