Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2009020	(X3) Date Survey Completed 01/09/2024
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	An initial CLIA certification survey was conducted for the Bridgewater Primary Care and Cardiology, PC laboratory on 01/09/2024 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: . Based on proficiency testing (PT) record review and an interview with the Technical Consultant (TC) on 1/09/24, the laboratory failed to enroll and participate in an HHS approved PT program for the specialty areas Chemistry and Hematology for which it seeks certification as evidenced by the following: The surveyor reviewed the American Proficiency Institute (API) PT records on 1/09/24 for calendar year 2023. The review revealed that the laboratory failed to enroll in an HHS approved PT program for all the testing under the Routine Chemistry subspecialty and the Hematology specialty for Events #1 and #2 of 2023 and all the testing under the Endocrinology subspecialty for Events #1, #2, and #3 for 2023. The TC confirmed in an interview on 1/09/24 at 10:01 A.M. that the laboratory failed to enroll in an HHS approved PT program for all the testing under the Routine Chemistry subspecialty and the Hematology specialty for Events #1 and #2 of 2023 and all the testing under the Endocrinology subspecialty for Events #1, #2, and #3 for 2023. The laboratory

	performs approximately 88,400 Routine Chemistry, 10,400 Endocrinology, and 31,200 Hematology tests annually. (Refer to D6041) .
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: . Based on quality control (QC) record review and an interview with the Technical Consultant (TC) on 1/09/2024, the laboratory failed to follow the manufacturer's instructions for establishing it's own quality control ranges for a testing system in the subspecialty Endocrinology as evidenced by the following: The surveyor reviewed the CLINIQA Liquid QC Immunoassay Control Level 1 (Lot 2008122A. Exp: 10/31/23) and Control Level 2 (Lot 2008123A. Exp: 10/31/23) Levy Jennings (LJ) charts for the period these controls were in use (12/26/22 through 07/31/23). The controls are used for the test system FREND Immunoassay Analyzer for Endocrinology tests: Free Thyroxine (FreeT4), Thyroid Stimulating Hormone (TSH), Prostate Specific Antigen (PSA), and Vitamin D 25OH (Vit. D). The review of FREND Immunoassay Analyzer's LJ charts revealed CLINIQA Control Level I and Control Level 2 QC ranges were not established by the laboratory. The review of the CLINIQA Liquid QC Immunoassay Control Level 1 and Control Level 2 manufacturer's package insert revealed that the Assignment of Values section states that the quality control range is provided to assist the laboratory until it has established its own mean and standard deviation for each test method. The CLINIQA guide for Level 1 and Level 2 control ranges are not exclusive for the laboratory's FREND Immunoassay Analyzer. The CLINIQA manufacturer obtains the test analytes' control ranges from different laboratories' various instrument platforms/ test methods/ test reagents, and from reference laboratories. The review of the CLINIQA Control Level 1 and Control Level 2 manufacturer's guidance revealed that the control ranges on the FREND Immunoassay Analyzer's LJ charts were the ranges from the CLINIQA manufacturer's guidance document for test methods FreeT4, TSH, PSA and Vit. D. The TC confirmed in an interview on 1/09/2024 at 1:10PM that the laboratory failed to established its own quality control ranges for CLINIQA Liquid QC Immunoassay Control Level 1 and Control Level 2 for four of four test methods (FreeT4, TSH, PSA and Vit. D). The laboratory performs approximately 10,400 Endocrinology tests annually. .
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: . Based on observations made in the laboratory's phlebotomy room and an interview with the Technical Consultant (TC) on 1/09/2024, the laboratory failed to monitor temperature conditions that are essential for proper storage of blood specimen collection tubes consistent with the manufacturer's instructions, and failed to record the room's temperature and maintain temperature records. The tubes are for the collection of blood specimens to perform tests of Routine Chemistry subspecialty, Hematology specialty and Endocrinology subspecialty. The blood collection tubes' manufacturer's package inserts have storage temperature as less than or equal to 25 degrees Celsius (25C). This failure is evidenced by the following: The surveyor observed in the phlebotomy room that there was no device for taking temperatures, no temperature charts in the room, and no phlebotomy room temperature charts to review. The TC confirmed in an interview on 1/09/2024 at 11:30AM that the laboratory failed to: monitor phlebotomy room temperature, record phlebotomy room temperatures, and maintain temperature charts essential for the proper storage of the blood collection tubes. The laboratory performs approximately 88,400 Routine Chemistry, 10,400 Endocrinology, and 31,200 Hematology tests annually. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observations and an interview with the Technical Consultant (TC) on 1/09 /2024, the laboratory failed to ensure laboratory reagents were not used when they had exceeded their expiration date as evidenced by the following: 1. The surveyor found on 1/09/24 in the laboratory's testing room in a freezer compartment of an undercounter refrigeration unit, one vial of expired CLINIQA liquid QC Immunoassay control (Expiration date 12/01/2023). The control material is placed in every run of each patient's specimen testing method for subspecialty Endocrinology (Free T4, TSH, PSA, Vit.D). The vial was opened with no markings that the laboratory had placed on the vial indicating that the control was expired and to not use the material. The TC confirmed in an interview on 1/09/2024 at 11:15AM that one vial of expired control material was present in the freezer compartment of the undercounter refrigeration unit. 2. The surveyor found in the laboratory's phlebotomy drawing room on 1/09/24 a package of expired Greiner K2EDTA purple top tubes (Lot B2208365. Expiration date 12/01/2023). The tubes are used to collect blood specimen's to perform Hematology specialty tests. The TC confirmed in an interview on 1/09/2024 at 11:35AM that one package of expired purple top tubes was present in the phlebotomy drawing room. The laboratory performs approximately 10,400 Endocrinology and 31,200 Hematology tests annually. .
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: . 1. Based on Reportable Range record review and an interview with the Technical Consultant (TC) on 1/09/2024, the laboratory failed to verify the Reportable Range of test results for the FREND Immunoassay Analyzer's Endocrinology subspecialty Free Thyroxine (Free T4) test method as evidenced by the following: The surveyor reviewed the FREND Immunoassay Analyzer User Manual's Reportable Range page for Free T4 reportable range 0.4-6.0 ng/dL, AND reviewed the record of the reportable range verification test run performed on 2/14/23 with five materials that comprised test points for the Free T4 reportable range. Results of test run were 0.63, 1.8, 3.01, 3.92, 4.95 ng/dL. The test run results did not verify the lowest value and the highest value of the Free T4 reportable range. The TC confirmed in an interview on 1/09/2024 at 11:50AM that the laboratory failed to verify the Free T4 reportable range. 2. Based on Reference Interval (Normal Range) record review and an interview with the Technical Consultant (TC) on 1/09/2024, the laboratory failed to verify the reference intervals (normal values) are appropriate for the laboratory's patient population for the FREND Immunoassay Analyzer's Endocrinology subspecialty test methods: Free Thyroxine (Free T4), Thyroid Stimulating Hormone (TSH), Prostate Specific Antigen (PSA), and Vitamin D 25OH (Vit. D) as evidenced by the following: The surveyor confirmed in an interview with the Technical Consultant (TC) on 1/09/2024 at 11:35AM that the laboratory used the FREND Immunoassay Analyzer manufacturer's reference interval (normal values) and other literature searches. The laboratory did not use their patient population's test results to verify the reference intervals. The laboratory failed to verify that the reference intervals (normal values) are appropriate for the laboratory's patient population for 4 of 4 Endocrinology tests: Free T4, TSH, PSA, Vit.D. The laboratory performs approximately 10,400 Endocrinology tests annually. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for

	verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC) on 1/09 /24, the laboratory failed to perform calibration verifications every six months or, as appropriate, as evidenced by the following: The surveyor reviewed the quality control records on 1/09/24 for calendar year 2023. The review revealed that calibration verifications of at least three points were not performed once every six months for seventeen (17) out of seventeen (17) chemistry analytes requiring calibration verification on the Horiba Pentra C400 analyzer. The last six-month calibration verifications for sodium, potassium, chloride, carbon dioxide, creatinine, blood urea nitrogen, albumin, total protein, calcium, aspartate aminotransferase, alanine transaminase, alkaline phosphatase, total bilirubin, glucose, cholesterol, high density lipoprotein, and triglycerides were performed on 3/27/23. The calibration verifications were not performed every six months. The TC confirmed in an interview on 1/09/24 at 12:14 P.M. that calibration verifications had not been performed every six months for seventeen (17) out of seventeen (17) chemistry analytes requiring calibration verification. The laboratory performs 88,400 chemistry 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 interview with the Technical Consultant (TC) on 1/09 /24, the laboratory failed to indicate on the final patient test report (FPTR) the correct name of the laboratory where the test was performed as evidenced by the following: The surveyor reviewed ten (10) FPTR between November 2022 and December 2023. The review revealed: The laboratory failed to indicate the correct name of the laboratory location where the test was performed on eight (8) out of the ten (10) PFTR. The incorrect name of the laboratory appeared on all FPTR beginning in 2023. The name of the laboratory on the FPTR was John Terzian MD. The name of the laboratory on the CLIA certificate is Bridgewater Primary Care and Cardiology, PC. The TC confirmed through interview on 1/09/24 at 4:04 PM that the FPTR did not indicate the correct name of the laboratory where the test was performed. The TC stated that the laboratory interfaced the analyzers with the EMR Athena in 2023 and the incorrect name of the laboratory was entered into the EMR. The laboratory performs approximately 88,400 Routine Chemistry, 10,400 Endocrinology, and 31,200 Hematology tests annually. .
D5807	TEST REPORT CFR(s): 493.1291(d)

	Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant (TC) on 1/09 /24, the laboratory failed to ensure the reference ranges on the final patient test report (FPTR) matched the reference ranges in the procedure manual (PM) for the subspecialty of Endocrinology. The surveyor reviewed ten (10) FPTR on 1/09/24. The review revealed that the reference ranges on the FPTR differed from the defined reference ranges as stated in the PM. The normal reference ranges for Free Thyroxine (FT4), Thyroid Stimulating Hormone (TSH), and Vitamin D 25OH (Vit D) were defined in the PM on 1/16/23 using the manufacturer's reference interval for each of the tests. Test Final Report Defined PM Reference Range Reference Range FT4 0.59 - 2.49 0.83 - 1.60 ng/ml TSH 0.4 - 4.2 0.49 - 3.82 mIU/L Vit D 30 - 100 40 - 80 ng/ml The TC confirmed in an interview on 1/09/24 at 4:32 P.M. that the reference ranges on the FPTR did not match the defined reference ranges stated in the PM. The laboratory performs approximately 10,400 Endocrinology 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 interview with the Technical Consultant (TC) on 1/09/24, the TC failed to ensure the laboratory enrolled in an HHS approved PT program for the Chemistry and Hematology specialties as evidenced by the following: The surveyor reviewed the American Proficiency Institute (API) PT records on 1/09/24 for calendar year 2023. The review revealed that the TC failed to enroll the laboratory in an HHS approved PT program for all the testing under the Routine Chemistry subspecialty and the Hematology specialty for Events #1 and #2 of 2023 and all the testing under the Endocrinology subspecialty for Events #1, #2, and #3 for 2023. The TC confirmed in an interview 1/09/2024 at 10:01 AM that the TC failed to enroll the laboratory in PT for all the testing under the Routine Chemistry subspecialty and the Hematology specialty for Events #1 and #2 of 2023 and all the testing under the Endocrinology subspecialty for Events #1, #2, and #3 for 2023. The laboratory performs approximately 88,400 Routine Chemistry, 10,400 Endocrinology, and 31,200 Hematology tests annually. (Refer to D2000) .