Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0866065	03/03/2026
Name of Provider or Supplier	**Street Address, City, State**	
Base Dermatology	26400 W 12 Mile Road Suite 180, Southfield, 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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 observation, record review, and interview with the histotechnician (HT), the laboratory failed to ensure the thermometer used to monitor room temperature and humidity was calibrated prior to patient testing for histopathology tissue slide review. Findings include: 1. During a tour of the laboratory on 03/03/2026 at 9:15 am, the surveyor observed an Extech Instruments Humidity Alert II thermometer in use for monitoring room temperature and humidity without a label indicating the calibration due date. 2. On 03/03/2026 at 9:16 am, the surveyor requested documentation of thermometer calibration from HT; none was provided. 3. A review of the thermometer manufacturer's instructions, in a section titled "Calibration", revealed the following: a. In the paragraph titled "RH Calibration," the instructions state to "insert the meter ' s sensor into a humidity chamber..." b. In the paragraph titled "Temperature Calibration," the instructions state to "place the sensor in a stabilized environment of approximately 21C and check the reading after 1 hour..." 4. An interview conducted on 03/03/2026 at 9:20 am with the HT confirmed the thermometer had not been calibrated prior to patient testing and was put into service on 03/02/2026. Four patients were tested on 03/03/2026 while the thermometer was in use.

D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: . Based on record review and interview with the histotechnician (HT), the laboratory failed to document biannual analytic systems quality assessment activities for 2 (2024 and 2025) of 2 years reviewed. Findings include: 1. A review of the laboratory's policy titled "Quality Systems Policies and Standard Control Measures" and the laboratory's "Quality Assessment Checklist", revealed that analytic systems quality assessment activities are to be completed in the "SPRING and the FALL of EACH YEAR". 2. A review of the laboratory's quality assessment records revealed a lack of documentation of biannual analytic systems quality assessment activities for 2024 and 2025. 3. On 03/03/2026 at 11:28 am, the surveyor requested documentation of quality assessment activities for 2024 and 2025 from the histotechnician (HT); however, none was provided. 4. An interview on 03/03/2026 at 11:45 am with the histotechnician (HT) confirmed that documentation of quality assessment activities for 2024 and 2025 was not available.