

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2049777	(X3) Date Survey Completed 04/28/2021
Name of Provider or Supplier Complete Emergency Care I, Llc	Street Address, City, State 10628 Culebra Road #200, 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
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.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of patient results and staff interview, it was revealed the laboratory failed to have documentation of following its policy to send out samples to resolve flags on CBC (complete blood count) results. The findings were: 1. A review of the laboratory's procedure titled "Laboratory Procedure CBC Horiba Micros 60" (effective date: January 4, 2019) under the section titled "Instrument Flags" revealed: "NOTE: All unresolved Anomalies and/or Abnormal distribution flags will be sent to a reference lab to be manually verified by the examination of a stained peripheral blood smear for the presence of pathological</p>

elements. Morphology flags on the platelet or WBC distribution curve will result in sending the sample to a reference lab for further studies to confirm the results." 2. A sampling of patient CBC results from March and April 2021 identified three patient results with flags. They were: a) Test date: 03/20/2021 Medical number: AGWST000 Flags: WBC Flag G1 Platelet Flag SCH b) Test date: 04/25/2021 Medical number: DELJE008 Flags: WBC Flag G1 c) Test date: 04/27/2021 Medical number: SPAMA002 Flags: WBC Flag G1 3. The laboratory was asked to provide documentation of following its policy and sending the samples out for additional testing. No documentation was provided. 4. An interview with the technical consultant on 04/28/2021 at 1230 hours in the office confirmed the findings. KEY: WBC white blood cells