Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2110360	07/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Westlake Complete Care Llc	6836 Bee Caves Rd Suite 112, Austin, 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.
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's policies and procedures, calibration verifications and interview, the laboratory failed to perform calibration verification every six

	months for Troponin I and D-Dimer performed on the Alere Triage for three of four events reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Triage Cardiac Panel, effective 10/25/2019, under Verification of Linearity and Precision stated, "Verification of the analyzer's linearity range for the instrument ensures that accurate results are being produced by the instrument. This range is determined by analyzing a set of standards, plotting the observed value against the concentration of the sample and then visually inspecting the graph to estimate the analytical range of the assay..." And, under Verification Frequency stated, "The verification of linearity and precision of the analyzer should be performed When a new analyzer is put into use and every 6 months after this date." B. Review of calibration verifications showed one performed on 07/13/2023. Additional calibration verifications were requested on July 13, 2023 1655 hours but not provided. C. Interview with the Technical Consultant on July 13, 2023 at 1655 hours in the break room confirmed they just performed their first calibration verification on the day of the survey.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, competency evaluations, pre-survey paperwork, training records, and interview, the technical consultant failed to document the performance of individuals performing moderately complex testing at least semiannually during the first year the individual tested patient specimens for five out of eight testing personnel reviewed for 2 of 2 years. Findings follow. A. Review of the laboratory's policy and procedure titled Competency and Skills Checks for Technical Personnel, approved 01/15/2019, under Competency and Skills Check at Frequency stated, "All employees are evaluated at least twice during the first year of employment for all tests they perform and annually each year thereafter. Annually is defined as a calendar year." B. Review of competency evaluations from 2021 and 2022 showed none for testing personnel #19, 20, 21, 22, and 23. C. Review of the pre-survey paperwork titled Laboratory Personnel showed the following testing personnel with their hire dates: Testing personnel # Hire date missing Competency Evaluations 1. 19 12/26/2022 6 month 2. 20 unknown 6 month, 12 month 3. 21 unknown 6 month, 12 month 4. 22 see below 6 month 5. 23 unknown 6 month, 12 month D. Review of documentation of training showed testing personnel #22 was trained on 08/06/2022. The other training documents for testing personnel #20, 21, and 23 did not have dates of training. E. Interview with the Nurse Manager/testing personnel #2 on July 13, 2023 at 1135 hours in the break room confirmed competency evaluations were not performed, and most of the testing personnel were PRN employees.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, competency evaluations, pre-survey paperwork, training records, and interview, the technical consultant failed to document the performance of individuals performing moderately complex testing at least annually after the first year the individual tested patient specimens for seven out of 12 testing personnel reviewed for 2 of 2 years. Findings follow. A. Review of the laboratory's policy and procedure titled Competency and Skills Checks for Technical Personnel, approved 01/15/2019, under Competency and Skills Check at Frequency stated, "All employees are evaluated at least twice during the first year of employment for all tests they perform and annually each year thereafter. Annually is defined as a calendar year." B. Review of competency evaluations from 2021 and 2022 showed none for testing personnel #10, 11, 12, 13, 15, 17, 18, and 23. C. Review of the pre-survey paperwork titled Laboratory Personnel showed the following testing personnel with their start dates: Testing personnel # Hire date missing Competency Evaluations 1. 10 unknown, see below 2022 2. 11 08/02/2019 2021, 2022 3. 12 09/13/2016 2021 3. 13 unknown 2021, 2022 4. 15 unknown 2021, 2022 5. 17 05/21/2018 2021, 2022 6. 18 unknown 2021, 2022 7. 23 unknown 2022 D. Review of documentation of training for testing personnel #10 showed she was trained on 10/22/20. The other training documents for testing personnel #13, 15, 18, and 23 did not have dates of training. E. Interview with the Nurse Manager/testing personnel #2 on July 13, 2023 at 1135 hours in the break room confirmed competency evaluations were not performed, and most of the testing personnel were PRN employees,