

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1077405	<b>(X3) Date Survey Completed</b>  06/10/2021
<b>Name of Provider or Supplier</b>  Winter Haven Dermatology Pa	<b>Street Address, City, State</b>  560 Ave K Se, Winter Haven, FL	
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>	44394 Winter Haven Dermatology clinical laboratory is not in compliance with 42 CFR part 493, Requirements for Laboratories. A CLIA recertification survey was conducted on 06/10/2021.
<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 record review and interview, the laboratory failed to perform yearly maintenance on the Micromaster microscope for 2 out of 2 years (2019 and 2020) reviewed. Findings included: Review of the maintenance records for the Micromaster microscope revealed that maintenance was last performed on 12/12/2018 and was due for service on 12/12/2019. Interview via e-mail correspondence on 6/10/2021 at 4:08 PM with the Laboratory Director confirmed maintenance on the Micromaster microscope had not been performed since 2018.</p>