Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2114820	01/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Eastway Medical Center And Urgent Care, Pllc	1220 Eastway Drive, Charlotte, 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
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based upon review of the 2023 Medonic quality control records, review of 2023 corrective action records, review of the October 2023 patient test log and interview with the TC (Technical Consultant) on 1/11/24, the laboratory failed to take corrective action to ensure that patient care was not adversely affected when three patients were tested and their results reported after two of three external quality control values performed outside of the acceptable range for hemoglobin on October 11, 2023. Findings: Review of the laboratory's October 2023 quality control records for the Medonic instrument revealed that the normal and high quality control values performed outside of the acceptable range for hemoglobin on October 11, 2023. Review of the laboratory's October 2023 corrective action records revealed no documentation concerning the quality controls performed on October 11, 2023. Review of the October 2023 patient test log revealed that three patients (19322, 33019, 33015) were tested on the Medonic instrument on October 11, 2023. In interview at approximately 11:30 a.m., the TC confirmed that the hemoglobin results of the three patients performed on October 11, 2023 have not been reviewed to ensure that patient care was not adversely affected.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR

	CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based upon review of verification records for the Medonic and BD Affirm instruments, review of personnel records, review of proficiency testing records, review of quality control records and interviews with the Clinical Consultant and Technical Consultant on 1/11/24, the LD (Laboratory Director) failed to provide overall management and direction for the laboratory services provided. Findings: The LD failed to ensure the verification of performance specifications for the Medonic and BD Affirm instruments prior to patient testing (see D6013). The LD failed to ensure 2 of 2 Testing Personnel received appropriate training prior to patient testing (see D6029). The LD failed to ensure that the laboratory was enrolled in an HHS (Health and Human Services) approved proficiency testing program for all testing performed (see D6015). The LD failed to ensure the laboratory performed two levels of external quality control material each day of testing and failed to implement an IQCP (Individualized Quality Control Plan) to allow the laboratory to decrease the frequency of quality control performance (see D6020).
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 upon the review of records to verify the performance specifications of the Medonic instrument and the BD Affirm instrument, and interview with the TC (Technical Consultant) on 1/11/24, the Laboratory Director failed to ensure the verification of performance specifications for the Medonic and BD Affirm instruments prior to patient testing. Review of records to verify the performance specifications of the Medonic and BD Affirm instruments revealed the following: 1. No records were observed to document the verification of performance specifications on the Medonic instrument. 2. The TC presented a package insert for verification swabs for the BD Affirm instrument. No further records to document the performance of these swabs were observed. In interview at approximately 9:15 a.m., the TC stated that performance specifications for the Medonic instrument were not performed prior to patient testing. In interview at approximately 10:00 a.m., the TC stated there was no record of the performance of verification samples on the BD Affirm instrument.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)

	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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based upon review of the laboratory's policies and procedures, review of 2022 and 2023 WSLHPT (Wisconsin State Laboratory of Hygiene Proficiency Testing) records and interview with the CC (Clinical Consultant) on 1/11/24, the LD (Laboratory Director) failed to ensure the laboratory was enrolled into an HHS (Health and Human Services) approved proficiency testing program for all testing performed. Findings: Review of the laboratory's procedure manual revealed the following: 1. A procedure for use of the Medonic hematology instrument was signed into use by the LD on May 25, 2023. 2. A procedure for use of the BD Affirm instrument was signed into use by the LD on August 29, 2023. Review of 2022 and 2023 WSLHPT records revealed documentation of enrollment for serum HCG (human chorionic gonadotropin), a test no longer performed by the laboratory. There were no records of enrollment for testing performed on the Medonic or BD Affirm instruments. In interview at approximately 11:00 a.m., the CC confirmed the laboratory was not enrolled in PT for testing performed on the Medonic and BD Affirm instruments in 2023. During the survey on 1/11/24, the CC enrolled the laboratory in WSLHPT for testing performed on the Medonic and BD Affirm instruments.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based upon review of BD Affirm 2023 and 2024 external quality control records, review of the BD Affirm reagent package insert, review of the laboratory's policies and interview with the TC (Technical Consultant) on 1/11/24, the LD (Laboratory Director) failed to ensure the laboratory performed two levels of external quality control material each day of testing and failed to implement an IQCP (Individualized Quality Control Plan) to allow the laboratory to decrease the frequency of quality control performance. Findings: Review of the laboratory's 2023 and 2024 BD Affirm quality control records revealed the performance of external quality controls for each new lot of reagent. Review of the BD Affirm VPIII Microbial Identification Test package insert revealed in "Quality Control" that "...Each reagent lot must be tested for adequate sample lysis and release of target nucleic acid..." Review of the laboratory's policies did not reveal an IQCP to support the laboratory's adherence of the manufacturer's quality control guidelines. In interview at approximately 10:00 a.m., the TC confirmed that an IQCP for use of the BD Affirm instrument has not been implemented.

D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based upon review of 2023 training and competency records and interview with the TC (Technical Consultant) on 1/11/24, the Laboratory Director failed to document the initial training of 2 of 2 TP (Testing Personnel) when the laboratory initiated use of the Medonic instrument in May 2023. Findings: Review of 2023 training and competency records revealed the following: 1. There was no documentation of the initial training for use of the Medonic instrument for TP#1. 2. TP#2 had documentation of a Medonic competency assessment performed in November 2023, but there was no documentation of initial training. In interview at approximately 9:45 a.m., the TC stated the following: 1. He did not perform the initial training of TP#1 or TP#2 for use of the Medonic instrument. 2. An individual from an affiliated office performed the initial training; however, this was not documented.
D6061	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1419(c) The clinical consultant must ensure that reports of test results include pertinent information required for specific patient interpretation. This STANDARD is not met as evidenced by: Based upon the review of two patient test reports and interview with the CC (Clinical Consultant) on 1/11/24, the CC failed to ensure that patient test reports generated by the laboratory contained all components required for interpretation of patient test results. Findings: Review of two patient test reports generated by the facility's EMR (electronic medical records) system revealed the following: 1. Both test reports displayed "Main Office" over the address, and did not include the name of the laboratory. 2. A test report for the BD Affirm instrument did not display reference /normal ranges for each analyte. 3. A test report for the Medonic instrument did not display the units of measure for each analyte. In interview at approximately 11:00 a.m., the CC reviewed the patient test reports and confirmed the findings.
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 upon review of October 2023 Medonic quality control records, review of the laboratory's policies and procedures and review of the October 2023 patient test log, TP (Testing Personnel)#2 failed to adhere to the laboratory's quality control policy. Findings: Review of the laboratory's October 2023 hematology quality control records for the Medonic instrument revealed that the normal and high quality control values were outside of the acceptable range for hemoglobin on October 11, 2023. Review of the laboratory's Patient Test Management policy revealed "Quality Control Failure:" ... "5. Do not report patient results until the problem is resolved. Send the patient sample to another laboratory." Review of the October 2023 patient test log revealed that hemoglobin results were reported for three patients (19322, 33019, 33015) on October 11, 2023 when two of three Medonic quality control values were outside of the acceptable range.