

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2224264	(X3) Date Survey Completed 11/28/2023
Name of Provider or Supplier Idaho Gastroenterology Associates	Street Address, City, State 1200 Garrity Boulevard, Nampa, ID	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on a direct observation and an interview with the laboratory supervisor on 11/28/2023, the laboratory failed to calibrate four (4) pipettes used for laboratory testing. The findings include: 1. During the laboratory tour on 11/28/2023 a direct observation of four (4) pipettes identified that the laboratory failed to calibrate the 2-10 ul, 10-100 ul, 100-1000 ul and 1000 ul-5000 ul pipettes since the last inspection on 4/19/2022. 2. An interview with the laboratory supervisor on 11/28/2023 at 11:14 am confirmed that the laboratory had no documentation of calibration for the four (4) pipettes. 3. The laboratory reports performing 31,000 tests annually.</p>