

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2222830	(X3) Date Survey Completed 07/29/2025
Name of Provider or Supplier Houston Gastro Institute, PLLC	Street Address, City, State 25230 Kingsland Blvd #102, Katy, TX	
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
D0000	An announced survey of the laboratory was conducted on 07/29/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations and staff interview, the laboratory failed to label two of two reagent containers observed sitting on the countertop with contents' identity, lot number and expiration dates. Findings included: 1. Surveyor's observation on 07/29/2025 at 1120 hours in the laboratory revealed two unlabeled containers sitting on the countertop in the specimen processing area, one containing pieces of gauze and a bluish solution and one with clear solution. Neither container was labeled with content's identity, lot number or expiration date. 2. In an interview on 07/29/2025 at 1120 hours in the laboratory, Technical Supervisor number two (as indicated on submitted form CMS 209) confirmed the findings.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have</p>

deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor's observations and staff interview, the laboratory failed to ensure reagents were not used beyond expiration date for one of one tissue marking dye used in laboratory's histology procedures. Findings included: 1. Surveyor's observation on 07/29/2025 at 1120 hours in the laboratory revealed an in-use Stat Lab Violet Tissue Marking Dye SL662VT-2, expired 2022-02-28, sitting on the countertop in the specimen processing area. 2. In an interview on 07/29/2025 at 1120 hours in the laboratory, Technical Supervisor number two (as indicated on submitted form CMS 209) confirmed the findings.