

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2246068	(X3) Date Survey Completed 07/16/2024
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 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.
D5391	<p>PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, test reports, and interview the laboratory failed to identify that the removal of the date on the slides made it impossible to determine when the quality control was prepared for one of 10 cases reviewed. Findings follow. A. Review of the laboratory policy and procedure titled Quality Assessment Plan under Purpose stated, "a quality assessment plan [was] designed to monitor and evaluate the ongoing and overall quality of pre-analytical, analytical, and post-analytical testing as a total process. The process begins with the test order and continues through collection, handling, testing of samples, and transmitting a report back to the person authorized to receive the results." B. Review of patient reports showed for case number PDP23-00123 was received on 07/21/2023 and reported on 07/24/2023. Review of the quality control slides for PAS showed quality control slides for the following dates: 07/21/2023 and 07/25/2023. Without dates on the slides, it was difficult to determine what date the patient/control slides were made. C. Interview with the Laboratory Manager on July 16, 2024 at 1725 hours acknowledged it was laboratory practice that on Day 1 the slide was processed, Day 2 the slides were interpreted and additional stains requested if needed, Day 3 additional slides prepared, and Day 4 slides interpreted. He confirmed it was impossible to</p>

determine when the slides were prepared without the date on the slide and acknowledged the slide may have been misfiled. And on July 16, 2024 at 1800 hours acknowledged they used to put the date prepared on the slides, but stopped including the date around July 2023 (elapsed time one year). D. Review of pre-survey paperwork showed the estimated annual test volume for dermatopathology was 36090.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of test reports, laboratory records and interview, the laboratory director failed to specify in writing the responsibilities and duties for two of three technical supervisors performing diagnostic interpretations in dermatopathology. Findings follow. A. Review of dermatopathology test reports (DP24-13254, DP24-13448, DP23-19730) showed three personnel performing diagnostic interpretations: technical supervisor position required, per 42 CFR 493.1273 (b). B. Review of laboratory records found no written delegation of responsibilities and duties for technical supervisors #2 and 3 (as listed on the CMS form 209). C. Interview with the Laboratory Manager on July 16, 2024 at 1030 hours confirmed they currently had three dermatopathologists that performed diagnostic interpretations and written delegation of duties were not available for technical supervisors #2 and 3.