Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2104701	08/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Complete Emergency Care La Vernia Llc	102 S Fm 1346, Suite 2, La Vernia, 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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D6063 - 42 C.F.R. 493.1421 Condition: Testing Personnel Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's chemistry proficiency testing records from 2022, and staff interview, it was revealed the laboratory failed to have documentation of testing personnel completing the attestation statement for 1 of 2 events reviewed. The findings include: 1. A review of the laboratory's American Proficiency Institute's chemistry proficiency testing records from 2022 (event 1 and event 2) revealed the laboratory failed to have documentation of testing personnel signing the attestation statement for samples CH -06, CH-07, CH-08, CH-09, and CH-10 for event 2. 2. The laboratory was asked to provide documentation of testing personnel signing the attestation for the identified samples.

	No documentation was provided. 3. An interview with the technical consultant on 08/4 /2022 at 0945 hours in the office - after her review of the records- confirmed the findings.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's hematology proficiency testing records from 2022, and staff interview, it was revealed the laboratory failed to test proficiency testing samples in the same manner at patient samples for 2 of 2 events. The findings include: 1. A review of the laboratory's American Proficiency Institute's hematology proficiency testing records from 2022 revealed each proficiency sample was tested in duplicate. a) 2022 event 1 Sample: HYS-1 tested: 03/24/2022 16:25 03/24/2022 16:28 Sample: HYS-2 tested: 03/24/2022 16:29 03/24/2022 16:31 Sample: HYS-3 tested: 03/24/2022 16:32 03/24/2022 16:34 Sample: HYS-4 tested: 03/24/2022 16:35 03/24/2022 16:27 Sample: HYS-5 tested: 03 /24/2022 16:40 03/24/2022 16:42 b) 2022 event 2 Sample: HYS-6 tested: 08/02/2022 12:10 08/02/2022 12:16 Sample: HYS-7 tested: 08/02/2022 12:12 08/-2/2022 12:18 Sample: HYS-8 tested: 08/02/2022 12:13 08/02/2022 12:19 Sample: HYS-9 tested: 08 /02/2022 12:14 08/02/2022 12:20 Sample: HYS-10 tested: 08/02/2022 12:15 08/02 /2022 12:21 2. The laboratory was asked to provide documentation of the laboratory repeating all patient samples in the same manner as the proficiency testing samples were tested. No documentation was provided. 3. An interview with the technical consultant on 08/04/2022 at 0940 hours in the office revealed the facility's policy was to repeat results with flags results. She agreed that none of the proficiency samples' results had flags and, therefore, should not have been repeated. This confirmed the findings.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of following its policy for the notification of critical values. The findings include: 1. A review the laboratory's policy titled "Review and Release of Patient Results Verification" revealed: "All critical values, notification personnel, date and time of notification and tech initials are documented on the Critical Value Log..." 2. A review of the laboratory's records revealed the facility had the following defined critical values for hematology testing: White Blood Cell: less than 2 or greater than 20 Hemoglobin: less than 6 or greater than 20 Hematocrit: less than 18 or greater than 60 Platelet: less than 90 or greater than 1 million 3. A random sampling of patient results from July 14, 2022 to July 24, 2022 identified the following patient results which met the

	laboratory's criteria as a critical value: a) July 14, 2022' Sample ID: 071411 White Blood Cell: 22.1 b) July 16, 2022 Sample ID: 071608 Platelet: 79 c) July 24, 2022 Sample ID: 072409 White Blood Cell: 21.7 3. A review of the laboratory's Critical Value Log revealed none of the identified critical value were documented as required by the laboratory's policy. 4. An interview with the technical consultant on 08/04 /2022 at 1145 hours in the laboratory - after her review of the records- confirmed the findings.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments on 5 of 5 testing personnel after a new instrument was installed. The findings include: 1. A review of the laboratory's instrumentation revealed the laboratory installed a new hematology analyzer in December 2021. 2. A review of the laboratory's personnel records revealed the facility failed to have documentation of the technical consultant performing competency assessments on 5 of 5 testing personnel prior to them reporting patient results. They were (as listed on Form CMS 209): Testing personnel number 1 Testing personnel number 2 Testing personnel number 4 Testing personnel number 9 Testing personnel number 10 3. The laboratory was asked to provide documentation of the missing competency assessments. No documentation was provided. 4. An interview with the technical consultant on 08/04/2022 at 1055 hours in the office revealed competency assessment were not performed when required. This confirmed the findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 6 of 16 testing personnel (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor

	of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 6 of 16 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 16 testing personnel. 2. A review of personnel records revealed the laboratory failed to have documentation of education to qualify 6 of the 16 personnel. They were (as listed on Form CMS 209): Testing personnel number 11 Testing personnel number 12 Testing personnel number 13 Testing personnel number 14 Testing personnel number 15 Testing personnel number 16 3. The laboratory was asked to provide documentation of education for the identified testing personnel. No documentation was provided. 4. An interview with the technical consultant on 08/04 /2022 at 1055 hours in the office - after her review of the records- confirmed the findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training on the Sysmex XP-300 hematology analyzer for 6 of 16 testing personnel. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 16 testing personnel. 2. A review of personnel records revealed the laboratory failed to have documentation of training for 6 of the 16 personnel on the Sysmex XP-300 hematology analyzer installed in December 2021. They were (as listed on Form CMS 209): Testing personnel number 11 Testing personnel number 12 Testing personnel number 13 Testing personnel number 14 Testing personnel number 15 Testing personnel number 16 3. The laboratory was asked to provide documentation of training for the identified testing personnel. No documentation was provided. 4. An interview with the technical consultant on 08/04/2022 at 1055 hours in the office - after her review of the records- confirmed the findings.