

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2159409	(X3) Date Survey Completed 08/27/2019
Name of Provider or Supplier Bellingham Urgent Care	Street Address, City, State 1 Wrentham St, Bellingham, 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 Bellingham Urgent Care laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review and interview, the laboratory director failed to approve, sign, and date all laboratory procedures as evidenced by the following: A review of the clinical laboratory procedure manual revealed that the laboratory director had not reviewed and approved the laboratory policy and procedure manual. The technical consultant confirmed in an interview on 8/27/19 at 9:55 a.m. that the laboratory director had not reviewed and approved of the procedures. .</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for newly introduced test methodologies as evidenced by the following:

Alere Triage Meter: a) A review of validation studies for the Alere Triage Meter revealed that validation studies for inter and intra assay precision studies were not available at the time of the survey for four (4) of four (4) analytes performed on the analyzer (D-dimer, troponin, myoglobin and CKMB) prior to utilizing the Alere triage meter for patient testing and reporting b) At the time of the survey the technical consultant was unable to confirm that inter and intra assay precision studies were performed on the four (4) analytes. The technical consultant confirmed in an email received on 8/28/19 at 10:11 a.m. that data obtained to demonstrate precision was being sent to the manufacturer of the analyzer for analysis.