

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2153578	(X3) Date Survey Completed 05/13/2022
Name of Provider or Supplier Woodlands Skin Surgery Center, Pa, The	Street Address, City, State 17100 Mueschke Road, Cypress, 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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, review of the submitted Laboratory Personnel Report (CLIA), Form 209, and staff interview it was determined the laboratory failed to document competency assessment for one of two Technical Supervisors employed by the facility. Findings included: 1. Review of the laboratory's personnel records revealed the laboratory failed to document competency assessment for Technical Supervisor number 2 (as described on submitted Form 209), one of two technical supervisors employed by the facility. 2. The laboratory was asked to provide documentation of competency evaluation for the position of Technical Supervisor and no such documentation was available for review. 3. In an interview on 05/13/2022 at</p>

0930 hours in the break room the laboratory's Histology Laboratory Technician (HTL) confirmed the findings.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor's observations on 05/13/2022 at 0910 hours in the laboratory, review of laboratory's quality control records, review of laboratory's patient test logs and staff interview it was determined the laboratory failed to ensure Eosin Yellow, one of two stain reagents used in Hematoxylin and Eosin (H&E) stain, was not expired prior to use in patient testing. Findings included: 1. Surveyor's observations on 05/13/2022 at 0910 hours in the laboratory revealed an open bottle of Eosin Yellow stain reagent (Lot: 082236) currently in use that has expired on 05/01/2022. 2. Review of the laboratory's quality control records for the H&E stain revealed the laboratory documented the stain quality of the stained slides, but did not document the lot and expiration dates of the stains on the date of testing. The laboratory documented the lot numbers, expiration dates, and dates of placement into use of each new reagent on a separate log. 3. Review of laboratory's patient test logs revealed the following patient samples were prepared using the expired Eosin Yellow reagent: Date of testing: 05/06/2022 Case number: CN22-188 CN22-189 CN22-190 CN22-191 CN22-192 CN22-193 CN22-194 CN22-195 CN22-196 CN22-197 CN22-198 CN22-199 CN22-200 CN22-201 CN22-202 CN22-203 Date of testing: 05/06/2022 Case number: CN22-204 CN22-205 CN22-206 CN22-207 CN22-208 CN22-209 CN22-210 4. In an interview on 05/13/2022 at 1000 hours in the break room the laboratory's Histology Laboratory Technician (HTL) confirmed the findings.