

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2336557	(X3) Date Survey Completed 07/30/2026
Name of Provider or Supplier United Gastroenterology Associates	Street Address, City, State 21216 Northwest Freeway Suite 640, Cypress, 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 07/30/2026. The laboratory was found in substantial 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.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, specimen transport records, estimated test volumes and staff interview, the laboratory failed to define and document specimen transport acceptability in relation to transport conditions for one of one test performed by the facility, Tissue Grossing for histopathology exam. Findings included: 1. Review of laboratory's "Specimen Collection and Labeling" policy/procedure (effective 01/06/2026) revealed: "Temperature-sensitive specimens must be transported in a manner that preserves their integrity" The policy did not define which samples were to be considered "temperature-sensitive" and what temperature ranges were acceptable. 2. Review of laboratory's " Laboratory Policy on Specimen Handling and Processing" policy/procedure (effective 01/06/2026) revealed: "Transport specimens in accordance with regulatory and safety guidelines to preserve specimen integrity. Use appropriate transport containers and adhere to specified transport conditions." The policy did not specify "transport conditions" and /or requirements for documentation of transport conditions. 3. The laboratory was

	asked to provide specimen transport records, and none were available for review by the time of survey exit. 4. Review of laboratory's estimated test volumes revealed the laboratory estimated 2500 tissue grossing procedures annually. 5. In an interview on 07/30/2026 at 1015 hours in the laboratory, the facility's Office Manager (as indicated on submitted Entrance/Exit Conference document) confirmed the findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, test records, estimated test volumes and staff interview, the laboratory failed to document the time of tissue fixation in formalin as per its policies for one of one test performed by the facility, Tissue Grossing for histopathology exam. Findings included: 1. Review of laboratory's "Formalin Fixation" policy/procedure (effective 01/06/2026) revealed: "The time of fixation must be documented for each specimen, and the technician must verify that the tissue has been adequately fixed before moving to further processing stages." 2. Review of laboratory's test records revealed the laboratory did not have documentation of the time of fixation for the received tissue samples. 3. Review of laboratory's estimated test volumes revealed the laboratory estimated 2500 tissue grossing procedures annually. 4. In an interview on 07/30/2026 at 1030 hours in the laboratory, the facility's Office Manager (as indicated on submitted Entrance/Exit Conference document) stated that the time of fixation was normally placed on the specimen container, but it was not recorded on any document. This confirmed the findings.