Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D2112485	03/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Yale Dermatology-Branford	322 East Main St Ste 2g, Branford, CT	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish competency assessment to assess their employees for the year of 2021 before patient testing is performed in the subspecialty of mycology. Findings include: 1. Record review on 03/17/2022 of the staff competency binder revealed lack of documentation for competency assessment for 10 of 10 testing personnel in 2021 for KOH fungal preparation. 2. Staff interview on 03/17/2022 at 9:32 AM with the Laboratory Director confirmed the following: a. The office was closed in 2020 due to COVID-19 pandemic. b. KOH fungal preparation was performed for 37 of 37 working days in the year of 2021 with no competency assessment documented. 3. The laboratory performs 350 tests annually in the subspecialty of mycology.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)

	The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish and follow an approved written procedure for KOH fungal preparation prior to patient testing in the subspecialty of mycology. Findings include: 1. Record review on 03/17 /2022 of the laboratory procedure binder revealed the following: a. A reference powerpoint training module for KOH fungal preparation not signed by the laboratory director (LD). b. Lack of an approved written procedure for KOH fungal preparation signed by the LD. 2. Staff interview on 03/17/2022 at 10:57 AM with the LD confirmed the above. 3. The laboratory performs 350 tests annually in the subspecialty of mycology.
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 record review and staff interview, the laboratory failed to provide an approved MOHS written procedure manual before patient testing in the subspecialty of histopathology. Findings include: 1. Record review on 03/17/2022 of the histopathology laboratory procedure manual revealed the following contents: a. MOHS Surgery Laboratory Technical Specifications. b. Technical Preparation. c. General Overview of the Procedure. d. Coverslipping. e. Placing Plate Type Anti-Roll Device and Cutting Sections. f. Quality Assurance Policy. g. Quality Assurance Procedure for Slides and Tissue. h. Sending Slides for Quality Assessment. i. Receiving Pathology Reading and Returned Q.A. Slides from Dermatopathology. j. MOHS Tissue Pathology Consultation. k. Protocol for Slide Requests. l. Requesting Slides from Outside Labs. m. Receiving Slides from Outside Labs. n. Submitting Outside Slides to Yale Dermpath. o. Returning Requested Slides to Original Labs. p. The above laboratory procedures were not signed and dated by the laboratory director (LD) prior to patient testing. 2. Staff interview on 03/17/2022 at 10:10 AM with the laboratory director confirmed the above finding and stated that "he was not aware that he was supposed to sign the laboratory procedure manuals". 3. The laboratory performs 1000 MOHS surgeries annually in the subspecialty of histopathology.
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 and staff interview, the laboratory failed to provide evidence of monitoring and documenting humidity requirements and room temperature in the subspecialty of histopathology. Findings include: 1. Record review on 03/17/2022 of the 'Yale MOHS Lab Cleaning and Maintenance Log' for the year of 2021 revealed lack of documentation of humidity levels and room temperature. 2. Record review on 03/17/2022 of the 'Leica CM1850 Cryostat Instructions for Use V2.0 English 03/2001' manual revealed the following: a. Air humidity must not exceed 60%. b. Room temperature maximum 35 degrees Celsius. 3. Staff interview on 03/17/2022 at 10:08 AM with the Laboratory Director (LD) revealed the following: a. The office was operational for 12 months in 2021 with limited staff for the first half of the year and fully staffed by the second half of the year. b. The LD was unaware that documentation of air humidity and room temperature was a requirement for proper function of the lab equipment. 4. The laboratory performs 1000 MOHS surgeries annually in the subspecialty of histopathology.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform and document the function checks within the laboratory's established limits before patient testing is conducted in the subspecialty of histopathology. Findings include: 1. Record review on 03/17/2022 of the 'Yale MOHS Lab Cleaning and Maintenance Log' from January 2021 through December 2021 revealed the following: a. Lack of documentation of maintenance for the months of September 2021 and October 2021 for the following: i. Thermo Scientific LiniStat Linear Stainer. ii. Eye wash station. iii. Cryo#1 temperature check iv. Cryo#2 temperature check b. H+E quality control slide was not documented for the months of September 2021 and October 2021. 2. Staff interview on 03/17/2022 at 10:30 AM with the laboratory director revealed that the laboratory was fully operating in 2021 and there was no documentation of the above findings. 4. The laboratory performs 1000 MOHS surgeries annually in the subspecialty of histopathology.