

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D0940907	<b>(X3) Date Survey Completed</b>  05/15/2023
<b>Name of Provider or Supplier</b>  Alliance Dermatology & Mohs Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Mohs documentation and Frozen Biopsy documentation for review (QC records, temperature logs and microscope maintenance records) and interview with the facility personnel, the laboratory failed to retain records of analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. Findings include: 1. The laboratory performs the microscopic interpretation of patient specimens in conjunction with the Mohs procedure and performs Frozen Biopsies under the subspecialty of Histopathology, with an approximate annual test volume of 760. 2. The laboratory maintains monthly logs (documented each day of patient testing) of the following analytic records for Mohs and Frozen Biopsy testing: Hematoxylin &amp; Eosin quality control logs, room temperature and cryostat temperature logs, and microscope maintenance logs. It is the practice of the laboratory to scan these monthly logs (as a packet, labeled by month and year) into the laboratory's computer system. 3. During the survey conducted on May 15, 2023, the laboratory failed to provide evidence of the monthly analytic records indicated above for June 2022. 4. The number of patients tested during June 2022 could not be determined at the time of the survey. 5. At approximately 11:10am on 5/15/23, the facility personnel confirmed the laboratory could not locate the analytic test records from June 2022 in the laboratory's computer system.</p>
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p>

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)  
(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to document the acceptability of Hematoxylin & Eosin (H&E) staining materials each day of use for intended reactivity to ensure predictable staining characteristics. Findings include: 1. The laboratory performs the microscopic interpretation of Frozen Biopsy specimens and patient specimens during the Mohs procedure in the sub-specialty of Histopathology, with a reported annual test volume of 760. Each specimen is stained with the H&E stain prior to the microscopic interpretation. 2. No documentation of the H&E stain acceptability was presented for review for testing that occurred during June 2022. 3. A total of 2 Frozen Biopsies were performed during June 2022. The number of patient specimens tested in conjunction with the Mohs procedure during June 2022 could not be determined at the time of the survey. 4. The facility personnel interviewed on May 15, 2023 at 11:05am confirmed the laboratory failed to provide evidence of the H&E stain acceptability, for intended reactivity to ensure predictable staining characteristics, from June 2022.