

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1066863	(X3) Date Survey Completed 01/23/2023
Name of Provider or Supplier Dermatology Of Boca Llc	Street Address, City, State 4601 N Federal Hwy, Boca Raton, FL	
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	A recertification survey conducted on 1/23/2023 found the DERMATOLOGY OF BOCA LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5433	<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 observation, record review and interview, the laboratory failed to have annual maintenance performed on the Leica CM 1510S cryostat, required by the manufacturer, and also failed to have annual maintenance performed on the microscope, during the year 2021.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the</p>

condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on observation, record review and interview, the laboratory failed to include in the Mohls test reports the (c)(2) name and address of the laboratory location where the test was performed.