

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0942775	(X3) Date Survey Completed 10/02/2024
Name of Provider or Supplier Clinical Gastrointestinal Associates	Street Address, City, State 1 Cornerstone Drive Suite 300, Langhorne, PA	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature records, and interview with the laboratory director (LD), the laboratory failed to monitor and document room temperature (RT) to ensure operating conditions were met to ensure reliable test system operation and test result reporting of histopathology microscopic slide examinations from 11/23/2022 to the day of survey. Findings Include: 1. The instruction manual for the Micronix Leica stated, "The Leica DM100 can be used at +10C to +40C." 2. On the day of the survey, 10/02/2024 at 10:00 am, the laboratory failed to provide RT monitoring records to ensure reliable test system operation for 1 of 1 Micronix Leica microscope prior to reporting microscopic histopathology slide examinations from 11/23/2022 to 10/02/2024. 3. The LD confirmed the findings above on 10/02/2024 at 10:00 am.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with</p>

each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's quality control (QC) staining records and interview with the laboratory director (LD), the laboratory failed to check for negative staining reactivity each time of use for 1 of 1 immunohistochemical (IHC) stain used for microscopic histopathology slide examinations performed from 11/23/2022 to the day of the survey. Findings Include: 1. On the day of the survey, 10/02/2024 at 09:50 am, review of the laboratory's QC records revealed the laboratory failed to check for negative staining reactivity each time of use for 1 of 1 IHC stain (Helicobacter Pylori) used for microscopic histopathology slide examinations performed from 11/23/2022 to 10/02/2024. 2. The LD confirmed the finding above on 10/02/2024 at 09:50 am.