Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0881101	(X3) Date Survey Completed 08/20/2024
Name of Provider or Supplier Hines Dermatology Associates Inc	**Street Address, City, State** 555 Pleasant St, Attleboro, MA	

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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on record reviewed and confirmed through an interview with the Laboratory Director (LD) and Administrative Assistant (AA), the laboratory failed to monitor and document temperature conditions for the proper storage of mycology dermatophyte test medium and incubation of patient samples for mycology testing. Findings include: 1. Record review on 8/20/2024 of the laboratory's 2023 and 2024 to date temperature monitoring records, revealed: a. The laboratory failed to record the incubator temperature for 189 out of 247 working days when the laboratory was open in 2023. b. The laboratory failed to record the incubator temperature for 136 out of 159 working days when the laboratory was open from January 1, 2024 to date. c. The laboratory failed to record the refrigerator temperature for 190 out of 247 working days when the laboratory was open in 2023. d. The laboratory failed to record the refrigerator temperature for 152 out of 159 working days when the laboratory was open from January 1, 2024 to date. 2. Staff interview with the LD and AA on 8/20/2024 at 11:30 AM confirmed the laboratory did not take daily temperatures of the incubator or mycology media refrigerator. 3. The laboratory performs 75 mycology cultures annually.