

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2105927	(X3) Date Survey Completed 03/03/2022
Name of Provider or Supplier Baystate Reference Laboratories	Street Address, City, State 26 Queen St, Worcester, 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	A CLIA recertification survey was conducted for the Baystate Reference Laboratories laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the general supervisor (GS) on 3/3/22, the TS failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: 1. A review of the CMS 209 Laboratory Personnel Report on 3/3/22 revealed that there was one (1) new testing person (TP) hired since the last CLIA recertification survey on 11/20/19. 2. A review of the training and competency documentation for the new TP revealed that there was no documentation of semiannual competency evaluations for TP who had been working for over a year. 3. The GS confirmed in an interview on 3/3/22 at 8:55 AM that no semiannual competency evaluations had been performed on the new TP.</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated</p>

to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on record review interview, the technical supervisor TS failed to evaluate and document the performance of individuals responsible for high complexity testing at least annually as evidenced by the following: a) A review of calendar years 2020 and 2021 annual competencies on testing personnel (TP) revealed that the TS failed to evaluate the competency of one (1) out of three (3) testing personnel in calendar year 2021 (testing person 2). b) General supervisor 1 confirmed in an interview on 3/3/22 at 8:55 AM that an annual competency for calendar year 2021 had not been performed on testing person 2.