

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2259174	(X3) Date Survey Completed 01/17/2024
Name of Provider or Supplier Meridian Dermatology	Street Address, City, State 3250 N Leslie Way Ste 110, Meridian, ID	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (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 a record review of laboratory logs, the cryostat manual and an interview with the laboratory histotechnician on 1/17/2024, the laboratory failed to document humidity and room temperature as required for operation of the Leica cryostat while performing Mohs procedures. The findings include: 1. A review of the laboratory's logs identified that the laboratory failed to document humidity and room temperature since beginning Mohs testing in February of 2023. 2. A review of the manual for the Leica CM1510S cryostat identified an operational humidity of less than 60% and an operating temperature of 18-35 C. 3. An interview with the laboratory histotechnician on 1/17/2024 at 11:25 am confirmed that the laboratory fail to document humidity and room temperature. 4. The laboratory reports performing 50 Mohs procedures annually.</p>
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</p>

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 a review of laboratory stain documents and an interview with the laboratory histotechnician on 1/17/2024, the laboratory failed to have documentation of daily Hematoxylin and Eosin (H&E) stain quality control (QC). The findings include: 1. A review of H&E stain logs identified that the laboratory failed to document QC of H&E stains since beginning Mohs testing in February 2023. 2. An interview with the laboratory histotechnician on 1/17/2024 at 11:33 am confirmed that the laboratory failed to have documentation of H&E stain QC. 3. The laboratory reports performing 50 Mohs cases annually.