Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2104701	04/27/2021
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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was 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 to be 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 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.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of patient test records, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to have documentation of performing quality control testing each day of patient testing. The findings were: 1. A review of the laboratory's test menu revealed the laboratory performed testing on the BioFire utilizing the Respiratory Panel 2.1. 2. The FDA lifted the EUA for the BioFire Respiratory Panel 2.1 on March 18, 2021. Therefore, the facility was required to perform quality control testing each

	day of patient testing, or perform an IQCP. 3. A review of patient test records from March 18, 2021 to April 27, 2021 revealed the laboratory performed testing on the following days: a) 04/08/2021 Medical record number: ALTJA000 b) 04/20/2021 Medical record number: BLAKI000 c) 04/22/2021 Medical record number: BROJO005 d) 04/25/2021 Medical record number: ALMSA000 4. A review of the laboratory's quality control records revealed the laboratory failed to have documentation of performing quality control on the identified days. 5. An interview with the technical consultant on 04/27/2021 at 1400 hours in the office confirmed the findings.