Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2172693	10/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
Framingham Dermatology	761 Worcester Road, Framingham, 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
D0000	A CLIA recertification survey was conducted for the Framingham Dermatology laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493. .
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow policies and procedures for twice annual verification of testing it performs that is not included in subpart I of this part as evidenced by the following: a) A review of the laboratory's policies for histopathology skin slide case reviews for MOHS surgery indicated that the Framingham Dermatology staff would select a random case and it would be submitted for review by a pathologist at another lab biannually. b) A review of histopathology skin slide case reviews performed for calendar year 2022 revealed that MOHS skin slide case reviews for accuracy verification were not performed biannually during calendar year 2022. There was only one documented case review performed on 4/25/22. c) The laboratory director confirmed in a telephone interview on 10/12/23 at 12:20 PM that that MOHS skin slide case reviews for accuracy verification were not performed biannually during calendar year 2022. The laboratory performs approximately 80 MOHS slide exams annually. .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the

	current laboratory director before use. This STANDARD is not met as evidenced by: Based on procedure manual review and interview, the laboratory director failed to approve, sign, and date laboratory procedures as evidenced by the following: a) A review of the clinical laboratory procedure manual for biannual quality assessment case reviews for MOHS skin slide exams revealed that the laboratory director had not reviewed and approved the laboratory policy. b) The laboratory director confirmed in a telephone interview on 10/12/23 at 12:20 PM that procedures were reviewed by her annually but documentation could not be found at the time of the survey to verify this fact. c) Based on the lack of procedure review by the laboratory director there was no assurance that laboratory personnel were following established policies and procedures (refer to D5217). The laboratory performs approximately 80 MOHS skin slide exams annually. .
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 review, laboratory personnel were not properly documenting temperature controlled spaces each day of laboratory operation as evidenced by the following: a) A review of temperature records for calendar years 2022 and 2023 revealed that the temperature of the laboratory refrigerator, freezer, cryostat, and water bath were documented for the month of August of 2022 (8/8/22) and for January of 2023 (1/9/23). However ditto marks were entered in subsequently for each of the following months and dates (nine subsequent dates in 2022 and eight subsequent dates in 2023) in lieu of actual temperatures being recorded. b) The laboratory director confirmed in a telephone interview on 10/12/23 at 12:20 PM that the actual temperature for temperature controlled space documentation was not being recorded. Based on the lack of actual temperatures being recorded there was no assurance that temperature controlled spaces were being appropriately monitored.