

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2221746	(X3) Date Survey Completed 02/08/2024
Name of Provider or Supplier Westlake Dermatology & Cosmetic Surgery	Street Address, City, State 2201 Onion Creek Parkway, 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.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observation, interview, review of manufacturer's instructions, and patient testing logs, the laboratory failed to provide the instructions for the various urine pregnancy tests performed in the dermatologist office for two of two test kits observed and performed on February 8, 2024. Findings follow. 1. During a tour of the laboratory on February 8, 2024 at 1120 hours, the surveyor observed the open test kit in the laboratory was the Medline hCG Pregnancy Test Cassette, Lot # W00130918, Exp 9/11/2025, with a sticker showing it was opened the same day, 02/08/2024. The package insert for the Medline test cassettes was requested on February 8, 2024 at 1123 hours but could not be found. 2. Interview with the histotechnologist on February 8, 2024 at 1125 hours acknowledged the laboratory gets different kits in depending on what's cheapest and confirmed the only instructions available was a quick guide on the inside lid of the Medline test cassettes box and instructions at the bottom of the pregnancy log for the Henry Schein dipstick. 3. During a tour of the laboratory on February 8, 2024 at 1127 hours surveyor found the Medline hCG Pregnancy Test Cassette package insert in the trash can. 4. Interview with the medical assistant on February 8, 2024 at 1130 hours acknowledged she just opened the new kit this morning and ran external controls, uses 3 drops of urine and sets on the counter and comes back and reads when she sees the control line in about 5 minutes, and does</p>

not use a timer. 5. Review of manufacturer's instructions for the Medline hCG Pregnancy Test Cassette under Directions for Use stated, "Holding a sample dropper vertically, add exactly four drops of the urine specimen to the sample well. Read results in 3-5 minutes. Do not read results after 5 minutes." 6. During a tour of the laboratory on February 8, 2024 at 1133 hours the surveyor found 2 Henry Schein One Step + cassettes in the trash can. 7. Interview with the medical assistant on February 8, 2024 at 1135 hours confirmed she used the Henry Schein cassettes on two patients that morning from the last kit. 8. Review of the Pregnancy Test Log on February 8, 2024 at 1135 hours showed two patients had been tested that morning, on 02/08/2024, no identifier other than Date of Birth noted on form, unable to list. 9. Review of the Henry Schein One Step + hCG Urine Cassette Test Instructional Insert (obtained by an outside source) under Directions for Use stated, "2. Place the test cassette on a clean and level surface. Hold the pipette vertically and transfer 3 full drops of urine (approximately 100 uL) to the specimen well of the test cassette, and then start the timer. 3. Wait for the red line(s) to appear. Read the result at 3-4 minutes. Do not interpret results after the appropriate read time. It is important that the background is clear before the result is read." 10. Interview with the histotechnologist on February 8, 2024 at 1140 hours confirmed the pregnancy test was used for their Accutane patients. 11. Review of the Pregnancy Test Log from 07/25/2023 - 02/08/2024 showed 47 patients had been tested. The package insert contains the full instructions for performing the pregnancy test, and the instructions vary by manufacturer and method - cassettes and strips.