

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2150709	<b>(X3) Date Survey Completed</b>  05/03/2022
<b>Name of Provider or Supplier</b>  Dermisurgery Associates-Willowbrook	<b>Street Address, City, State</b>  18220 State Highway 249, Suite 270, Houston, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<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>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Procedure Manual, review of laboratory's personnel records and staff interview it was determined the current laboratory director failed to approve, sign and date all the laboratory policies and procedures upon assumption of the laboratory director's position. Findings included: 1. Review of the laboratory's Procedure Manual revealed all policies and procedures were last approved, signed and dated by the former laboratory director. There was no evidence of current laboratory director's approval of the policies and procedures used by the laboratory. 2. Review of the laboratory's personnel records revealed the current</p>

	<p>laboratory director assumed his position in September of 2020. 3. In an interview on 5 /3/2022 at 1500 hours in the laboratory the facility's Director of Operations confirmed the findings.</p>
<p><b>D5609</b></p>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(e)(f)</p> <p>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records for January to April of 2022 and staff interview it was determined the laboratory failed to include lot numbers, expiration dates, and the actual measurements/acceptability of reaction for 1 of 1 stains used in the laboratory, toluidine blue (TB). Findings included: 1. Review of the laboratory's QC records for January to April of 2022 revealed the laboratory documented QC for Tissue Quality with TB stain each day of use, but failed to include the lot numbers, expiration dates, and the actual measurements/acceptability of reaction on the QC sheet. 2. Further review of the QC records for the same time interval revealed that the Toluidine Blue ThermoFisher: Shandon Lini Stainer QC forms documented the changes, addition and/or filtration of the stain solutions, but failed to include the lot numbers, and expiration dates of the solutions in use. 2. In an interview on 05/03/2022 T 1415 hours in the laboratory the MOHS Tech confirmed the findings.</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Procedure Manual, review of laboratory's personnel records and staff interview it was determined the current laboratory director failed to approve, sign and date all the laboratory policies and procedures upon assumption of the laboratory director's position. Refer to D5407.</p>