

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2110360	(X3) Date Survey Completed 07/16/2025
Name of Provider or Supplier Westlake Complete Care Llc	Street Address, City, State 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. Standard level deficiencies were cited.
D6047	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(i)</p> <p>(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, competency evaluations, and interview, the technical consultant failed to assess test performance through direct observation of routine patient test performance including specimen collection through testing for 13 out of 18 testing personnel competencies reviewed for moderately complex testing. 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... Direct observation of routine test performance." B. Review of the competency evaluations from 2023, 2024, and only 6-month evaluations from 2025, showed the following testing personnel were missing test performance through direct observation of routine patient test performance including specimen collection through testing for: 1. Testing personnel #1 (TP#1) (as listed on the CMS Form 209) from 05 /2024 for CBC on the Sysmex, Met12 on the Piccolo and Troponin I and D-Dimer on the Triage. 2. TP#2 from 1st 6-month evaluation in 04/2024 for Met12 on the Piccolo, and Troponin I and D-Dimer on the Triage. 3. TP#2 2nd 6-month evaluation from 01 /2025 for Met12 on the Piccolo, and Troponin I and D-Dimer on the Triage. 4. TP#4 from 12/2023 for CBC on the Sysmex, Met12 on the Piccolo, and Troponin I and D-Dimer on the Triage. 5. TP#4 from 04/2024 for CBC on the Sysmex, Met12 on the</p>

Piccolo, and Troponin I and D-Dimer on the Triage. 6. TP#5 from 1st 6-month evaluation from 01/2025 for Troponin I and D-Dimer on the Triage. 7. TP#5 from 2nd 6-month evaluation from 04/2025 for Met12 on the Piccolo. 8. TP#6 from 06/2023 for CBC on the Sysmex, Met12 on the Piccolo and Troponin I and D-Dimer on the Triage. 9. TP#6 from 10/2024 for CBC on the Sysmex. 10. TP#7 from 1st 6-month evaluation from 12/2023 for Met12 on the Piccolo and Troponin I and D-Dimer on the Triage. 11. TP#7 from 2nd 6-month evaluation from 05/2024 for Troponin I and D-Dimer on the Triage. 12. TP#8 from 05/2024 for Met12 on the Piccolo. 13. TP#9 from 05/2024 for Troponin I and D-Dimer on the Triage and on 07/2024 for CBC on the Sysmex C. Interview with the Technical Consultant (as listed on the CMS Form 209) on July 16, 2025 at 1130 hours in the office confirmed test performance through direct observation of routine patient test performance including specimen collection through testing was not done for all testing personnel for each competency evaluation.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(v)

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedure, 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 10 out of 18 testing personnel competencies reviewed for moderately complex testing. 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 competency evaluations from 2023, 2024, and only 6-month evaluations from 2025, showed the following testing personnel were missing test performance through previously analyzed specimens, internal blind testing samples, or external proficiency testing samples: 1. Testing personnel #2 (TP#2) (as listed on the CMS Form 209) from 1st 6-month evaluation in 04/2024 was missing Met12 testing on the Piccolo. 2. TP#2 2nd 6-month evaluation from 01/2025 was missing the Met12 testing on the Piccolo, and Troponin I and D-Dimer on the Triage. 3. TP#3 from 04/2023 was missing CBC on the Sysmex. 4. TP#3 from 06/2024 was missing the Met12 on the Piccolo and Troponin I and D-Dimer on the Triage. 5. TP#4 from 12/2023 was missing the Met12 on the Piccolo and Troponin I and D-Dimer on the Triage. 6. TP#4 from 04/2024 was missing the Met12 on the Piccolo and Troponin I and D-Dimer on the Triage. 7. TP#5 from 2nd 6-month evaluation from 04/2025 was missing the CBC on the Sysmex. 8. TP#6 from 06/2023 was missing the CBC on the Sysmex, Met12 on the Piccolo and Troponin I and D-Dimer on the Triage. 9. TP#7 from 1st 6-month evaluation from 12/2023 was missing the Met12 on the Piccolo and Troponin I and D-Dimer on the Triage. 10. TP#7 from 2nd 6-month evaluation from 04/2024 was missing the CBC on the Sysmex. C. Interview with the Technical Consultant (as listed on the CMS Form 209) on July 16, 2025 at 1130 hours in the office confirmed test performance through previously analyzed specimens, internal blind testing samples, or external proficiency testing was not done for all testing personnel for each competency evaluation.