

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2028847	<b>(X3) Date Survey Completed</b>  01/14/2022
<b>Name of Provider or Supplier</b>  Great Lakes Medical Laboratories Inc	<b>Street Address, City, State</b>  13530 Michigan Avenue Suite 248, Dearborn, MI	
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>D5433</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> 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 interviews with the Technical Supervisor (TS), the laboratory failed to establish and perform maintenance for the Nikon microscope used in histopathology and cytopathology testing for 2 (January 2020 to January 2022) of 2 years reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of maintenance for the Nikon microscope and a policy for how often maintenance is to be performed. 2. An interview on 1/14/22 at 3:57 pm with the TS revealed the laboratory's policy is to have the microscope serviced annually. 3. The surveyor requested the policy and the documentation of microscope maintenance performed annually on 1/14/22 at 3:57 pm and the documents were not made available. 4. An interview on 1/14/22 at 4:14 pm with the TS confirmed the laboratory did not have a policy or documentation of annual microscope maintenance.</p>