Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2107705	07/25/2023
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	An onsite survey conducted 07/25/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of laboratory policy, proficiency testing (PT) records, and confirmed in interview, the laboratory failed to document corrective action and remedial action for one of one unsatisfactory analyte failure, hemoglobin, reviewed for the Hematology Coagulation PT events reviewed in 2022. The findings included: 1. Review of the laboratory policy titled "Proficiency Testing" subsection D "Results Review" had the following instruction: "Should any result(s) be evaluated as "UNACCEPTABLE", corrective action should be initiated within one week. An Unacceptable Proficiency Test Results Evaluation Form should be completed by the Technical Consultant or designee to document investigation and projected corrective actions. Full documentation should accompany any correspondence or in-service precipitated by this evaluation." 2. Review of the American Proficiency Institute (API) PT records for 2022 Hematology / Coagulation - 2nd Event included the following unsatisfactory score (satisfactory performance is 80% or greater): Analyte - Score Hemoglobin - 60% Review of the API "Performance Review and Corrective Action" documentation, signed by the laboratory director on 9/19/2022, had the

	following information: "HSY-07, event sample ran was HSY-06. Repeat sample self evaluation 100% HSY - 08, repeat sample is also within range for analytes missed. This corrective action is most likely related to inadequate mixing for API events." Surveyor queried for any additional quality assurance (QA) documentation to include re-education and remedial actions; none were provided. 3. In an interview on 7/25 /2023 at 13:45 hours, in the office, technical consultant (TC) 1 and TC 2 confirmed that corrective action including testing personnel re-education and patient remedial action were not documented.
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 on a review of laboratory policy, quality control (QC) records, patient test records, and confirmed in interview the laboratory failed to document corrective action for 9 of 23 QC failures on the Sysmex XP-300 hematology analyzer for the months of May, July, September, and December 2022. The findings included: 1. Review of the laboratory policy titled "Laboratory Procedure CBC Sysmex XP-300", section "Quality Control" had the following statement: "CAUTION: No patient samples may be tested if QC does not fall within acceptable ranges. All out-of-range QC results must be resolved, and corrective action must be documented prior to patient testing." 2. Review of laboratory QC records for the Sysmex XP-300 hematology analyzer, had the following nine QC failures with no documented corrective action: May 2022: 5/8/2022 at 19:21 hours; QC Level 1 Lot 21100710, Exp 7/27/2022 Analyte: result - (acceptable range) HGB (g/dL): - 7.0 - (5.9 - 6.7) 3 patients ran since the last acceptable QC on 5/8/2022 at 06:55 hours: MRN: 45788 MRN: 45794 MRN: 45787 5/4/2022 at 20:01 hours; QC Level 3, Lot 21100712, Exp 7 /27/2022 Analyte: result - (Acceptable range) MXD% - 14.2 - (15 - 20.5) NEUT% - 50.6 - (42.6 - 50.4) 1 patient ran since the last acceptable QC on 5/4/2022 at 07:00 hours: MRN: 45706 July 2022: 7/3/2022 at 19:09 hours; QC Level 1, lot 21100710, Exp 7/27/2022 Analyte: result - (acceptable range) MXD% - 3.1 - (6.9 - 16.5) NEUT%: 75.3 - (63 - 73.) MXD# (10^3/uL): 0.1 - (0.2 - 0.6) 1 Patient ran since the last acceptable QC on 7/27/2022 at 06:49 hours: MRN: 47007 7/15/2022 at 20:08 hours; QC Level 1, lot 21100710, Exp 7/27/2022 Analyte: result - (acceptable range) MXD%: 3.8 - (6.9 - 16.5) NEUT%: 74.7 - (63 - 73.) MXD# (10^3/uL): 0.1 - (0.2 - 0.6) 2 patients tested since the last acceptable QC on 7/15/2022 at 07:01 hours: MRN: 47272 MRN: 47290 7/17/2022 at 19:30 hours; QC Level 3, lot 21100712, Exp 7/27 /2022 Analyte: Result - (Acceptable Range) RBC (10^6/uL): 5.74 - (4.99 - 5.51) HCT (%): 50.1 - (41.3 - 48.5) September 2022: 9/25/2023 at 06:50 QC Level 1, Lot21940710, Exp: 10/19/2022 Analyte: Result - (Acceptable Range) WBC (10^3 /uL): 6.9 - (2.7 - 3.7) RBC (10^/6uL): 4.32 - (2.17 - 2.57) HGB (g/dL): 12.6 - (4.8 - 5.6) HCT (%): 35.1 - (14.3 - 17.3) MCV (fL): 81.3 - (53.6 - 79.6) MCH (pg): 29.2 - (17.8 - 26.2) PLT (10^3/uL): 212 - (62 - 93) LYM%: 30.4 - (14.7 - 22.1) NEUT%: 58.0 - (65.5 - 75.7) LYM# (10^3/uL): 2.1 - (0.4 - 0.8) MXD# (10^3/uL): 0.8 - (0.2 -

	0.4) NEUT# (10^3/uL): 4.0 - (1.9 - 2.7) RDW-SD (fL) : 31.3 - (36.3 - 47.9) RDW-CV (%): 8.3 - (14.8 - 18.2) December 2022: 12/15/2022 at 19:19 hours QC Level 1, Lot 22780710, Exp 1/11/2023 Analyte: Result - (Acceptable Range) WBC (10^3/uL): 6.9 - (2.7 - 3.7) RBC (10^6/uL): 4.52 - (2.45 - 2.85) HGB (g/dL): 13.3 - (6.0 - 6.8) HCT (%): 37.8 - (17.6 - 20.6) MCH (pg): 29.4 - (19.9 - 28.3) PLT (10^3/uL): 230 - (63 - 97) 1 patient ran since the last acceptable QC on 12/15/2023 at 07:36 hours: MRN: 51035 12/29/2022 at 20:22 hours QC Level 1, Lot 22780710, Exp 1/11/2023 Analyte: Result - (Acceptable Range) PLT (10^3/uL): 99 - (63 - 97) 3 patients ran since the last acceptable QC on 12/29/2023 at 07:03 hours: MRN: 51498 MRN: 51485 MRN: 51495 3. In an interview on 7/25/2023 at 11:45 hours, in the office, the technical consultant (TC) 1 and TC 2 confirmed that the above QC failures did not include corrective action documentation by testing personnel and that patient remedial action had not been performed. Key: WBC: white blood cell RBC: Red Blood Cell HGB: hemoglobin HCT: Hematocrit MCV: Mean corpuscular volume MCH: Mean corpuscular hemoglobin PLT: platelet LYM%: Percent Lymphocytes NEUT%: Percent Neutrophils MXD%: Percent Mixed White cells LYM#: Absolute Lymphocyte NEUT#: Absolute Neutrophils MXD#: Absolute Mixed White Cells MRN: Medical Record Number
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of laboratory quarterly quality assessment (QA) records, and temperature documentation, and confirmed in interview, the laboratory failed to identify issues and take corrective actions to resolve problems found in analytic systems in chemistry for three of four quarterly reviews performed in 2022. The findings included: 1. Review of QA documentation for the Triage Cardiac Panel Individualized Quality Control Plan (IQCP) summary sheet for the year in review 2022, signed by the technical consultant and laboratory director on 3/16/2023, indicated an "Acceptable Risk" for the quarterly evaluation of risk factors. The technical consultant stated that they reviewed the risks defined in the risk assessment quarterly through analytical records and recorded the summation as part of the laboratory QA program. 2. A review of the quarterly QA records for the RA review, and environmental records, had the following evaluations documented inconsistently with the daily record kept by testing personnel in 2022 as follows: January 2022 QA form for room temperature documented 31 out of 31 (31/31) days with acceptable temperature. A review of the "Room Temperature and Humidity Log" for January 2022 had 25/31 days with acceptable temperatures. The temperature was outside of acceptability, 20 - 24(degrees) Celsius (C), with no documentation of corrective action for the following six days: Date Temperature 01/15/2022 19.6 (degrees) C 01 /20/2022 18.7 (degrees) C 01/21/2022 19.7 (degrees) C 01/24/2022 19.3 (degrees) C 01/27/2022 18.3 (degrees) C 01/28/2022 19.1 (degrees) C February 2022 QA form for room temperature documented 22/28 days with acceptable temperature. A review of the "Room Temperature and Humidity Log" for February 2022 had 21/28 days with acceptable temperatures. The temperature was out of acceptability, 20 - 24(degrees)

	C, with no documentation of corrective for the following seven days: Date Temperature 02/09/2022 19.5 (degrees) C 02/19/2022 19.5 (degrees) C 02/20/2022 19.9 (degrees) C 02/21/2022 18.6 (degrees) C 02/24/2022 19.8 (degrees) C 02/26 /2022 19.1 (degrees) C 02/27/2022 19.2 (degrees) C March 2022 QA for room temperature was not assessed; the comment in the column section includes an assessment for March 2023. A review of the "Room Temperature and Humidity Log" for March 2022 had 26/31 days with acceptable temperatures. The temperature was out of acceptability, 20 - 24(degrees) C, with no documentation of corrective action for the following 5 days: Date Temperature 03/02/2022 19.7 (degrees) C 03/05/2022 19.74 (degrees) C 03/12/2022 19.5 (degrees) C 03/13/2022 18.7 (degrees) C 03/16 /2022 19.2 (degrees) C April 2022 QA for room temperature was not assessed; the comment in the column section includes an assessment for April 2023. December 2022 QA form for room temperature documented 31/31 days with acceptable temperature. A review of the "Room Temperature and Humidity Log" for December 2022 had 30/31 days with acceptable temperatures. The temperature was out of acceptability, 20 - 24(degrees) C, with no documentation of corrective action for the following day: Date Temperature 12/23/2022 19.8 (degrees) C 3. In an interview on 7 /25/2023 at 13:25 hours, in the office, the technical consultant (TC) 1 confirmed the laboratory failed to identify issues in the quarterly QA review and take corrective action to resolve the problems found for the environmental records.