

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2008472	<b>(X3) Date Survey Completed</b>  09/24/2021
<b>Name of Provider or Supplier</b>  Dermatology & Skin Cancer Surgery Center	<b>Street Address, City, State</b>  1020 W Ralph Hall Pkwy, Suite 102, Rockwall, TX	
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>	<p>An entrance conference was held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiency and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<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 direct observation, review of the Leica CM 1520 Cryostat operator's manual (V1.5 RevG-10/2016), review of the Leica ST4020 Automated Stainer operator's</p>

manual (V1.0-02/20), review of laboratory environmental records (01/02/2020-09/21/2021), and confirmed in staff interview, the laboratory failed to ensure room temperature ranges were within specifications for the Leica CM 1520 Cryostat and the Leica ST 4020 Automated Stainer for 100 of 100 days. Findings included: 1. During a tour of the laboratory area on 09/24/2021 at 10:25 am, a Leica CM 1520 cryostat (Serial Number 1369) and a Leica ST4020 Automated Stainer (Serial Number 0365) were observed in use. Another Leica CM 1520 Cryostat was observed in a facility office area. 2. Review of the Leica CM 1520 cryostat operator's manual (V1.5 RevG-10/2016) stated the following in the section titled "Installation Site Requirements": "The place of installation must meet the following requirements: Room temperature consistently 18C - 35C." 3. Review of the Leica ST4020 Automated Stainer operator's manual (V1.0-02/20) stated the following in the section titled, "Instrument Components and Specifications": "3.5 Technical Data ...Operating Temperature Range: 15C - 30C ..." 4. Review of laboratory environmental records (01/02/2020-09/21/2021), titled "Temperature Monitor Log-Cryostat" revealed the laboratory defined an acceptable temperature range of 5 - 25 C. The laboratory failed to ensure the acceptable room temperature was within manufacturer's specifications for the Leica CM 1520 Cryostat and the Leica ST4020 Automated Stainer. 5. In an interview on 09/24/2021 at 10:15 am in the facility office area, after review of the environmental records and instrument specifications, the laboratory representative confirmed the above findings.