

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2266906	(X3) Date Survey Completed 03/21/2023
Name of Provider or Supplier Iowa Dermatology Clinic	Street Address, City, State 6000 University Avenue Suite 230, West Des Moines, IA	
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 observation during the laboratory tour, lack of temperature records, review of immunohistochemical (IHC) and special stain package inserts, and confirmed by laboratory personnel identifier # 1 (refer to the Laboratory Personnel Report) at approximately 2:45 pm on 03/21/2023, the laboratory failed to document refrigerator and room temperatures for 56 out of 56 days of patient testing from 01/01/2023- 03/21/2023. The findings include: 1. During a tour, observation of the laboratory revealed IHC stains in the refrigerator and special stains on shelves at room temperature. 2. Review of the IHC stain manufacturer package inserts indicated storage temperature is between 2 and 8 degrees Celsius. 3. Review of the special stain manufacturer package inserts indicated storage temperature is between 15 and 30 degrees Celsius. 4. At the time of the survey, personnel identifier #1 confirmed that the laboratory did not document refrigerator or room temperatures from 01/01/2023 to 03/21/2023.</p>