Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0670655	11/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Burke Primary Care	103 Medical Heights Drive, Suite 201, Morganton, NC	

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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, surveyor observation and interview with TP #1 11/28/23, the laboratory failed to label quality control (QC) reagent for glycosylated hemoglobin (HgA1c) testing performed on the TOSOH G8 analyzer with an expiration date after opening. Findings: Review of laboratory procedure "TOSOH G8 Procedure Manual" revealed "TOSOH Controls...After opening, sets are stable for one week when stored at 2-8 degrees Celsius (C).". During laboratory tour at approximately 3:30 p.m., surveyor observed 2 bottles of QC reagent, TOSOH Bioscience Inc Hemoglobin A1c Control, Level 1 and 2, Lot #7134, on a shelf in the door of a small white refrigerator with an open date of 10/3/23. The 2 bottles of QC reagent were not labeled with an expiration date. The QC reagents expired on 10/17 /23 and were available for use until date of survey. Interview with TP #1 during time of laboratory tour confirmed the 2 bottles of QC reagent were not labeled with an expiration date. He also confirmed the QC reagents were stable for one week after opening and had expired 10/17/23. The QC reagents were disposed of immediately.
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 surveyor observation and interview with TP #1 11/28/23, the laboratory failed to discard 5 blood collection tubes that had exceeded their expiration date. Findings: During laboratory tour at approximately 3:30 p.m., surveyor observed 5 dark blue top BD Vacutainer trace element tubes with an expiration date of 10/31/23 available for use in the phlebotomy station. Interview with phlebotomist at time of laboratory tour confirmed the 5 blood collection tubes had expired. The phlebotomist disposed of them immediately.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of operators manual and review of maintenance logs 11/28/23, the laboratory failed to change the filter as required on the TOSOH G8 analyzer from 7/24 /23 until 8/21/23, a period of approximately 27 days. Findings: Review of operators manual for the TOSOH G8 analyzer revealed "SECTION 1...Daily Maintenance Procedure...5. Record filter count. Change filter after 400 injections." Review of maintenance logs for the TOSOH G8 analyzer revealed a filter count of 412 on 7/24 /23 and a filter count of 1588 on 8/18/23. The filter was changed on 8/21/23.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of 2023 TOSOH G8 analyzer calibration records and interview with testing personnel (TP #1) 11/28/23, the laboratory failed to perform monthly calibration of the glycosylated hemoglobin (HbA1c) for 3 of 6 months reviewed. Findings: The laboratory began testing HbA1c on the TOSOH G8 analyzer in June of 2023. Review of laboratory procedure "Tosoh G8 Calibration adjustments:" revealed "...if qc is acceptable with not shifts or trends,

	calibration can be ran monthly or bi-monthly. BPC will be running a monthly calibration unless there are issues with QC." Review of 2023 calibration records for HbA1c revealed no documentation of monthly calibrations in August, September and October of 2023. Interview with TP #1 at approximately 12:00 p.m. confirmed there was no documentation of monthly calibrations in August, September and October of 2023. He stated he thought they were performed but could not locate any documentation of the calibrations.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, review of laboratory procedures and review of 2022 and 2023 quality control (QC) records for the Alere Triage meter 11/28/23, the laboratory failed to perform D-dimer external QC every 30 days as established by the laboratory's individual quality control program (IQCP) for 1 of 23 months reviewed. Findings: Review of laboratory records revealed the laboratory had established an IQCP for the performance of D-dimer testing on the Alere Triage meter in 2016. Review of laboratory procedure "Alere Triage D-Dimer" revealed "External controls are run in accordance with the manufacturer's instructions, with each lot or shipment and at least every 30 days." Review of 2022 and 2023 D-dimer QC records revealed external QC was performed 11/9/22. The next performance of external QC was documented on 1/23/23, a period of approximately 74 days in which external QC was not performed.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of 2021, 2022 and 2023 laboratory quality assessment (QA) records, review of the laboratory's policies and procedures, and interview with TP #1 11/28/23, the laboratory failed to establish a QA policy for review of calculated chemistry results and failed to perform reviews to verify the accuracy of the calculated results for approximately three years during 2021, 2022, and 2023. Findings: Review of 2021, 2022 and 2023 laboratory QA records revealed no documentation of a periodic review of the following calculated chemistry results: 1. Albumin/Globulin ratio 2. Low-density lipoprotein (LDL) calculation 3. Bun/Creatinine ratio 4. Estimated glomerular filtration rate (eGFR) Review of the laboratory's policies and procedures

	revealed the laboratory did not have a policy for review of calculated chemistry results to ensure the accuracy of results reported. Interview with TP #1 at approximately 4:00 p.m. confirmed the laboratory had not established a QA policy that included a periodic review of calculated chemistry results.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of laboratory records, review of laboratory procedure and review of 2021, 2022 and 2023 laboratory quality assessment (QA) records 11/28/23, the laboratory director failed to ensure the individual quality control plan (IQCP) established for D-dimer testing on the Alere Triage Meter was reviewed annually to assure the accuracy of D-dimer testing, a period of approximately 3 years in which an annual review was not performed. Findings: Review of laboratory records revealed the laboratory had established an IQCP for the performance of D-dimer testing on the Alere Triage meter in 2016. Review of laboratory procedure "Alere Triage D-Dimer" revealed "External controls are run in accordance with the manufacturer's instructions, with each lot or shipment and at least every 30 days. ...This plan will be reviewed annually and following any QC failure and will be revised if needed.". Review of 2021, 2022 and 2023 laboratory QA records revealed no documentation of an annual review of the IQCP established for the D-dimer testing.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2021, 2022, and 2023 hematology quality control records 11/28/23, testing personnel failed to follow the laboratory's procedure for verification of each new lot of hematology quality control material. Review of the laboratory's "QUALITY CONTROL" policy revealed "... New Quality Control Lot Verification For each new lot of controls, we will run each level at least five times on different days, at different times of the day, and by different operators, while the old lot is still in use as daily QC. We will then compare our results with those of the manufacturer to ensure that the integrity of the materials has been maintained and that we can achieve the manufacturer's specifications. ... QUALITY CONTROL PROCEDURES ... 1. Verification We will not implement a new lot of control material until it has been verified as described above. ..." Review of 2021, 2022, and 2023 hematology records revealed the laboratory failed to follow their policy for verifying each new lot of Boule Con-Diff

	hematology quality control material. Examples: 1. For lot #22106-31, 32, 33, all verification testing was performed the same day (10/12/21) by the same person. 2. For lot #22201-31, 32, 33, all verification testing was performed the same day (5/13/22). 3. For lot #22307-31, 32, 33, all verification testing was performed the same day (9/19 /23).