

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2009020	(X3) Date Survey Completed 09/30/2025
Name of Provider or Supplier Bridgewater Primary Care And Cardiology, Pc	Street Address, City, State 711 West Center Street, West Bridgewater, 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 Bridgewater Primary Care and Cardiology, PC laboratory on 09/30/2025 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 (PT) record review and an interview with the Technical Consultant (TC) on 9/30/2025, the laboratory failed to enroll and participate in an HHS approved PT program for the specialty area of Chemistry for which it seeks certification as evidenced by the following: The surveyor reviewed the American Proficiency Institute (API) PT records on 9/30/2025 for calendar years 2024 and 2025. The review revealed that the laboratory failed to enroll in an HHS approved PT program for the Glycosylated Hemoglobin (Hgb A1c) analyte under the Routine Chemistry subspecialty for Events #2 and #3 of 2024 and Events #1, #2, and #3 for 2025. The TC confirmed in an interview on 9/30/2025 at 12:09 P.M. that the laboratory failed to enroll in an HHS approved PT program for the HgbA1C analyte under the Routine Chemistry subspecialty for Events #2 and #3 of 2024 and for Events #1, #2, and #3 for 2025. The laboratory performs approximately 2,600 HgbA1C tests annually. (Refer to D6041) This is a repeat deficiency. .</p>

D6041

TECHNICAL CONSULTANT RESPONSIBILITIES

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

(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 interview with the Technical Consultant (TC) on 9/30/2025, the TC failed to ensure the laboratory enrolled in an HHS approved PT program for the specialty of Chemistry as evidenced by the following: The surveyor reviewed the American Proficiency Institute (API) PT records on 9/30/2025 for calendar years 2024 and 2025. The review revealed that the laboratory failed to enroll in an HHS approved PT program for the Glycosylated Hemoglobin (Hgb A1c) analyte under the Routine Chemistry subspecialty for Events #2 and #3 of 2024 and Events #1, #2, and #3 for 2025. The TC confirmed in an interview on 9/30/2025 at 12:09 P.M. that the laboratory failed to enroll in an HHS approved PT program for the HgbA1C analyte under the Routine Chemistry subspecialty for Events #2 and #3 of 2024 and for Events #1, #2, and #3 for 2025. The laboratory performs approximately 2,600 HgbA1C tests annually. (Refer to D2000) This is a repeat deficiency. .

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

. Based on personnel competency record review and interview with the Technical Consultant (TC) on 9/30/2025, the TC failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: The surveyor asked for the personnel competency records for review. The review revealed that semiannual competency evaluations were not performed and documented for the one (1) out of the one (1) newly hired testing person (TP) in their first year of performing moderate complexity testing. Only one competency evaluation was performed in the first twelve (12) months. TC confirmed in an interview on 9/30/2025 at 9:29 AM that the TC failed to perform and document semiannual competency evaluations for one (1) newly hired TP in their first year of performing moderate complexity testing. The laboratory performs 101,400 chemistry tests and 31,200 hematology tests annually.