

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0885259	<b>(X3) Date Survey Completed</b>  08/24/2021
<b>Name of Provider or Supplier</b>  Tulane Medical Center-Dermatology	<b>Street Address, City, State</b>  4720 South I10 Service Rd West, Metairie, LA	
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>D0000</b>	An Initial survey was performed on August 24, 2021 at Tulane Dermatology Clinic, CLIA ID # 19D0885259. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<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 observation by surveyor, review of the laboratory's temperature logs, manufacturer's instrument manual, and interview with personnel, the laboratory failed to monitor the room humidity where the cryostat is utilized for twelve (12) of twelve (12) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on August 24, 2021 at 1:46 pm revealed the laboratory utilizes the Leica CM 1520 cryostat for Mohs (histopathology) testing. 2. Review of the manufacturer's manual revealed the following: "All specifications related to temperature of the cooling unit are valid only for an ambient temperature of 22 degrees Celsius and a relative humidity of no more than 60%." 3. Review of the laboratory's temperature logs from September 2020 through August 2021 revealed the laboratory did not document humidity readings each day of operation. 4. In interview on August 24, 2021 at 2:16 pm, the Mohs Tech stated the laboratory does not monitor humidity.</p>
<b>D6087</b>	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5413.