

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2184670	(X3) Date Survey Completed 05/11/2026
Name of Provider or Supplier Tyler Tx Emer Ctr, Llc	Street Address, City, State 2222 E Southeast Loop 323, Tyler, 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 the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of an validation survey completed on May 11, 2026. Standard level deficiencies were cited.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of instrument analytical print outs, patient test records, laboratory verification records, and confirmed in interview, the laboratory failed to ensure one of two Triage MeterPros had verification studies, for accuracy, precision, reportable range, and reference range, prior to patient testing for one of one patients with testing performed in January 2026. The findings included: 1. In a tour of the laboratory on 5/11/2026 at 10:32 hours, the following Triage MeterPro was on the laboratory counter used in patient testing for D-dimer, CKMB, and Troponin testing. Serial Number: 87308 2. Review of laboratory proficiency testing for the first event 2026 performed in January 2026 included instrument analytical records with the following Triage MeterPro serial number: Serial Number: 102688 Surveyor asked for the verification records pertaining to the Triage MeterPro 102688, and none could be provided. On 5/11/2026 at 10:40 hours, in the break room, testing personnel one stated that Triage MeterPro 102688 was a back up device, and it had been used in</p>

proficiency testing unintentionally. 3. Review of laboratory patient testing in January 2026 included the following one patient with testing performed on the Triage MeterPro 102688: Date: Patient Account, test performed 1/15/2026: 1004273-1, CKMB, MYO, TNI 4. In an interview on 5/11/2026 at 11:50 hours, in the breakroom, the laboratory director and testing personnel one, confirmed Triage MeterPro 102688 did not have verification studies performed to ensure the accuracy of results prior to testing patients.