

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2112898	(X3) Date Survey Completed 09/08/2025
Name of Provider or Supplier Star Er,Llc	Street Address, City, State 7007 Indiana Ave, Lubbock, 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 recertification survey completed on September 9, 2025.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory proficiency testing records, and confirmed in interview, the laboratory failed to ensure successful twice annual accuracy for Troponin performed on the Triage chemistry analyzer for records reviewed in 2023. The findings included: 1. Review of the laboratory policy titled "Laboratory Procedure Proficiency Testing", effective, November 1, 2020, stated the following: "The purpose of proficiency testing is to provide an external method of verifying the overall quality of the laboratory functions to include all regulated and unregulated analytes." Subsection "E. Corrective Actions" : "If a laboratory fails two of three events for the same test system or analyte, the laboratory must take that analyte, or test system out of service and notify both API and CLIA (or COAL - the accrediting body) the system is out of service until proper corrective actions are completes and the system is proven to be back in proper working order." 2. Review of the 2023 laboratory proficiency testing records for Troponin I on the Triage chemistry analyzer included a score of 40% for the first event (an 80% or greater is passing), and an artificial score of 100% for the second event due to two out of the five scores requiring self-grading with peer group data. Review of the submitted laboratory results and peer group data provided by the American Proficiency Institute for the Triage Cardiac Troponin resulted in the following self-grade assessment for the two 'Not Graded' submissions: Sample, Reported Results, [Peer Results] - score CM-06</p>

0.97 [0.03 - 0.64] - unacceptable CM-09 2.63 [0.47 - 1.37] - unacceptable Two failed results out of five is a score of 60%, where an 80% or greater is passing. Surveyor asked if the laboratory had participated in any additional proficiency testing to have a successful twice annual accuracy or and none could be provided. 3. In an interview on 9/8/2025 at 14:10, in the breakroom, the technical consultant confirmed a successful twice annual accuracy assessment had not been performed for Troponin I on the Triage chemistry analyzer in 2023.