

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2085872	(X3) Date Survey Completed 07/29/2024
Name of Provider or Supplier Orange Texas Emer Ctr, Llc	Street Address, City, State 1321 N 16th Street, Orange, 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 in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a validation survey conducted on July 29, 2024.
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory instruments, laboratory records, and interview with facility personnel, the laboratory failed to evaluate and define the relationship between test results using different instruments for the analytes CK-MB, Myoglobin and Troponin I performed on Triage analyzers Serial number 88583 and 87409 at least twice each year in 2022 and 2023. The findings included: 1. Based on review of laboratory instrumentation test menu documentation, the laboratory performed the Cardiac Panels including Troponin I, Myoglobin, CK-MB using two Alere Triage meters. 2. Based on review of laboratory test records for the Triage Cardiac Panel found the laboratory last performed comparison of results for the Cardiac Panel completed July 20, 2022. No other comparison studies were available for review. 3. During interview of the regional lab supervisor conducted July 29, 2024 at 12:52 PM, he confirmed that the laboratory did not perform instrument comparisons at least twice annually in 2022 and 2023.</p>