Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2009020	05/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Bridgewater Primary Care And Cardiology, Pc	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 paper desk review of proficiency testing was conducted for the Bridgewater Primary Care and Cardiology, PC on 05/12/2025 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493 and the following Condition level deficiencies were deemed to be not met: D2016 - 42 CFR 493.803 Condition: Proficiency Testing - Successful Participation D6000 - 42 C. F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director .
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: . Based on a proficiency testing desk review of the Certification and Survey Provider

	Enhanced Reporting (CASPER) 0155D report and the American Proficiency Institute (API) 2024 (Event 3) and 2025 (Event 1) records, the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to achieve satisfactory performance (80% or better) for the same analyte for two consecutive testing events for the hematology Erythrocyte Red Cell Count (RBC) and the Hematocrit (HCT) analytes leading to an initial unsatisfactory performance. Refer to D2130 .
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on a proficiency testing desk review of the CASPER 0155D report and the American Proficiency Institute (API) 2024 (Event 3) and 2025 (Event 1) records, the laboratory failed to attain an overall testing event score of at least 80 percent for the hematology Erythrocyte Red Cell Count (RBC) and the Hematocrit (HCT) analytes leading to an unsuccessful performance for the specialty of hematology RBC and HCT as evidenced by the following specialty scores obtained. Review of the CASPER 0155D report revealed the following results: Hematology 2024-3rd Event the laboratory received an unsatisfactory score of 60% for RBC Hematology 2025-1st Event the laboratory received an unsatisfactory score of 60% for RBC Hematology 2024-3rd Event the laboratory received an unsatisfactory score of 60% for HCT Hematology 2025-1st Event the laboratory received an unsatisfactory score of 20% for HCT A review of the API Proficiency Testing records confirmed the laboratory received the above results. .
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on a proficiency testing desk review of the CASPER 0155D report and the American Proficiency Institute (API) 2024 (Event 3) and 2025 (Event 1) Proficiency Testing records, the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure the overall quality of the laboratory services provided. Refer to D6016 .
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

	This STANDARD is not met as evidenced by: . Based on a proficiency testing desk review of the CASPER 0155D report and the American Proficiency Institute (API) 2024 (Event 3) and 2025 (Event 1) Proficiency Testing records, the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2130