Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2117237	06/27/2022
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, humidity charts, EMR query, interview, and pre-survey paperwork, the laboratory failed to monitor the humidity within the Sysmex XP-300 manufacturer's specifications for performing CBC testing for 26 of 115 days reviewed. Findings follow. A. Review of the Sysmex XP-300 Instructions for Use, AU553517 November 2017, at 14. Technical Information, 14.1 Specifications, stated, "Operating Environment... Relative humidity: 30% to 85%". B. Review of the laboratory's Temperature and Humidity Log had an acceptable humidity of 23-80%. Review of logs from May 2022 - February 2022 showed the laboratory exceeded the manufacturer's range on 26 of 115 days reviewed. The dates were then compared to a EMR query from 04/09/2022 - 02/04/2022 showing patient testing by date: Date % Humidity # patients tested 04/07/2022 27 4 04/08/2022 26 10 04/09/2022 25 4 03/01/2022 25 4 03/02/2022 26 5 03/08/2022 27 7 03/09/2022 29 2 03/10/2022 27 3 03/12/2022 25 4 03/13/2022 25 4 03/15/2022 29 4 03/19/2022 28 5 03/20/2022 28 0 03/24/2022 26 2 03/26/2022 28 8 02/04/2022 25 5 02/05/2022 25 2 02/06/2022 25 2 02/07/2022 28 3 02/08/2022 28 8 02/09/2022 26 7 02/10/2022 27 2 02/11/2022 26 4 02/18/2022 27 1 02/19/2022 25 6 02/22/2022 29 6 C. Interview with Technical Consultant #1 on the CMS form 209, on June 15, 2022 at 1700 hours in the

	break room acknowledged Sysmex had a letter stating labs could establish their own humidity range but had not performed that study in this laboratory. D. Review of the pre-survey paperwork showed an annual test volume of 12,000. KEY: EMR = Electronic Medial Record CBC = Complete Blood Count
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, observation, interview, and pre-survey paperwork, the laboratory failed to label their 5% bleach solution used to maintain their Sysmex XP-300 for performing CBC testing to include prepared date and expiration date. Findings follow. A. Review of the laboratory's policy and procedure titled CBC Sysmex XP-300 on page 22 under Maintenance stated, "IMPORTANT NOTE FOR ALL MAINTENANCE Clorox bleach is available with different concentrations of sodium hypochlorite. Refer to the label of the product in use for the sodium hypochlorite concentrations. The Sysmex XP-300 Instructions for Use recommends using a 5% sodium hypochlorite solution. Clorox must be diluted to the appropriate concentration of sodium hypochlorite prior to use. The example below describes how to make a liter of 5% sodium hypochlorite solution from Clorox (6% sodium hypochlorite concentration). Store prepared 5% bleach in a dark place for up to one week to prevent solution degradation from exposure to light." B. Surveyor observed on June 15, 2022 at 1530 hours in the laboratory a specimen cup labeled "Cell Clean", and a second specimen cup labeled "5% bleach solution" in the cabinet near the Sysmex XP-300. C. Interview with Technical Consultant #1, as listed on the CMS form 209, on June 15, 2022 at 1530 hours in the laboratory confirmed the 5% sodium hypochlorite was used to clean the Sysmex XP-300 daily and was missing the prepared and expiration dates. She checked with testing personnel #11, on the CMS form 209, and added he normally makes it up fresh each week but didn't make any this week. D. Review of the pre-survey paperwork showed an annual test volume of 12,000. KEY: CBC = Complete Blood Count
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the

	range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory records, and interview, the laboratory failed to perform calibration verification every six months for CKMB, Troponin I, and D-Dimer performed on the Alere Triage for three of three events for 18 months reviewed. Findings follow. A. Review of laboratory records showed no calibration verifications. Calibration verifications were requested on June 15, 2022 at 1730 hours but not provided. B. Interview with Technical Consultant #1 on June 15, 2022 at 1730 hours in the break room confirmed they did not perform calibration verifications on the Triage. KEY: CKMB = Creatinine kinase MB fraction
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory test reports, interview, and pre-survey paperwork, the laboratory failed to include the name and address of the laboratory for three of 15 test reports reviewed. Findings follow. A. Review of 7 patients' test reports with an aggregate of 15 moderately complex tests, showed three Biofire RP 2.1 (respiratory panel) test reports did not have the name and address of the laboratory: Account Date of Service 1. 28783 May 12, 2022 2. 29435 June 3, 2022 3. 29463 June 4, 2022 B. Interview with Technical Consultant #1, as listed on the CMS form 209, on June 15, 2022 at 1800 hours in the break room confirmed the findings. C. Review of the pre-survey paperwork showed an annual test volume of 12,000.