

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0704441	<b>(X3) Date Survey Completed</b> 02/21/2024
<b>Name of Provider or Supplier</b> Gastroenterology Associates Of Fredericksburg, Pc	<b>Street Address, City, State</b> 1031 Care Way, Fredericksburg, VA	
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>	An announced CLIA recertification survey was conducted at Gastroenterology Associates of Fredericksburg on February 21, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
<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 tour, review of maintenance records, procedures, lack of documentation, and interview, the laboratory failed to follow their established policy of annual service /maintenance for one (1) of 1 microscope utilized for histopathology test results in calendar year 2022. Findings include: 1. During a tour with the laboratory director (LD) at 2:00 PM, the inspector noted a Nikon Eclipse E100 Serial #715504 microscope in use for the histopathology slide reading/resulting. 2. A review of equipment maintenance records revealed microscope service was performed by H &amp; M and Merco vendors on 11/22/21 and 5/11/23 respectively for the Nikon microscope outlined above. 3. Review of the laboratory procedure manual revealed a quality assurance policy under "Equipment" section that outlined: "The microscope will be cleaned, aligned, and serviced annually". The inspector requested to review</p>

maintenance service documentation performed in calendar year 2022. No documentation was available. 4. An exit interview with the LD on 2/21/24 at 3:00 PM confirmed the above findings.