

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2001550	(X3) Date Survey Completed 09/23/2021
Name of Provider or Supplier Center For Dermatology & Skin Surgery, Llc	Street Address, City, State 1 West Ridgewood Avenue, Suite 103, Paramus, NJ	
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 surveyor review of the Temperature Log (TL) and interview with the Office Manager (OM), the laboratory failed to define an acceptable temperature range for the Leica Cryostat used in Histopathology tests from 2/3/19 to the date of the survey. The OM confirmed on 9/23/21 at 10:00 am that an acceptable range was not defined.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of the Final Report (FR), Mohs Maps (MM), Accession Log (AL) and interview with the Office Manager(OM), the laboratory failed to ensure that test results are accurately transcribed from the AL to the final destination from 2/3 /19 the date of the survey. The finding includes: 1. One out of ten AL did not correspond with the Mohs map and stage number on the FR. 2. The OM confirmed on 9/23/21 at 10:30 am the laboratory did not ensure that all results were entered accurately.