

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2017722	(X3) Date Survey Completed 09/04/2024
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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation for one out of four testing dates reviewed during the survey 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. No documentation of the H&E stain acceptability was presented for review for Mohs testing that occurred on October 19, 2023. 2. A total of 9 Mohs cases were performed on the date indicated above. 3. The facility personnel interviewed on September 04, 2024 at 11:50 AM confirmed the laboratory failed to document the H&E stain acceptability on the testing date indicated above, for intended reactivity to ensure predictable staining characteristics.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p>

This STANDARD is not met as evidenced by:

Based on lack of quality assessment (QA) documentation from 2023 and interview with the facility personnel, the laboratory failed to follow established QA policies and procedures to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. Findings include: 1. It is the practice of the laboratory to perform an annual review of the patient testing process and document the review on a form titled, "Quality Assessment Review Form and Checklist". 2. No QA documentation was provided for review from 2023. 3. The facility personnel interviewed on 09/04/24 at 12:10 PM confirmed the laboratory failed to provide documentation of an annual QA review from 2023.