Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2100324	04/22/2024
Name of Provider or Supplier	**Street Address, City, State**	
Complete Emergency Care City Base Llc	2619 Se Military Drive, Suite 101, San Antonio, TX	

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) 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 review of the manufacturer's package insert for the Roche CoaguChek XS, review of patient test records from October 1, 2023 to April 9, 2024, and staff interview, the laboratory failed to follow the manufacturer's instructions for three of five patients tested. The findings included: 1. A review of the manufacturer's package insert for the Roche CoaguChek XS (2020-12 V3.0) under the section titled "Purpose" determined: "The CoaguChek XS Plus System is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy." 2. A review of CoaguChek XS testing records from January 2023 to December 2023 identified the laboratory performed testing on five patients. A review of the patients records determined three of the five patients did not have a history of taking oral anticoagulation medication. They were: Date Identification Number 11/17 NUNPE000 12/09 CAMCA005 02/21 GALAR004 3. The technical consultant confirmed the findings in an interview conducted on 04/09/2024 at 1650 hours in the office.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's chemistry core proficiency testing results from 2022 and 2023, and staff interview, the laboratory failed to have documentation performing corrective actions for unacceptable proficiency testing results for 1 of 3 events. The findings include: 1. A review of the laboratory's American Proficiency Institute's chemistry core proficiency testing results from 2022 and 2023 identified the laboratory had unacceptable proficiency testing results for the following 3 analytes: 2022 Event 2 Phosphorous Score: 20% 2023 Event 1 Troponin Score: 40% 2023 Event 3 B-Type Natriuretic Peptide Score: 60% 2. Further review of the proficiency testing records determined 2022 Event 2 Phosporous was self graded by the facility due to the incorrect response of "Instrument out of service" being reported. A self evaluation resulted in a score of 20%. The reported results and acceptable ranges were: Sample Result Acceptable CH-06 7.9 5.8 - 6.6 CH-07 2.7 2.2 - 2.8 CH-08 6.0 4.6 - 5.3 CH-09 4.9 3.6 - 4.3 CH-10 7.8 5.5 - 6.3 3. The laboratory was asked to provide documentation of performing corrective actions to determine the possible cause of the failure. No documentation was provided. 4. The technical consultant confirmed the findings in an interview conducted 04/09/2024 at 1200 hours in the office.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer, review of patient test records from 04/01/2024 to 04/09/2024, and staff interview, the laboratory failed to have documentation of following the manufacturer's instructions for resolving flags on 1 of 3 Complete Blood Count (CBC) results. The finding included: 1. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Revised March 2017) under the section titled "Display and Output Analysis Results" identified possible flags for CBC results, the possible causes, and steps to take to address the flags. Examples are: a) Flag: F1, F2, F3 Probable Cause: Presence of CML or other immature granulocytes, sample with high values for monocytes, eosinophils, and basophils, incomplete lysing of red blood cells, aged sample, etc. Correction: Check smear, etc. Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37C for 30 minutes and repeat analysis, etc. b) Flag: AG Probable Cause: Presence of nucleated red blood cells,effect for fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction: Check smear, etc. 2. A review of patient test records from April 1, 2024 to April 9, 2024 identified 3 patient results with flagged results. One of the three was reported to the provider without documentation of corrective actions being taken to resolve the flags. It was: Test date: 04/07/2024 Sample Identification: 040709 Flag (s): F1, F2 3. The laboratory was asked to provide documentation of performing corrective actions prior to reporting the flagged results to the provider. No documentation was provided. 4. The technical consultant confirmed the findings in a interview conducted on 04/09/2024 at 1700 hours in the laboratory. II. Based on review of the manufacturer's instructions for corrective actions to perform for recalled

	QuidelOrtho Triage Troponin kits, review of patient test records from December 2022 to June 2022, and staff interview, the laboratory failed to have documentation of following manufacturer's instructions for 3 of 3 recalled test kits. The findings included: 1. A review of the manufacturer's instructions for the QuidelOrtho Triage Troponin kits (July 12, 2023) identified the following steps the laboratory was to follow if patient samples were tested with the recalled test kits: "If unaffected product is not immediately available or you do not have an alternate method or testing site with an alternate test method is not available, please follow these steps, as applicable, to minimize patient risk: - Flag all negative results reported to clinicians as possibly inaccurate until lots of unaffected products are used. - Use results from an alternate clinical laboratory analyzer when troponin results are below or close to the cutoff and myocardial infarction is suspected. - Perform serial sampling. Keep patients until at least 3 negative troponin values have been obtained. - Use all triage troponin results in conjunction with the patient's risk factors, clinical presentation, EKG, and other imaging. - Consider recommendations by the ACC, ESC guidelines and the Fourth Universal Definition of Myocardial Infarction for monitoring a patient for a rise or fall patter of troponin." 2. Further review of the manufacturer's instructions stated the lot number of the recalled kits. They were: Lot: T13664RN Lot: T13708RN Lot: T13943RN 3. A review of patient troponin testing records from December 2022 to May 2023 identified the following 143 patients (see patient alias list) tested with each lot of recalled reagent: Lot: T13664RN 79 patients tested In use: 12/23 to 03/20 Lot: T13708RN 44 patients tested In use: 03/22 to 05/15 Lot: T13943RN 20 patients tested In use: 05/20 to 06/02 4. The laboratory was asked to provide documentation of following the manufacturer's corrective actions listed in the recall letter. No documentation was provided. 5. The technical consultant confirmed the findings in an interview conducted 04/09/2024 at 1330 hours in the office.