Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2117237	04/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Lakeway Complete Care Llc	1518 Ranch Road 620 South,Suite 200, Lakeway, 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 VIK Complete Care Lakeway 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 a recertification validation survey on 04/09 /2026 and recertification is recommended. Standard level deficiency was cited.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. This STANDARD is not met as evidenced by: Based on review of the laboratory policies and procedures, patient logs, quality control (QC) records, test reports, and interview, the laboratory failed to include two levels of control material each eight hours of operation using the Triage for D-Dimer for 2 out of 12 QC events reviewed from 11/17/2025 - 11/31/2025 and 03/04/2026 - 03 /10/2026. Findings follow. A. Review of the laboratory policy and procedure titled D Dimer Triage, issued 10/06/2023, under External Quality Control Samples stated,"2. QC Frequency... b No IQCP in place, testing with the Triage Total 5 Controls 1 and 2 is performed: Before the 1st patient of the day. At 8-hour intervals thereafter for each day of patient testing. With each new lot of reagents. With each new shipment of reagents. When training new operators (one set is acceptable). Any time the accuracy of patient results is in question (frequency is variable). B. Review of the Master Patient Log from 11/17/2025 - 11/31/2025 and 03/04/2026 - 03/10/2026, against the Triage 8-hr Control QC worksheet showed 2 patients were tested without QC performed as listed by sample ID and date of service: Sample Test Performed Last QC Run Elapsed Time 1. 45932-1 11/24/2025 @ 1821 11/23/2025 @ 0830 1 day, 9 hours, 51 minutes 2. 46008-1 11/30/2025 @ 1417 11/27/2025 @ 1745 2 days, 20 hours, 32 minutes C. Review of patient reports showed the results had been reported. D.

	Interview on April 8, 2026 at 1445 hours with the Technical Consultant in the work area confirmed the findings.