

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0525768	(X3) Date Survey Completed 11/02/2023
Name of Provider or Supplier Cedar Dermatology	Street Address, City, State 166 W 1325 N #250, Cedar City, UT	
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 document review, direct observation, and interview with the lab manager, room temperature and humidity of the laboratory was not monitored and documented since the last survey conducted on 10/30/2019. The laboratory performs approximately 2798 MOHS procedures annually using the Microtome Cryostat HM 505 E. Findings include: 1. Document review of the Microtome Cryostat HM 505 E Instruction Manual revealed the cryostat requires an operating environment of 5C to 40C and relative humidity of up to 60%. 2. Direct observation of the laboratory on 11/02/2023 at 10:00 AM failed to locate a thermometer or hygrometer in the laboratory. 3. In an interview on 11/02/2023 at 10:05 PM, the lab manager confirmed room temperature and humidity was not monitored and documented for the Microtome Cryostat HM 505 E</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3)</p>

Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on direct observation and interview with the lab manager, the laboratory failed to properly label eight of eight bottles of tissue marking dyes used in MOHS procedures since the last survey on 10/30/2019. The laboratory performs approximately 2798 MOHS procedures annually. Finding include: 1. Direct laboratory observation on 11/02/2023 at approximately 9:50 AM, found eight of eight bottles of tissue marking dyes were not labeled with their storage requirements, preparation dates, and expiration dates. 2. In an interview on 11/02/2023 at approximately 9:55 AM, the lab manager confirmed that the tissue marking dyes were not properly labeled.