

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0378556	(X3) Date Survey Completed 05/08/2019
Name of Provider or Supplier Dermatology & Skin Surgery Center	Street Address, City, State 2121 Spring Arbor Rd, Jackson, MI	
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 record review and interview with the office manager, the laboratory failed to monitor and document the room temperature of the laboratory for 2 of 2 years. Findings include: 1. Review of the Operator's Manual under the "Technical Specifications" section for the LINISTAT automatic stainer stated the "Environmental Conditions" for the instrument operation is 5 to 40 degrees Celsius. 2. An interview with the office manager on 5/8/19 at 10:19 am confirmed the above findings.</p>