

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2092620	(X3) Date Survey Completed 05/02/2023
Name of Provider or Supplier Cataldo Ambulance Service Db a Smartcare, Llc	Street Address, City, State 25 Eastern Avenue, Malden, 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 Cataldo Ambulance Service d/b/a SmartCare, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC) on 5/02/2023, the laboratory failed to indicate on the patient final test report the correct name of the laboratory where the test was performed as evidenced by the following: The surveyor reviewed five (5) patient final test reports between March 2023 and May 2023. The review revealed: The laboratory failed to indicate the correct name of the laboratory location where the test was performed on five (5) out of five (5) patient final test reports. The name of the laboratory on the patient final test reports was SmartCare. The laboratory's name on the CLIA certificate is Cataldo Ambulance Service d/b/a SmartCare, LLC. The TC confirmed through interview on 5/02/2023 at 12:30 PM that the patient final test reports did not indicate the correct name of the laboratory where the test was performed. The laboratory performs 3,840 routine chemistry tests and 480 hematology tests annually.</p>

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Consultant (TC) on 5/02/2023, the laboratory failed to make available pertinent reference intervals to the authorized person who ordered the tests based on the following: The surveyor reviewed five (5) patient final test reports between March 2023 and May 2023 for the Chem8+ Panel (nine tests) performed on the Abbott iStat. The review revealed: There was no reference interval for the Chem8+ Panel (nine tests) performed on the Abbott iStat available to the ordering providers for four (4) out of the five (5) final patient test reports reviewed. The TC confirmed through interview on 5/02/2023 at 12:30 PM that the laboratory failed to make reference intervals available to the authorized person who ordered the test. The laboratory performs 3,840 routine chemistry tests and 480 hematology tests annually.