

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D2066117	(X3) Date Survey Completed 01/14/2025
Name of Provider or Supplier Bingham Dermatology Group	Street Address, City, State 2855 E Brown Rd Ste 28, Mesa, 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
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> <p>This STANDARD is not met as evidenced by: Based on lack of accuracy verification documentation for Mohs and interview with the testing personnel, the laboratory failed to verify the accuracy of testing performed under the subspecialty of Histopathology at least twice annually during 2023 and 2024. Findings include: 1. No documentation was presented for review to indicate the laboratory verified the accuracy of Mohs testing at least twice annually during 2023 and 2024. 2. The testing personnel interviewed on 1/14/25 at 12:00 PM confirmed the laboratory failed to verify the accuracy of Mohs testing testing at least twice annually during 2023 and 2024. 3. The laboratory's reported annual test volume under the subspecialty of Histopathology is 700.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p>

This STANDARD is not met as evidenced by:

Based on lack of humidity records for review from 2023 and 2024, review of the manufacturer's specifications for the Advantik QS12 Cryostat and interview with the facility personnel, the laboratory failed to monitor and document the ambient humidity of the room where the cryostat is utilized. Findings include: 1. The laboratory utilizes the Advantik QS12 Cryostat in conjunction with Mohs testing under the subspecialty of Histopathology with an annual test volume of 700. 2. The manufacturer's specifications for the Advantik QS12 Cryostat reviewed during the survey listed an operating relative humidity range of 0%-60%. 3. The laboratory failed to provide documentation demonstrating the ambient humidity of the room where the cryostat is utilized was monitored and recorded on each day of patient testing from 2023 through 2024 (through the survey date of 1/14/2025). 4. The facility personnel interviewed on 1/14/2025 at 11:50 AM confirmed the laboratory failed to monitor and document the ambient humidity as indicated above.