

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2113612	(X3) Date Survey Completed 09/17/2026
Name of Provider or Supplier Eminent Medical Center, Llc	Street Address, City, State 1351 West President George Bush Hwy, Richardson, 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	A recertification survey was completed on 09/17/2026. Standard level deficiency was cited.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (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. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, verification studies in 2026, patient final reports and confirmed in interview, the laboratory failed to verify manufacturer's reference ranges for two of two coagulation analytes performed in 2026. Findings included: 1. During a tour of the facility, the surveyor observed one Hemochron Signature Elite coagulation analyzer currently available for patient testing (Serial Number: 29108). 2. Review of laboratory policy, "Individualized Quality Control Plan (IQCP) Hemochron Signature Elite Citrate APTT" (approved by the laboratory director on: 04/02/2026) revealed the following: " ...4. EMC Adopted Reference Intervals Based on the EMC verification study, the following intervals are adopted for Hemochron Signature Elite testing: Citrate APTT: 20.6 38.6 seconds" Further review of laboratory policy, "Individualized Quality Control Plan (IQCP) Hemochron Signature Elite Citrate PT" (approved by the laboratory director on: 04/02/2026) revealed the following: " ...4. EMC Adopted Reference Intervals Based on the EMC verification study, the following intervals are adopted for Hemochron Signature

Elite testing: ...Citrate PT: 8.0 to 15.0 seconds" 3. Review of laboratory verification studies performed in 2026 on the Hemochron Signature Elite coagulation analyzer, revealed the following: APTT Manufacturer's reference range: 20.6 38.6 seconds Laboratory data obtained during study: 25.2 to 38.3 Seconds PT Manufacturer's reference range: 8.0 to 15.0 seconds Laboratory data obtained during study: 8.4 to 14.4 seconds The laboratory was asked to provide documentation of the laboratory instrumentation obtaining the manufacturer's verified reference range. No documentation was provided. 4. Random review of patient final reports in 2026, revealed the following reference ranges provided by the laboratory: a. APTT: 20.6 38.6 seconds b. PT: 8.0 to 15.0 seconds 5. In an interview on 09/17/2026 in the facility break room, the laboratory technical supervisor (TS-1) confirmed the laboratory failed to verify manufacturer's reference ranges for two of two coagulation analytes performed in 2026. Word Key PT- Prothrombin Time APTT- Activated Partial Thrombin Time EMC- Eminent Medical Center