Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0099096	03/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Yale Dermatopathology Laboratory	15 York Street Lci 504-505, New Haven, 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 have a policy in place to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's competency records on 3/1/19 revealed the following: a. The laboratory did not have policy in place to assess the competency of the clinical consultant, technical supervisor, and general supervisor. b. Competency documentation for the above laboratory personnel was not available. 2. Staff interview with the laboratory manager on 3/1/19 at 12:50 PM confirmed the laboratory did not have a policy in place to assess the competency of the above laboratory personnel and they were not assessed.
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 ensure temperature readings on instrumentation were recorded in the subspecialty of histopathology and oral pathology. Findings include: 1. Record review of the laboratory 2018 and 2019 maintenance logs on 3/1/19 revealed the following: Log Name Temperature range (Celsius) a. Waterbath Serial # (SN) 9507808 38-45 b. Cryostat SN 0583/10.2006 -20- -30 c. Embedding Center SN51013034-0914 58-64 d. Waterbath #6 Station 38-45 e. Waterbath SN C&AU070413 38-45 f. Embedding Center# Station 58-64 g. Oven Routine 78-82 Overnight 30-40 The above logs contain daily checkmarks with a translation equaling 'within range'. Documentation of the actual temperature record was not available. 2. Staff interview with the laboratory manager on 3/1/19 at 11:45 AM confirmed the above findings. 3. The laboratory performs 93,949 pathology tests annually.