

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  03D1026009	<b>(X3) Date Survey Completed</b>  11/08/2023
<b>Name of Provider or Supplier</b>  Ronald M Mann, Md, Pc DbA Catalina Dermatology	<b>Street Address, City, State</b>  7355 E Tanque Verde, Tucson, AZ	
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>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 lack of humidity records for review from 2021, 2022 and 2023, review of the manufacturer's specifications for the cryostat, and interview with the facility personnel, the laboratory failed to monitor and document the humidity of the area where the cryostat is utilized. Findings include: 1. The laboratory utilizes the Leica CM1860 Cryostat to process patient samples for Mohs testing. The laboratory's reported annual test volume in the subspecialty of Histopathology is 1,100. 2. The manufacturer's specifications for the Leica CM1860 Cryostat reviewed during the survey listed an operating relative humidity range of 20% - 60%. 3. On the survey date of 11/08/2023, no documentation was provided to indicate the laboratory monitored and documented the humidity of the room where the cryostat is utilized for each day of patient testing during 2021, 2022 and 2023, through the date of the survey. 4. The facility personnel interviewed on November 8, 2023 at 12:00 PM confirmed the laboratory failed to monitor and document the humidity as indicated above.</p>