

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2194223	(X3) Date Survey Completed 07/13/2021
Name of Provider or Supplier Beth Israel Lahey Health Urgent Care	Street Address, City, State 100 Walter J Hannon Parkway, Quincy, 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 Beth Israel Lahey Health Urgent Care laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: . Based on proficiency testing record review and an interview with the Laboratory Administrative Director on 7/13/21, the laboratory failed to enroll and participate in a HHS approved proficiency testing (PT) program for the specialty areas (Chemistry and Hematology) for which it seeks certification as evidenced by the following: The surveyor requested to review Chemistry and Hematology PT records on 7/13/21 for calendar year 2021. The review revealed that the laboratory did not enroll in a HHS approved PT testing program for the specialties and subspecialties performed. The Laboratory Administrative Director confirmed in an interview on 7/13/21 at 10:30 A. M. that the Technical Consultant failed to enroll in a HHS approved PT program for 2021. The laboratory performs approximately 1,300 Chemistry and 4,600 Hematology tests annually. (Refer to D6041) .</p>
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:

. Based on record review and an interview with the Laboratory Administrative Director on 7/13/21, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer of a new test system before reporting patient test results as evidenced by the following: The laboratory implemented the Abbott i-Stat analyzer for PT/INR testing on 10/28/2020 and the Quidel analyzer for D-dimer testing on 12/30/2020. The surveyor requested to review the validation studies for the two analyzers on 7/13/21. The review revealed that the laboratory did not perform validation studies for each of the analyzers prior to patient testing. The Laboratory Administrative Director confirmed in an interview on 7/13/21 at 11:50 A.M. that the laboratory failed to perform validation studies prior to reporting patient test results on the Abbott i-Stat for PT/INR and the Quidel for D-dimer testing. The laboratory performs approximately 100 PT/INR tests and 100 D-dimer 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 an interview with the Laboratory Administrative Director on 7/13/21, 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 eight (8) patient final test reports between December 2020 through May 2021. The review revealed: The laboratory failed to indicate the correct name of the laboratory location where the test was performed for eight (8) out of eight (8) patient final test reports. The name of the laboratory on the patient final test reports is BILH Urgent Care - Quincy Laboratory. The laboratory's name on the CLIA certificate is Beth Israel Lahey Health Urgent Care. The Laboratory Administrative Director confirmed in an interview on 7/13/21 at 1:48 P.M. that the patient final test reports did not indicate the correct name of the laboratory where the test was performed. The laboratory performs approximately 1,300 Chemistry and 4,600 Hematology tests annually. .

D6041

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(3)

(b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

This STANDARD is not met as evidenced by:

. Based on proficiency testing (PT) record review and an interview with the Laboratory Administrative Director on 7/13/21, the Technical Consultant (TC) failed to enroll and participate in a HHS approved PT program commensurate with the services offered as evidenced by the following: The laboratory began Chemistry and Hematology patient testing on 10/28/2020. The surveyor requested to review Chemistry and Hematology PT records for calendar year 2021. The review revealed that that laboratory did not enroll in a HHS approved PT program for the specialties and subspecialties performed. The Laboratory Administrative Director confirmed in an interview on 7/13/21 at 10:30 A.M. that the TC failed to enroll in a HHS approved PT program for 2021. The laboratory performs approximately 1,300 Chemistry and 4,600 Hematology tests annually. (Refer to D2000) .