

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0457792	<b>(X3) Date Survey Completed</b>  11/06/2020
<b>Name of Provider or Supplier</b>  Laplace Dermatology Clinic	<b>Street Address, City, State</b>  398 Belle Terre Boulevard, Laplace, LA	
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>	A Certification Survey was performed on November 6, 2020 at LaPlace Dermatology, CLIA ID # 19D0457792. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5433</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's microscope maintenance records, policies, and interview with personnel, the laboratory failed to perform microscope grounding checks every six (6) months per laboratory policy for one (1) of four (4) checks reviewed. Findings: 1. Review of the laboratory's "Equipment Quality Control Form 1: Microscope Use Protocol" revealed "Grounding check is monitored every six months." 2. Review of the laboratory's "Maintenance Record-Microscope" records for 2019 and 2020 revealed the laboratory did not have documentation of grounding check performance due January 2020. 3. In interview on November 6, 2020 at 9:42 am, the laboratory's medical assistant stated she did not know why the microscope's grounding check was not documented in January 2020. The medical assistant confirmed the laboratory did not have documentation of a grounding check in January 2020.</p>
<b>D6095</b>	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure required maintenance was performed to ensure acceptable levels of performance. Refer to D5433.