Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0670655	02/06/2020
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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2018 and 2019 API (American Proficiency Institute) proficiency testing records, and interview with TP (testing personnel) 2/6/20, the laboratory failed to test proficiency samples in the same manner as patient specimens are routinely tested. The laboratory's "QUALITY ASSESSMENT PLAN" states "... 6. Proficiency Testing This laboratory will enroll in formal proficiency testing appropriate to the test menu and treats all proficiency test challenge specimens the same as patient specimens. ... " The "GENERAL LABORATORY QUALITY SYSTEMS" policy states "... We will treat the proficiency testing specimens exactly as we treat patient samples, from accessioning through reporting. We will repeat the tests only if we would repeat patient samples under the same conditions (for example, if the result is a critical value). ..." The laboratory's "Critical Lab Values Policies and Procedure" states "... Procedure: In-house Critical Lab Values: All critical value laboratory results requires specimen to be re-run to verify accuracy of results. ... Laboratory staff will document all critical communication in LabDaq LIS system..." Review of 2018 and 2019 API proficiency testing records revealed the laboratory failed to test proficiency samples in the same

	manner as patient specimens are routinely tested. Examples: 1. 2018 3rd event hematology - sample HSY-14 had a critical value for hemoglobin. There was no documentation that the sample was retested to confirm the critical value. 2. 2019 3rd event hematology - sample HSY-12 had a critical value for hemoglobin. There was no documentation that the sample was retested to confirm the critical value. 3. There was no documentation available at the time of the survey to show that hematology proficiency samples for the 2018 3rd event and the 2019 3rd event were accessioned and reported in the LIS (laboratory information system). During interview at approximately 11:30 a.m., TP #1 stated that patient specimens with panic values are retested to confirm and the repeat testing is documented in the LIS. He stated proficiency samples should be treated the same way.
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 review of manufacturer's instructions, review of 2018 and 2019 calibration records, interview with TP (testing personnel) 2/6/20, and review of 2/7/20 email, the laboratory failed to discard calibration material that exceeded its expiration date. The Boule Cal calibrator assay sheet states "Open vial stability 5 days". The Medonic M-series User's Manual states "Section 7: Calibration ... 7.1 Preparations before calibration ... Never use an open vial longer than recommended by the manufacturer ...". Review of 2018 and 2019 calibration records for the Medonic M-series hematology analyzer revealed the analyzer was calibrated on the following dates: 3/22 /18, 6/5/18, 9/10/18, 10/2/18, 11/7/18, 3/7/19, 4/3019, and 9/18/19. Review revealed the calibration performed 10/2/18 included an assay sheet for Boule Cal lot #21803-24 with an expiration date of 6/7/18. During interview 2/6/19 at approximately 1:40 p.m., TP #1 stated that the Medonic won't let you use an expired calibrator, so they must have put the wrong package insert with the 10/2/18 calibration. In an email to the surveyor 2/7/20, TP #1 stated that the laboratory used the calibrator from the calibration performed 9/18/18 (lot #21807-44, expiration 10/12/18) to calibrate the analyzer on 10/2/18.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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, review of the laboratory's policies and procedures, review of 2018, 2019, and 2020 hematology records, and interview with TP (testing personnel) 2/6/20, the laboratory failed to perform and document all maintenance as specified by the manufacturer for the Medonic M-series hematology analyzer. 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. ..." The laboratory's "ANALYTIC SYSTEMS" policy states "... 5. Maintenance and Function Checks ... Procedure We follow the manufacturer's recommended schedule for routine preventive maintenance and for professional service. We document all activities on our Preventive Maintenance forms ...". Review of 2018, 2019, and 2020 hematology records revealed the laboratory had not documented daily cleaning of the Medonic M-series hematology analyzer. During interview at approximately 3:05 p.m., TP #1 confirmed that they had not documented daily cleaning.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, review of 2018 and 2019 PT (proficiency testing) records, and interview with TP(testing personnel #1) 2/6/20, the LD(laboratory director) failed to ensure TC (technical consultant) duties were performed by personnel meeting the qualification requirements for a TC and failed to ensure that all duties were properly performed. Findings: The laboratory's "GENERAL LABORATORY QUALITY SYSTEMS" policy states for PERSONNEL COMPETENCY, " The laboratory director is responsible for competency assessments or has reassigned responsibility of testing personnel competency assessments to the technical consultant...." Under PROFICIENCY TESTING POLICY, the policy states, "The director will carefully evaluate any unacceptable, unsatisfactory, or unsuccessful proficiency testing result in an effort to identify the cause of failure....." Review of the laboratory's policies and procedures revealed a letter of delegation from the LD dated 1/2/19. The LD delegated the following responsibilities to TP#1: "Signing the Proficiency Testing Attestation Forms" and "Review, initiating corrective actions and signing off Proficiency Testing reports". Review of personnel records and PT records revealed: 1. TP#1 has an associate degree in medical laboratory technology and does not meet the education requirements to serve as TC. 2. TP#1 performed competency evaluations for TP#4, TP#5, TP#7, and TP#8. 3. Semiannual competency evaluations were not performed or documented for TP#3 and TP#8. See D6053. 4. Annual competency evaluation was not performed or documented for TP#5. See D6054. 5. TP#1 signed PT attestation forms and PT reports. At approximately 1pm, TP#1 confirmed that he performed the competency evaluations for the TP and the LD signed off behind him.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)

	The technical consultant is responsible for 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 review of personnel records and interview with TP (Testing personnel #1) 2/6/20, the TC (Technical Consultant) failed to perform and document competency evaluation for 2 of 8 TP (TP #3 and #8) at least semiannually during the first year. Findings: Review of personnel records revealed TP#3 was trained in May 2017 and competency evaluation was not completed until May 2018. TP#8 was trained in July 2018 and competency evaluation was not completed until June 2019. There was no documentation of a semiannual competency completed for TP#3 and TP#8 during the first year of testing patient specimens. During interview at approximately 1pm, TP#1 confirmed a semiannual competency evaluation was not performed for TP#3 and TP#8.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with TP (testing personnel #1) 2/6/20, the TC (technical consultant) failed to perform and document annual competency evaluation for 1 of 8 TP (TP#5). Findings: Review of personnel records revealed TP#5 was trained in October 2018. A semiannual competency evaluation was performed on 2/13/19. There was no documentation of an annual competency evaluation completed for TP#5 in 2019. At approximately 1pm, TP#1 confirmed there was no annual competency evaluation completed for TP#5 in 2019.