

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1056427	(X3) Date Survey Completed 11/29/2023
Name of Provider or Supplier Woodlands Skin Surgery Center, Pa,The	Street Address, City, State 3786 Fm 1488 Suite 200, Conroe, 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 11/29/2023. The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations and staff interview, the laboratory failed to label 14 of 14 secondary containers with reagents used for Hematoxylin and Eosin (H&E) staining of Mohs surgery tissue. Findings included: 1. Surveyor's observations on 11/29/2023 at 0905 hours in the laboratory revealed an automated stainer with 14 containers filled with various unidentified solutions/reagents. A legend listing the reagents for the H&E stain was posted above the stainer, but individual receptacles were not labeled to indicate what solutions each contained. 2. In an interview on 11/29/2023 at 0910 hours in the laboratory, facility's Histotechnologist (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.</p>
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p>

This STANDARD is not met as evidenced by:

Based on review of laboratory's temperature records, corrective action records and staff interview, the laboratory failed to document corrective action for out-of-range room temperature for 14 of 79 room temperature records reviewed from July to November 2023. Findings included: 1. Review of laboratory's temperature records revealed the laboratory defined acceptable room temperature as 68-78F (20-25.5C). 2. Further review of temperature records revealed the following temperatures were out of laboratory's acceptable range: Date: Temperature: 09/15/2023 19.6C 09/18/2023 19.4C 10/31/2023 19.6C 11/01/2023 17.0C 11/06/2023 19.1C 11/07/2023 19.0C 11/09/2023 19.4C 11/13/2023 19.4C 11/14/2023 19.3C 11/15/2023 19.3C 11/16/2023 19.2C 11/21/2023 16.0C 11/27/2023 16.0C 11/28/2023 16.0C 3. Review of laboratory's corrective action records for the out-of-range temperatures revealed there was no documentation of corrective action for the out of range temperatures. 4. In an interview on 11/29/2023 at 0940 hours in the break room, facility's Histotechnologist (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings. Key: C = Degrees Celsius F = Degrees Fahrenheit