

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2049777	(X3) Date Survey Completed 01/16/2019
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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's API (American Proficiency Institute) proficiency testing (PT) attestation statements, review of instrument printout results for PT samples from 2016, 2017, and 2018, and confirmed in interview of facility personnel, the laboratory failed to test proficiency testing samples the same number of times as patient samples. The findings were: 1. A review of API proficiency testing attestation statements from 2016 (event 3), 2017 (events 1, 2, and 3), and 2018 (events 1, 2, and 3) revealed that testing person 6 (as listed on Form CMS-209) and testing person 8 (as listed on Form CMS-209) had each signed the attestation statement. The attestation statement revealed that both of the testing persons performed testing on the following samples: HEM-11 HEM-12 HEM-13 HEM-14 HEM-15 2. Testing Person 6 signed the attestation statement November 13, 2018. 3. Testing Person 8 signed the attestation statement November 14, 2018. 4. A review of Horiba instrument print out results for PT records from 2016 (event 3), 2017 (events 1, 2, and 3), and 2018 (events 1, 2, and 3) revealed that each hematology sample for Hematology (2018-Event 3) was tested on 2 different days. Sample ID: HEM-11 Performed by Testing Person 8 (as listed on Form CMS-209) Date: 11-13-2018 Sample ID: HEM-11 Performed by Testing Person 6 (as listed on Form CMS-209) Date: 11-14-2018 Sample ID: HEM-12 Performed by Testing Person 8 (as listed on Form CMS-209) Date: 11-13-2018 Sample ID: HEM-12 Performed by Testing Person 6 (as listed on Form CMS-209) Date: 11-14-2018 Sample ID: HEM-13 Performed by Testing Person 8 (as listed on Form CMS-209) Date: 11-13-2018 Sample ID: HEM-13 Performed by Testing Person 6 (as listed on Form CMS-209) Date: 11-14-2018 Sample ID: HEM-14 Performed by Testing Person 8 (as listed on Form CMS-209) Date: 11-13-2018 Sample ID: HEM-</p>

14 Performed by Testing Person 6 (as listed on Form CMS-209) Date: 11-14-2018
Sample ID: HEM-15 Performed by Testing Person 8 (as listed on Form CMS-209)
Date: 11-13-2018 Sample ID: HEM-15 Performed by Testing Person 6 (as listed on
Form CMS-209) Date: 11-14-2018 5. An interview with the Nurse Manager on
January 16, 2019 at 11:30 hours in his office confirmed the findings. Key: CMS -
Centers for Medicare and Medicaid Services

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other
supplies must not be used when they have exceeded their expiration date, have
deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observations, and interview of facility personnel, the laboratory
failed to ensure that expired items were not available for use in patient testing. The
findings were: 1. At 09:00 hours on January 16, 2019, the surveyor observed the
following expired blood culture bottles on the top shelf in the laboratory in a clear
plastic container. BACTEC Peds Plus IF Culture vials Lot 8024759 Expiration Date:
11-30-18 Quantity of 2 2. An interview with the technical consultant on January 16,
2019 at 09:05 hours the above findings were confirmed.