

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D1027924	<b>(X3) Date Survey Completed</b>  04/09/2026
<b>Name of Provider or Supplier</b>  Dmg Dermatology Institute	<b>Street Address, City, State</b>  2155 City Gate Lane, Naperville, IL	
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>D5413</b>	<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> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, cryostat maintenance records, and interview with the testing personnel (TP) #9; the laboratory failed to record cryostat temperatures for six of six days of patient testing reviewed for Mohs micrographic surgery. Findings include: 1. Review of the laboratory's policy and procedure manual revealed the procedure titled "Mohs tissue processing and mapping protocol" which stated " 6. Ensure the cryostat temperature is set at the optimum cutting temperature, between -18 and -35 degrees (C). 7. Update logs for temperature." 2. Review of "Cryostat maintenance record" documents revealed the laboratory failed to document cryostat temperatures for six of six patient testing days reviewed for Mohs micrographic surgery testing. Mohs Case #: Date of testing: SM24-346 04/19/2024 SM24-656 07/11/2024 SM25-01 01/09/2025 SM25-533 05/05/2025 SM25-1602 12/18/2025 SM26-96 01/22/2026 3. Interview with TP #9 on 04/09/2026 at 11:36 am confirmed the laboratory failed to record cryostat temperature prior to use for six of six patient testing days.</p>
<b>D6128</b>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p>

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Review of the laboratory's policies and procedures, personnel records, lack of documentation, and interview with the laboratory representative; the technical supervisor (TS) failed to ensure competency evaluations were completed for three of eight testing personnel (TP) that performed potassium hydroxide (KOH) preparations. Findings Include: 1. Review of the laboratory's policy and procedure manual revealed the policy titled "Derm Lab Competency Assessment Policy" which stated: "Policy Competency of personnel is assessed on an on-going basis with appropriate intervention when necessary. Assess and document the performance of individuals responsible for testing semiannually during the first year and annually thereafter." 2. Review of laboratory personnel records revealed no competency assessments for three of eight TP listed on the CMS-209 as TP #4, #5 and #6 for KOH preparations in 2025. 3. On survey date 04-09-26, at 10:30 am, the laboratory representative confirmed that the laboratory failed to perform competency assessments for three of eight TP that perform KOH preparations.