

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2194763	(X3) Date Survey Completed 04/01/2025
Name of Provider or Supplier Lakeshore Gastro & Liver Disease Institute, S C	Street Address, City, State 150 N River Rd - Ste 210, Des Plaines, IL	
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
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 each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the laboratory representative, the laboratory failed to document immunohistochemical (IHC) stain quality control (QC) for positive and negative reactivity for six of six patient IHC testing dates reviewed in the subspecialty of histopathology. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled, "Immunohistochemistry Controls", which stated, under "B. Cutting diagnostics slides", "2. For each case there should be one positive control per antibody ordered" 2. Review of patient testing results for six of six IHC stain testing dates found that IHC stain control positive and negative reactivity was not documented. Report Date: Patient ID: IHC QC comment: 04/06/2023 1880235 "Excellent" 08/18/2023 7005165 "Excellent" 12/29/2023 2298216 "Satisfactory" 05/07/2024 6835437 "Excellent" 10/25/2024 5286530 "Satisfactory" 02/03/2025 7185689 "Acceptable" 3. Interview with the laboratory representative on 04/01/2025, at 10:17 am, confirmed the laboratory failed to document IHC stain QC for positive and negative reactivity.</p>