

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2145966	(X3) Date Survey Completed 05/22/2024
Name of Provider or Supplier Medical City Er Argyle, A Department Of	Street Address, City, State 7214 Crawford Road, Argyle, 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 substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, calibration verification documentation and confirmed in interview, the laboratory failed to follow their own policy for calibration verification on the Triage analyzer for four of four events in 2022 and 2023. Findings Included: 1. During a tour of the facility on 05/22/2024 at 01:05 PM, the surveyor observed two Triage analyzers performing D-Dimer testing on patient specimens. 2. Review of laboratory policy, "Triage MeterPro IQCP (Troponin, D-Dimer and Urine Tox Screen" (Effective on: 12/01/2023) revealed the following: "...QC Plan: Periodic ...C. Every 6 months, calibration verification, and comparison against devices are performed and reviewed by the medical director or designee." 3. Review of Triage documentation in 2022 and 2023 revealed no calibration verifications documented every six months. The surveyor requested documentation of calibration verifications for Troponin, D-Dimer and Urine Tox Screens in 2022 and 2023, and none were provided. 4. In an interview on 05/21/2024 at 01:15 PM, Technical Consultant 2 (TC-2) confirmed the laboratory failed to follow their own policy for calibration verification on the Triage analyzer for four of four events in 2022 and 2023.</p>
D5803	TEST REPORT

CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:

Based on review of Centers for Medicare and Medicaid Services (CMS) 116 form, patient final reports, and confirmed in interview, the laboratory failed to have a system in place to readily obtain patient results for three of three hematology tests prior to November 2023. Findings Included: 1. Review of laboratory CMS-116 form submitted at time of survey, revealed the laboratory performed the following hematology testing from 2022 to currently in 2024: a. Complete Blood Counts (Sysmex XP 300 Analyzer) b. INR and PTT (Hemochron) c. D-Dimer (Triage) 2. The surveyor requested patient reports prior to November 2023 in the above hematology specialties. The facility stated retrieval of the hematology patients would be a lengthy process, and they would be unable to retrieve the results by the end of the survey. This confirmed the laboratory failed to have a system in place to readily obtain patient results for three of three hematology tests prior to November 2023. 3. In an interview on 05/21/2024 at 01:20 PM, Technical Consultant 2 (TC-2) confirmed the above. Word Key INR- International normalised ratio PTT- Partial thromboplastin time