Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2107705	03/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Complete Emergency Care Tyler Llc	1809 Capital Drive, Tyler, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of the EIGHTCHECK-3WP X-TRA hematology controls manufacturer's package insert, and staff interview it was determined the laboratory failed to document amended expiration dates on 3 of 3 opened controls in use. Findings included: 1. On 03/17/2022 at 0920 hours in the laboratory, surveyor observed opened/in use hematology controls stored in the refrigerator that did not have an amended date of expiration documented. These were: X-TRA-L Abnormal low Lot 20260710 Manufacturer expiration: 2022-05-04 X-TRA-

	N Normal Lot 20260711 Manufacturer expiration: 2022-05-04 X-TRA-H Abnormal High Lot 20260712 Manufacturer expiration: 2022-05-04 2. Review of the EIGHTCHECK-3WP X-TRA hematology controls' package insert revealed: "Storage and shelf life after opening Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8 C after being re-capped." 3. In an interview on 03/17/2022 at 0930 hours in the office the technical consultant number 1 (as described on submitted Form 209 signed by laboratory director on 03/15 /2022), after review of the control vials in question, confirmed the findings.
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 for the laboratory's Sysmex XP-300 hematology analyzer's Instructions for Use, review of the laboratory's maintenance logs for the same instrument from December of 2021 to March of 2022 and staff interview it was determined the laboratory failed to document manufacturer required weekly instrument maintenance for 3 of 13 weeks reviewed. Findings included: 1. Review of for the laboratory's Sysmex XP-300 hematology analyzer's Instructions for Use (Sysmex-XP300; Revised March 2017), Section 12 Cleaning and Maintenance, page 12-1 revealed: "Perform maintenance according to the schedule below." And, "Weekly Clean SRV tray (see 12.5)" 2. Review of the laboratory's maintenance logs for Sysex XP-300 from December of 2021 to March of 2022 revealed the following 3 of 13 reviewed weekly intervals were missing documentation of performance of the SRV tray cleaning: 12/24/2021 to 12/31/2021 02/12/2022 to 02/19/2022 02/19/2022 to 20/26/2022 3. In an interview on 03/17/2022 at 1200 hours in the office the technical consultant number 1 (as described on submitted Form 209 signed by laboratory director on 03/15/2022), after review of the data, confirmed the findings.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quidel Triage quality control (QC) records for the D-dimer coagulation test from July 2021 to March of 2022, review of the laboratory's Individualized Quality Control Plans (IQCP), review of patient testing logs for the same interval and staff interview it was determined the laboratory failed to document performance of QC for coagulation D-dimer testing according to regulatory requirements (every 8 hours) for 72 of 75 instances QC was required. Findings included: 1. Review of the laboratory's QC records for the Quidel Triage D-dimer coagulation test from July 2021 to March of 2022 revealed QC was performed once each month of testing and/or with each new lot of reagents as follows: 07/09/2021 07

	/12/2021 08/11/2021 08/25/2021 09/24/2021 10/23/2021 11/22/2021 12/21/2021 01/03 /2022 01/04/2022 01/28/2022 01/29/2022 02/27/2022 03/16/2022 2. Review of the laboratory's IQCP revealed the laboratory completed a consecutive 30-day IQCP study on 12/28/2016 where QC was tested once each day of the study. There was no documentation of IQCP evaluation encompassing D-dimer QC testing every eight hours for 30 days in order to validate the QC schedule the laboratory was following. 3. Review of the patient test log for July 2021 to March of 2022 revealed there were 97 samples tested for D-dimer within the time interval. Refer to master list attached. 4. In an interview on 03/17/2022 at 1245 hours in the office the technical consultant number 1 (as described on submitted Form 209 signed by laboratory director on 03/15 /2022), after review of the data, confirmed the findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of a sampling of the laboratory's Room Temperature & Humidity Logs from July to September of 2021 and staff interview it was determined the laboratory failed to document corrective action for 17 of 17 instances when room temperatures were out of laboratory defined range. Findings included: 1. Review of a sampling of the laboratory's Room Temperature & Humidity Logs from July to September of 2021 revealed the laboratory defined room temperature as 18-24C. 2. Further review of the logs revealed room temperature was out of defined range on the following days: Date: Temperature: 07/19/2021 24.1C 07/21/2021 24.1C 08/28/2021 24.4C 08/29/2021 24.9C 08/30/2021 24.2C 09/04/2021 24.2C 09/07/2021 25.3C 09/08 /2021 24.1C 09/10/2021 26.3C 09/12/2021 25.1C 09/14/2021 25.7C 09/20/2021 24.2 C 09/21/2021 24.1C 09/22/2021 25.0C 09/23/2021 24.1C 09/24/2021 24.3C 09/29 /2021 24.8C 3. The laboratory was asked to provide documentation of corrective action for the out of range temperatures and no such documentation was provided. 4. In an interview on 03/15/2022 at 1300 hours in the office technical consultant number 1 (as described on submitted Form 209, signed by laboratory director on 03/15/2022), after review of the data, confirmed the findings.