

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0663823	(X3) Date Survey Completed 09/09/2026
Name of Provider or Supplier Uscg Tracen Cape May	Street Address, City, State 1 Munro Avenue, Cape May, NJ	
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 recertification survey was conducted on September 09, 2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiency was cited.
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 direct observation, review of the laboratory's written policies and procedures, freezer temperature settings, and interview with the Laboratory Director (LD), the laboratory failed to define temperature conditions essential for proper storage of specimens for 1 of 1 freezer. Findings Included: 1) During a laboratory tour on 9/9/2026 at 1:08 PM, 1 Helmer freezer (Serial Number LBXFRZ29083310) was observed in use storing patient samples after testing, with an acceptable temperature range setting of -17 degrees Celsius and colder. 2) Review of the laboratory's written policy titled 'USCG Laboratory Environmental Monitoring Temp + Humidity Control' stated an acceptable freezer temperature range of -20 degrees Celsius and colder. 3) In an interview on 9/9/2026 at 1:09 PM, the LD confirmed the acceptable freezer temperature setting was above the defined upper limitations.