

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0937844	<b>(X3) Date Survey Completed</b>  03/11/2024
<b>Name of Provider or Supplier</b>  Gastroenterologists, Ltd	<b>Street Address, City, State</b>  1105 W Park Ave, Ste 1, Libertyville, IL	
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>D5601</b>	<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 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the project manager (PM); the laboratory failed to document the quality control (QC) reactions for immunohistochemical (IHC) staining for 14 of 14 patient test results in 2022 through date of survey 03/11/2024. Findings include: 1. Review of the "Gastroenterologists, Ltd. General Workflow" policy revealed the following guidelines: "E. Quality Control and Improvement - i. Pathologist reviews slides for stain quality and tissue representation prior to reading any cases. Quality control forms are completed and filed in the QC binder by date indicating stain quality is acceptable." 2. Review of patient test results and laboratory QC records, found no documentation of the IHC QC stain results for the following 14 of 14 IHC patient test results: Report Date Case ID IHC Stain 10/13/2022 TC22-23108 CD 3 PAS/Alc Blue H. pylori 03/23/2023 TC23-05972 CD 3 PAS/Alc Blue H. pylori 07/03/2023 TC23-13820 CD 3 PAS/Alc Blue H. pylori 11/02/2023 TC23-22808 PAS/Alc Blue 01/03/2024 TC24-00063 CD 3 PAS/Alc Blue H. pylori 02/07/2024 TC24-01577 PAS/Alc Blue 3. On 03/11/2024, at 1:30 p.m., the PM confirmed the above findings.</p>