Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2082398	05/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Complete Care Southlake	321 W Southlake Blvd Suite 140, Southlake, 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	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, calibration verification records from 2023 for the Triage analyzer , review of patient test volumes, and staff interview, the laboratory failed to have documentation of performing calibration verification on the Triage analyzer every six months for two of two events in 2023. Findings include: 1. Review of the laboratory's policies "Laboratory Procedure Triage Cardiac Panel" and "Laboratory Procedure Triage D Dimer", approved by the laboratory director on 11/01 /2023 determined : "Verification of Linearity and Precision B. Verification Frequency When a new analyzer is put into use and every 6 months after this date." Tests performed on the Triage Cardiac Panel are: a) CK-MB (Creatinine Kinase - Myocardial Band) b) Troponin-I 2. The laboratory was asked to provide documentation of performing calibration verification for Cardiac Panel and D-Dimer cartridges on the Triage analyzer in 2023. No documentation was provided. 1. Review of patient test volumes for the Triage analyzer in 2023 revealed the following: a) Cardiac Panel: 207 tests b) D-Dimer: 89 tests 2. Technical Consultant-1 and Technical Consultant-2 (as listed on the CMS-209 form) confirmed the findings during an interview on 05/14/2024 at 1130 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services