Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0670655	10/09/2025
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor observation, review of package inserts and testing personal (TP) #1 interview, 10/09/25, the laboratory failed to monitor the temperature in the downstairs storage room in which laboratory test kits were stored. Findings: At approximately 2: 30 p.m. surveyor observed the following boxes of test kits on shelves in the downstairs storage room: 1. 1 box of "Consult Strep A Tests Dipstick". 2. 1 box of "Consult Hcg Urine Tests Dipstick". 3. 1 box of "Quick Vue RSV Test". 4. 2 boxes of "Consult Influenza A & B Tests Cassette". 5. 1 box of "Hemosure iFOB test". 6. 2 boxes of "One Step + ER fecal occult blood". 7. 1 box of "Globe Scientific Sedi-Rate". 8. 8 boxes of "Cepheid Xpert Xpress CoV-2/Flu/RSV plus". Review of package inserts for the above listed test kits revealed the following: 1. Test kits #1 through # 6 listed above require a storage and stability temperature of 36 - 86 degrees Fahrenheit (F). 2. Test kit # 7 listed above requires a storage and stability temperature of 59 - 86 degrees F. 3. Test kit # 8 listed above requires a storage and stability temperature of 2 - 8 degrees Celsius (C). Interview with TP #1 at time of observation confirmed the laboratory failed to monitor the temperature of the downstairs storage room.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test

	procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of reagent package inserts and interviews with testing personnel (TP) #1 and laboratory director (LD) 10/09/25, the laboratory procedure manual failed to include the types and levels of quality control (QC) reagents utilized by the laboratory for the performance of QC on the Vitros 5600 analyzer. Findings: The laboratory performs testing of approximately 47 analytes on the Virtros 5600 analyzer. Review of laboratory procedure "Vitros 5600" revealed "Quality Control Procedure: Two levels of controls are run each day of patient testing...". The procedure fails to state the types and fails to define the specific levels of QC reagents utilized by the laboratory for the performance of QC on the Virtos 5600 analyzer. During interview at approximately 10:30 a.m. the LD stated the types and levels of controls used for each analyte are found in the reagent package insert for each analyte. Review of random reagent package inserts revealed the package inserts failed to list the type and levels of QC utilized by the laboratory. For example: 1. Phosphorus (PHOS) package insert revealed "Quality Control...Quality Control Material Selection...Control materials other than VITROS Performance Verifiers may show a difference...Quality Control Procedure Recommendations...Choose control levels that check the clinically relevant range...". 2. Potassium (K) package insert revealed "Quality Control...Quality Control Material Selection...Control materials other than VITROS Performance Verifiers may show a difference...Quality Control Procedure Recommendations...Choose control levels that check the clinically relevant range...". 3. Amphetamine (AMPH) package insert revealed Quality Control...Quality Control Material Selection...Choose control levels that are appropriate for the selected cutoff value.". During interview at approximately 11:00 a.m. the LD and TP #1 confirmed the reagent package inserts and the laboratory procedure failed to include what types and levels of QC utilized by the laboratory for the testing performed on the Vitros 5600 analyzer. TP #1 stated the analyzer would let us know what was required to perform QC.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 surveyor observation, review of package insert and testing personal (TP) #1 interview, 10/09/25, the laboratory failed to monitor the temperature in the downstairs storage room in which laboratory test kits were stored. Findings: At approximately 2: 30 p.m. surveyor observed 8 boxes of "Cepheid Xpert CT/NG" test kits on shelves in the downstairs storage room. Review of package insert for the "Cepheid Xpert CT /NG" test kit revealed a storage and stability range of 2 - 8 degrees Celsius. Interview with TP #1 at time of observation confirmed the laboratory failed to monitor the temperature of the downstairs storage room.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, and interview with TP #1, 10/09/25, the laboratory failed to label 3 bottles of Ferritin (FERR) calibration reagent and 2 bottles of Vitamin D (VITD) calibration reagent with the new expiration date after opening. Findings: At approximately 2:00 p.m. surveyor observed the following calibration reagents on a shelf in the door of a small refrigerator in the laboratory: 1. 3 bottles of FERR calibration reagent, Lot #3130, labeled with the date of 8/6. 2. 2 bottles of VITD calibration reagent, Lot #2150, tabled with the date of 9/2. Review of manufacturer's instructions revealed FERR calibration reagent "Open Vial Stability...13 wks refrig" and VITD "Open Vial Stability...1 wk refrig". Interview with TP #1 at approximately 2:00 p.m. revealed the labeled dates of 8/6 and 9/2 were the dates in which the reagents were opened. They also confirmed that the calibration reagents were not labled with the new expiration date after opening and also confirmed the VITD calibration reagent had expired on 09 /09/25. This deficiency was previously cited 11/28/23.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and 2025 Medonic hematology

	records 10/9/25, the laboratory failed to perform and document daily maintenance for the Medonic hematology analyzer as required for 8 of 22 days in July 2025. Findings: The Medonic M-series User's Manual states "Section 8: Cleaning, Maintenance & Transport ... 8.1 Daily Cleaning ... Clean the aspiration and pre-dilute probes using an alcohol wipe. Remove possible traces of salt crystals or blood at the top of the aspiration and pre-dilute probes, probe rinse cup, and around top of sampling device probe inlet (if applicable) using a paper tissue with a disinfecting solution. ..." Review of 2025 Medonic maintenance logs revealed the laboratory failed to perform and document the manufacturer's specified daily maintenance on 8 of 22 days in July 2025 (7/1, 7/7, 7/8, 7/11, 7/17, 7/18, 7/22, 7/28).
D5805	TEST REPORT CFR(s): 493.1291(c) (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 review of performance specification records and instrument settings for the Vitros 5600 analyzer toxicology drug screens, review of patient test reports, review of package insert and interviews with testing personnel (TP #1) and laboratory director (LD) 10/09/25, the patient test reports for toxicology drug screens failed to have the correct cut-off values established by the laboratory for 4 of 9 analytes tested and the patient test reports for Prostate-specific antigen (PSA) failed to specify the analytic method utilized by the laboratory. 1. The patient test reports for toxicology drug screens failed to have correct cut-off values established by the laboratory for 4 of 9 analytes tested. Findings: Review of performance specification records and instrument settings for the Vitros 5600 analyzer toxicology drug screens revealed the following 4 analytes established cut-off values: a. Barbiturates (BARB) - performance specification records verified a cut-off value of 200 nanogram's (NG)/Milliliter (ML). Vitros 5600 instrument settings for BARB were set at a cut-off value of 200 NG/ML b. Benzodiazapines (BENZ) - performance specification records verified a cut-off value of 200 NG/ML. Vitros 5600 instrument settings for BENZ were set at a cut-off value of 200 NG/ML c. Methadone (METH) - performance specification records verified a cut-off value of 300 NG/ML. Vitros 5600 instrument settings for METH were set at a cut-off value of 300 NG/ML d. Opiates (OPI) - performance specification records verified a cut-off value of 300 NG/ML. Vitros 5600 instrument settings for OPI were set at a cut-off value of 300 NG/ML Review of patient test reports, patient identification numbers: DT13194, DT13200 and DT13205, for BARB, BENZ, METH and OPI cut-off values revealed: a. BARB cut-off value of 1000 NG /ML. b. BENZ cut-off value of 1000 NG/ML. c. METH cut-off value of 1000 NG? ML. d. OPI cut-off value of 2000 NG/ML. Interview with TP #1 at approximately 2: 15 p.m. confirmed the instrument settings of the Vitros 5600 analyzer for the BARB, BENZ, METH and OPI cut-off values. Interview with LD at approximately 2:30 p.m. confirmed the test reports had the incorrect cut-off values established by the performance specifications for BARB, BENZ, METH and OPI drug screen testing. 2.

	The patient test reports for PSA failed to specify the analytic method utilized by the laboratory. Findings: Review of package insert for PSA reagent revealed the following analytic method; "Principles of the Procedure...An immunometric test technique is used.". Review of patient test reports for PSA, Patient identification numbers; 6145 and 326313, revealed the comment "Treated with the Ortho 5600". The test report comment does not indication the analytic method of the PSA reagent. Interview with LD at approximately 3:00 p.m. confirmed the patient test reports for PSA testing failed to include the specific analytic method utilized by the laboratory.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the technical consultant (TC) 10/9/25, the laboratory failed to document the performance of annual competency evaluations for 4 of 7 TP (testing personnel) during 2024. Findings: Review of personnel records for TP #1, #2, #4, and #5 revealed documentation of annual competency evaluations performed in November 2023, but none in 2024. During interview at approximately 11:30 a.m., the TC stated that competency evaluations were performed in November 2024, but the records had been lost.