Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2117237	06/11/2024
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 laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, quality control (QC) records and interview, the laboratory failed to document corrective action taken when QC failed on the Sysmex XP-300 Complete Blood Count (CBC) analyzer for six (6) out of seven (7) events reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Laboratory Procedure CBC Sysmex XP-300, approved 09/01/2023, under Quality Control, QC Results "2. unacceptable QC Results If there is a persistent problem with one control level, this may be indicative of a control that is not working properly. In the event different levels of control material do not typically fall within prescribed ranges, an instrument problem may be indicated. When control results are not within the acceptable range, perform the following steps until the control result is within acceptable range. a. Verify the following: The correct control

	and lot number is being used; it is not expired and has been properly stored and prepared. The correct reagent type and lot number in use is being used; it has not expired and has been properly stored and prepared. All necessary maintenance has been performed on the analyzer. There are no error messages or flags on the analyzer or results. b. Rerun the control ensuring proper mixing technique. If QC fails, then: c. Open a fresh vial of QC material and run the control again. d. If the QC is still out of range, investigate the problem by following the Control Interpretation Guidelines found in the QA Section of the SOP. e. Call Technical Assistance (1-888-879-7639) if no obvious reason for the QC failure is identified. f. Document all QC failures and troubleshooting steps on the appropriate logs and forms." B. Random review of QC records from 02/09/2024 - 04/28/2024 showed six (6) out of seven (7) events of repeating QC with no documentation of corrective action: 1. 03/03/2024: Level 2 was repeated two (2) times 2. 04/05/2024: Level 1 was repeated four (4) times 3. 04/12 /2024: Level 1 was repeated five (5) times 4. 04/13/2024: Level 1 was repeated two (2) times 5. 04/15/2024: Level 2 was repeated three (3) times 6. 04/24/2024: Level 3 was repeated two (2) times C. Interview with the Technical Consultant (as listed on the CMS 209) on June 11, 2024 at 1415 hours confirmed the findings.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, proficiency testing records, competency evaluations, and interview, the technical consultant failed to assess test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples for two (2) out of eight (8) testing personnel competencies reviewed for the Complete Blood Counts (CBC) on the Sysmex XP-300, Troponin and D-Dimer using the Alere Triage MeterPro, and Metlac 12 on the Abaxis Piccolo Xpress. Findings follow. A. Review of the laboratory's policy and procedure titled Laboratory Procedure Competency and Skills Checks for Technical Personnel, revised 08/31/2023, under Competency and Skills Checks at 2. Procedure stated, "c. The Technical Consultant will also use the following methods of validating competency... Testing of previously analyzed specimens or Proficiency Samples." B. Review of the American Proficiency Institute (API) proficiency testing records attestation statements from the 1st, 2nd, and 3rd events of 2023, and the 1st, 2nd, and 3rd events of 2022 showed testing personnel #7 and 8, as listed on the CMS form 209, did not participate in proficiency testing. C. Review of the competency evaluations from 2022 and 2023 revealed the form was prefilled with "E" under the column for "Verification Methods", where E = "Testing of previously analyzed specimens" for all testing personnel including testing personnel #7 and 8 for the CBC, Troponin, D-Dimer, and the Metlac 12. D. Interview with the Technical Consultant (as listed on the CMS Form 209) on June 11, 2024 at 1315 hours confirmed test performance through previously analyzed specimens, internal blind testing samples, or external proficiency testing was not done for testing personnel #7and 8 who were also PRNs.