Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D1057164	(X3) Date Survey Completed 11/23/2021
Name of Provider or Supplier Seaport Dermatology Mohs Surgery Center	**Street Address, City, State** 34 Water St, Mystic, 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
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 temperature and humidity requirements. Findings include: 1) Record review on 11/23/2021 of the laboratory log books for 2020 and 2021 revealed no documentation of room temperature and humidity levels for either year. 2) Record review on 11/23/2021 of the Advantik Cryostat QS11/QS11UV operator manual revealed the following: a) Temperature requirement for operating conditions is "+5C up to +35C." b) Humidity requirement for operating conditions "max. rel. humidity of up to 60%." 3) Staff interview on 11/23/2021 at 10:45 AM with the medical assistant confirmed that room temperature and humidity levels were not recorded. 4) The laboratory performs 1,140 MOHS micrographic surgery procedures annually in the subspecialty of histopathology.