Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2246392	09/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Brewster Ambulance Service	25 Main St, Weymouth, 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	An initial CLIA certification survey was conducted for the Brewster Ambulance Service laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: . Based on proficiency testing (PT) review and interview with Technical Consultant (TC) on 9/27/2023, the laboratory did not document and maintain a copy of all PT records as evidenced by the following: The surveyors reviewed American Proficiency Institute (API) PT records for calendar years 2022 and 2023. The review revealed that the signed attestation statements provided by the PT program and the final reports were not available for the following events: API Chemistry Core 2022 Event #3 and 2023 Event #2. Two (2) out of two (2) attestation statements were not present and signed by the analyst and the laboratory director and two (2) out of two (2) final reports were not present and signed by the laboratory director or designee. 2023 Event #1 was not performed due to the API order was placed too late for calendar year 2023 to receive the first testing kit. The TC confirmed in an interview on 9/27/2023 at 11:

	04 AM that the attestation statements and final reports were not present and signed by the analyst and/or laboratory director. The laboratory performs 3,360 routine chemistry and 480 hematology tests annually. .
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC) on 9/27 /2023, the laboratory failed to indicate on the final test report either the patient 's name and identification number, or a unique patient identifier and identification number. The surveyors reviewed five (5) patient final test reports from June 2023 thru September 2023. The record review revealed that the laboratory failed to indicate the patient's name and identification number on five (5) out of the five (5) patient final test reports. The TC confirmed on 9/27/2023 at 12:03 PM that the five (5) patient final test reports did not indicate the patient's name and identification number, or a unique patient identifier and identification number. The laboratory performs 3,360 routine chemistry and 480 hematology tests annually.