Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2231650	03/19/2026
Name of Provider or Supplier	**Street Address, City, State**	
Woodlands Dermatology Associates, The	9303 Pinecroft Dr, Suite 310, The Woodlands, 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	An announced survey of the laboratory was conducted on 03/19/2026. The laboratory was found in substantial compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. However, the laboratory failed to notify State Agency of address/location change (form Suite 310 to Suite 100) within the required 30 days as per requirement 493.39(b). STANDARD LEVEL DEFICIENCIES were also cited.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, twice-annual test accuracy verification records and staff interview, the laboratory failed to document twice-annual test accuracy verification for two of two events in 2025. Findings included: 1. Review of laboratory's policy "Proficiency Testing" (last revised 04/30/2024) revealed: "Semi-annually in January and July the tech or Risk Manager will send ten cases from the prior semester containing the original slides, label it with only the surgical case number, and send it out for microscopic examination by a Board Certified Dermatopathologist." 2. Review of laboratory's twice-annual test accuracy verification records revealed facility's "Proficiency Testing 2025 I" and "Proficiency Testing 2025 II" events were both signed by an external Board-Certified Dermatopathologist on 03/04/2026. It was unclear when the slides were sent for review, and there were no other 2025 twice-annual test accuracy verification records available for review. 3. In an interview on 03/19/2026 at 0925 hours at an empty nurses' station in the hallway, the Laboratory Director (as indicated on submitted Form CMS -209) confirmed the findings.

D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures and twice-annual test accuracy verification records, the laboratory failed to document evaluation of twice-annual test accuracy verification results for two of two events in 2025. Findings included: 1. Review of laboratory's policy "Proficiency Testing" (last revised 04/30/2024) revealed: "Upon receipt of pathology report from the pathologist, diagnosis of the slide specimen will be matched to the in-house diagnosis by the physician." The policy did not address the necessity for documentation of evaluation for result acceptability of the twice-annual test accuracy verification by laboratory director of designee. 2. Review of laboratory's twice-annual test accuracy verification records after survey exit revealed facility's "Proficiency Testing 2025 I" and "Proficiency Testing 2025 II" events did not have documentation of whether the laboratory's twice-annual test accuracy verification results were acceptable, nor any documentation that the laboratory director or designee evaluated the overall performance of the laboratory's participation in twice-annual test accuracy verification. 3. The Laboratory Director (as indicated on submitted Form CMS -209) was notified of this finding on 03 /23/2026 at 1000 hours via email.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of a random laboratory's final patient report and staff interview, the laboratory failed to ensure correct address was included on patient's final report for one of one random patient report reviewed from March 2026. Findings included: 1. In an interview on 03/19/2026 at 0900 hours in the building's entryway, the Laboratory Director stated that the laboratory moved to Suite 100, the current location, in January of 2026. 2. Review of a random laboratory's final patient report from March 2026 for case accession number WD26-2377 revealed the performing laboratory's address contained the old suite number, "Suite 310", instead of the current "Suite 100". 3. In an interview on 03/19/2026 at 1050 hours at an empty nurses' station in the hallway, the Laboratory Director (as indicated on submitted Form CMS -209), after reviewing the report, confirmed the findings.