

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0674899	<b>(X3) Date Survey Completed</b>  12/28/2022
<b>Name of Provider or Supplier</b>  Beth Isreal Lahey Health Care Center Danvers	<b>Street Address, City, State</b>  480 Maple St, Danvers, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A CLIA recertification survey was conducted for the Lahey Outpatient Center Danvers laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493. .
<b>D6049</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the technical consultant failed to include a documented review of quality control records as part of the evaluation of the competency of the staff as evidenced by the following: a) A review of quality control testing records for calendar year 2022 (12 months of laboratory operation) for routine chemistry and hematology performed on the IStat revealed that the designated technical consultant had not documented a review of quality control records. b) The Point of Care Manager confirmed in an interview on 12/28/22 at 10:03 AM that the technical consultant was mainly responsible for the competency of the staff performing testing but this aspect of quality control reviews had not been included. c) The laboratory performs approximately 9,801 routine chemistry and hematology tests annually.</p>