Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1042463	06/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
East Coast Medical, Pllc	22545-B Highway 17 North, Hampstead, 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 and review of 2020, 2021, and 2022 MLE (Medical Laboratory Evaluation) and 2023 AAB (American Association of Bioanalysts) MLE proficiency testing records 6/5/23, the laboratory failed to test proficiency samples in the same manner as patient specimens are routinely tested for 10 of 10 events reviewed. Findings: Review of the laboratory's "Proficiency Testing" procedure revealed "... PROCEDURE: ... 4. Proficiency test samples will be tested in exactly the same manner as patient samples are tested. ... b. Samples will only be repeated (e.g. with panic values) if a patient sample would have been repeated under the same circumstances. ..." Review of the Medonic M-series procedure revealed "... CRITICAL VALUES: Critical values must be rerun to verify before reporting. ..." The procedure listed critical values for WBC (white blood cell count), hemoglobin, and platelets. Review of 2020, 2021, 2022, and 2023 proficiency testing records revealed proficiency samples were not rerun as required when critical values were obtained as specified in the laboratory's procedures. Examples: 1. MLE 2020 - 3 of 3 test events (M1, M2, M3) had critical values for hemoglobin that were not repeated; 2. MLE 2021 - 3 of 3 test events (M1, M2, M3) had critical values for hemoglobin that were not repeated; 3. MLE 2022 - 3 of 3 test events (M1, M2, M3)

	had critical values for hemoglobin that were not repeated; 4. AAB MLE 2023 - 1 of 1 test events (M1) had critical values for hemoglobin that were not repeated.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2020, 2021, and 2022 MLE (Medical Laboratory Evaluation) and 2023 AAB (American Association of Bioanalysts) MLE proficiency testing records 6/5/23, the laboratory failed to ensure all TP (testing personnel) participated in proficiency testing for 8 of 10 testing events. Findings: Review of the laboratory's "Proficiency Testing" procedure revealed "PROCEDURE: 1. Proficiency testing will be rotated among the techs so that everyone working in a lab discipline participates in the testing throughout the year. ..." Review of 2020, 2021, 2022, and 2023 proficiency testing records revealed: 1. MLE 2020 - TP #2 tested all samples in 2 of 3 events (M2 and M3); 2. MLE 2021 - TP #2 tested all samples in 3 of 3 events (M1, M2, M3); 3. MLE 2022 - TP #2 tested all samples in 2 of 3 events (M1 and M2); 4. AAB MLE 2023 - TP #2 tested all samples in 1 of 1 events (M1).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 the laboratory's policies and procedures, review of manufacturer's instructions, and interview with the TC (technical consultant) 6/5/23, the laboratory's hematology procedure had not been updated to reflect the laboratory's current Medonic M-Series hematology analyzer. Review of the laboratory's policies and procedures revealed a procedure for the Medonic CA620 hematology analyzer. The

	title had been marked out and "Medonic M-Series - new analyzer October 2020 See instrument manual" was handwritten at the top of the page and signed by the TC 8/11 /21. The procedure had not been updated to remove references to the Medonic CA620 and include specific requirements for the Medonic M-Series. For example: The maintenance section in the laboratory's procedure stated "MAINTENANCE: Daily, monthly, and 3-monthly instrument maintenance is performed according to manufacturer's instructions, utilizing the Boule cleaning kit. Detailed instructions for maintenance found in the Medonic CA620 User's Manual, Chapter 13. ..." Manufacturer's maintenance instructions for the Medonic M-Series found in Section 8 of the User's Manual include required daily and monthly cleaning, and a recommendation for 6-month cleaning. During interview at approximately 3:30 p.m., the TC confirmed that the procedure needed to be updated.
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 2023 maintenance records, the absence of records, and interview with the TC (technical consultant) 6/5/23, the laboratory failed to perform and document the manufacturer's specified daily and monthly maintenance for the Medonic M-Series hematology analyzer for 12 of 12 months in 2021 and 12 of 12 months in 2022, and failed to document the manufacturer's specified daily maintenance for 5 of 5 months in 2023. Findings: Review of manufacturer's instructions for the Medonic M-series revealed maintenance requirements for daily and monthly cleaning, and a recommendation for 6-month cleaning. Review of 2023 maintenance records revealed the laboratory documented monthly maintenance for 5 of 5 months (January, February, March, April, May) in 2023, but there were no records available to indicate daily maintenance was performed. The laboratory failed to utilize the maintenance log provided by the manufacturer, but had documented monthly maintenance on a plain sheet of printer paper. There were no records available for daily or monthly maintenance in 2021 or 2022. During interview at approximately 3:30 p.m., the TC stated the 2021 and 2022 maintenance was done and was documented, but they were not able to locate the records.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by:

	Based on review of validation records for the Medonic M-Series hematology analyzer and interview with the TC (technical consultant) 6/5/23, the laboratory director failed to review and approve the validation of the analyzer prior to the initiation of patient testing. Review of validation records for the Medonic-M Series analyzer revealed the analyzer was installed in October 2020. The physician's assistant who operates the laboratory had signed the following statement 10/29/20: "I have reviewed the correlation specimens and startup materials (if applicable) for the Medonic M Series and have found that the correlations are good. The laboratory can start using the above instrument for testing in the laboratory ...". There was no documentation available to indicate that the laboratory director reviewed the validation records to ensure the testing was adequate to validate the accuracy, precision, and reportable range for the Medonic M-Series prior to use for patient testing. During interview at approximately 11:45 a.m., the TC stated that the Medonic M-Series validation had not been reviewed by the laboratory director.