

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2231650	(X3) Date Survey Completed 04/30/2024
Name of Provider or Supplier Woodlands Dermatology Associates, The	Street Address, City, State 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 04/30/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited.
D3013	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations, review of laboratory's temperature/humidity logs, policies/procedures and staff interview, the laboratory failed to define and monitor slides/tissue blocks storage conditions to ensure proper preservation for one of one room with slide/block storage. Findings included: 1. Surveyor's observations on 04/30/2024 at 0930 hours in the facility revealed tissue blocks and slides were stored in the office. 2. Review of laboratory's temperature/humidity logs revealed the laboratory did not have documentation of monitoring slide storage conditions in the office. 3. Review of laboratory's policies/procedures revealed the laboratory did not have a protocol in place defining the storage conditions (temperature/humidity) for tissue blocks/slides. 4. In an interview on 04/30/2024 at 0930 hours in the office, the Laboratory Director (as indicated on submitted form CMS 209) confirmed the findings.</p>
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>

This STANDARD is not met as evidenced by:
Based on review of laboratory's twice annual test accuracy verification records, policies/procedures and staff interview, the laboratory failed to document two of two twice annual test accuracy verifications for 2023. Findings included: 1. Review of laboratory's twice annual test accuracy verification records for 2022, 2023 and 2024 revealed there were no test accuracy verification events documented in 2023. 2. Review of laboratory's policy/procedure "Proficiency Testing" (last modified 05/01 /2023) revealed: "... annually, the tech or Risk Manager will send ten cases containing the original slides, label it (sic) with only the surgical case number, and send it out for a microscopic examination by a Board Certified Pathologists." 3. In an interview on 04 /30/2024 at 0830 hours in the office, the Laboratory Director (as indicated on submitted form CMS 209) confirmed the findings.

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on review of laboratory's microscope maintenance records from January 2023 through April 2024, manufacturer instructions for use and staff interview, the laboratory failed to document microscope maintenance for four of four months in 2024, January through April. Findings included: 1. Review of laboratory's microscope maintenance records revealed the following microscope maintenance was required by the laboratory: "1. The microscope should be covered at the close of every day 2. Take extra care to keep stage of the microscope clean 3. Wipe eye pieces and lenses with lens cloth 4. Change bulbs as needed and have regular service contracts performed 5. Document daily, monthly care." 2. Review of laboratory's microscope maintenance records from January 2023 through April 2024 revealed there was no documentation of microscope maintenance for the following four months: January 2024 February 2024 March 2024 April 2024 3. The laboratory was asked to provide manufacturer instructions for use for its Olympus BH-2 microscope, and no such document was available for review prior to survey exit. 4. In an interview on 04/30 /2024 at 0915 hours in the office, the Laboratory Director (as indicated on submitted form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid