

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2017722	(X3) Date Survey Completed 01/13/2026
Name of Provider or Supplier Alliance Dermatology	Street Address, City, State 313 S Beeline Hwy, Payson, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel policies and interview with the facility personnel on 1/13/26 at 11:59 AM, the laboratory failed to follow established policies and procedures to assess the competency of one out of three testing personnel (TP-1) who perform the microscopic interpretation of Mohs specimens. Findings include: 1. The laboratory performs the microscopic interpretation of Mohs specimens in the subspecialty of Histopathology, with an approximate annual test volume of 1,200. 2. The CMS-209, Laboratory Personnel Form listed 3 testing personnel who read and interpret slides. 3. The laboratory policy reviewed during the survey states, "Ensure accuracy verification is completed for everyone who reads/interprets slides. The accuracy verification can be used as evidence of annual competency for these individuals." 4. The laboratory failed to perform and document annual competency for TP-1 during 2025, as evidenced by the lack of accuracy verification records specific to TP-1 during 2025. 5. The facility personnel interviewed on 1/13/26 at 11:59 AM confirmed the laboratory failed to follow the established personnel competency policy indicated above to assess the competency of TP-1 during 2025.</p>
D5217	<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>

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 on 1/13/26 at 11:50 AM, the laboratory failed to verify the accuracy of Frozen Biopsy testing performed under the subspecialty of Histopathology at least twice annually during 2025. 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 2025. 2. The facility personnel interviewed on 1/13/26 at 11:50 AM confirmed the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2025. 3. The laboratory performed 8 frozen biopsies in 2025.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

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.

This STANDARD is not met as evidenced by:
Based on lack of established policies and procedures for review and interview with the facility personnel on 1/13/26 at 11:55 AM, the laboratory failed to establish policies and procedures for the accuracy verification process of Mohs and Frozen Biopsy specimens tested by the laboratory. Findings include: 1. The laboratory performs the microscopic interpretation of Mohs and Frozen Biopsy specimens in the subspecialty of Histopathology with a reported annual test volume of 1,200. 2. No documentation was presented for review to indicate the laboratory established policies and procedures related to the accuracy verification process for Mohs and Frozen Biopsy testing, including but not limited to, the frequency of the review, number of cases reviewed, individual or laboratory performing the review and a remedial action plan in the event of a noted discrepancy. 3. The facility personnel interviewed on 1/13/26 at 11:59 AM confirmed the laboratory failed to provide evidence of an established policy and procedure specific to the verification of accuracy process for the microscopic interpretation of Mohs and Frozen Biopsy specimens.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

(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.

This STANDARD is not met as evidenced by:
Based on review of test procedures on 1/13/26 at 11:45 AM for testing performed in the subspecialty of Histopathology and interview with the facility personnel, the laboratory failed to establish a written test procedure for Frozen Section Biopsy testing. Findings include: 1. The laboratory performs testing in the subspecialty of Histopathology with a reported annual test volume of 1,200. 2. No evidence was

presented for review during the survey conducted on 1/13/26 to indicate the laboratory established a written test procedure for Frozen Section Biopsy testing. 3. The facility personnel interviewed on 1/13/26 at 11:45 AM confirmed the laboratory failed to establish a written test procedure for Frozen Biopsy testing. 4. The laboratory performed the microscopic interpretation of 8 Frozen Biopsy specimens in 2025.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of pathology test reports for Frozen Biopsy interpretations and interview with the facility personnel on 1/13/26 at 11:40 AM, the laboratory failed to include the test report date, gross description and two patient identifiers on 1 out of 1 frozen biopsy test reports reviewed during the survey. Findings include: 1. The laboratory performs the diagnostic interpretation of Frozen Biopsy specimens in the subspecialty of Histopathology, and performed 8 Frozen Biopsies in 2025. 2. One out of one frozen biopsy test reports reviewed during the survey failed to include the test report date, the gross description and failed to include at least two positive patient identifiers. 3. The facility personnel interviewed on 1/13/26 at 11:40 AM acknowledged that the test report date, gross description and two positive patient identifiers were missing from the frozen biopsy test report reviewed during the survey.