

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2246068	(X3) Date Survey Completed 05/13/2026
Name of Provider or Supplier Westlake Dermatology And Cosmetic Surgery	Street Address, City, State 8825 Bee Caves Road Lower Level Suite B, 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 Westlake Dermatology and Cosmetic Surgery 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 survey on 05/13/2026 and recertification is recommended. Standard level deficiencies were cited.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, accuracy assessments, pre-survey paperwork, and interview, the laboratory failed to verify the accuracy of grossing dermatopathology specimens at least twice annually for 2 of 2 years reviewed in 2024 and 2025. Findings follow. A. Review of the laboratory's policy and procedure titled Pathology Peer Review Protocol, effective 05/2022, did not include peer reviews for grossing. B. Accuracy assessments from 2024 and 2025 for grossing dermatopathology specimens were requested on May 13, 2026 at 1210 hours but not provided. C. Review of the CMS Form 116 showed an estimated annual volume of 47,085 cases, special stains, and IHCs (Immunohistochemical stains). D. Interview with the Laboratory Director on May 13, 2026 at 1210 hours in the breakroom confirmed they did not have peer reviews for grossing.</p>
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for</p>

high 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, and interview, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing in diagnostic interpretations of dermatopathology specimens and individuals responsible for grossing dermatopathology specimens at least semiannually during the first year for 2 of 2 new employees. Findings follow. A. Review of the laboratory's policy and procedure titled Personnel Assessment Policy under Procedure at Personnel Competency Assessment stated, "Observed assessment of all personnel to include specimen handling, instrument use, proficiency testing, test reporting, worksheets and printouts, laboratory records, and communication skills. Performed at hire, 6 months, and annually thereafter. Technical Supervisor or Laboratory Manager, if qualified, is responsible to ensure testing personnel competency evaluations are performed in the required timeframes." B. 1. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #2 (as listed on the CMS form 209) responsible for diagnostic interpretations of dermatopathology specimens, was hired in July 2023 and completed training 07/05/2023. 2. Review of the pre-survey paperwork titled Laboratory Personnel showed testing personnel #5 responsible for grossing dermatopathology specimens, was hired in August 2024 and completed training 08/05/2024. C. 1. Review of the laboratory records for testing personnel #2 showed one semi-annual competency evaluation performed 01/04/2024. A second semi-annual competency evaluation was requested on May 13, 2026 at 1110 hours but not provided. 2. Review of the laboratory records for testing personnel #5 showed one semi-annual competency evaluation performed 02/04/2025 and another performed 10/09/2025 (elapsed time 1 year 2 months). D. Review of the CMS 116 showed approximately 47,085 cases, special stains, and IHCs (Immunohistochemical stains) were performed per year. E. Interview with the Laboratory Manager on May 13, 2026 at 1110 hours and 1120 hours in the breakroom confirmed the findings.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure, competency evaluations, pre-survey paperwork, and interview, the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing in diagnostic interpretations of dermatopathology specimens at least annually for one of three testing personnel in 2024. Findings follow. A. Review of the laboratory's policy and procedure titled Personnel Assessment Policy under Procedure at Personnel Competency Assessment stated, "Observed assessment of all personnel to include specimen handling, instrument use, proficiency testing, test reporting, worksheets and printouts, laboratory records, and communication skills. Performed at hire, 6 months, and annually thereafter. Technical Supervisor or Laboratory Manager, if qualified, is

responsible to ensure testing personnel competency evaluations are performed in the required timeframes." B. Review of annual competency evaluations from 2024 and 2025 for diagnostic interpretations in dermatopathology specimens for testing personnel #1 (as listed on the CMS form 209) showed none for 2024. Additional competency evaluations were requested but not provided on May 13, 2026 at 1110 hours. C. Review of the CMS 116 showed approximately 47,085 cases, special stains, and IHCs (Immunohistochemical stains) were performed per year. D. Interview with the Laboratory Manager on May 13, 2026 at 1110 hours in the breakroom confirmed they were missing a competency evaluation in 2024.