Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2020900	04/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology & Liver Associates, Pllc	3030 S Gessner Rd, Suite 290, Houston, 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	The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found in compliance with applicable CLIA conditions, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records for 2021, 2022 and 2023, and staff interview it was determined the laboratory failed to document testing personnel and director/designee required attestation signatures for 6 of 23 PT events reviewed. Findings included: 1. Review of the laboratory's CAP PT records for 2021 , 2022 and 2023 revealed the following 6 of 23 events reviewed did not have documentation of testing personnel (TP) and director/designee (LD) attestation signatures: Event: TVAG-A Trichomonas vaginalis, Molecular Date tested: 05/31/2022 TP and LD attestation signatures not

	documented Event: MVP-C 2022 Molecular Vaginal Panel Date tested: 11/21/2022 TP and LD attestation signatures not documented Event: ID5-C HSV, VZV - Molecular Date tested: 12/15/2022 TP and LD attestation signatures not documented Event: MGEN-B 2022 Mycoplasma genitalium, Molecular Date tested: 12/15/2022 TP and LD attestation signatures not documented Event: CHPV-C 2022 Human Papillomavirus Date tested: 12/22/2022 TP and LD attestation signatures not documented Event: HC6-A Chlamydia/GC by NNA Date tested: 02/07/2023 TP and LD attestation signatures not documented 2. Further review of the abovementioned CAP PT records revealed: CAP Form: "Attestation/Use of Other Form ...The laboratory director of designee and the testing personnel must sign on the results form. You may use the attestation page provided in the kit instructions or, alternatively, print, sign, and retain a copy of this page for your records and inspection purposes." 3. The laboratory was asked to provide documentation of signing attestation forms for the above evens and no such documentation was available for review at time of survey exit. 4. In an interview on 04/13/2023 at 1025 hours in the storage/break room, the laboratory's General Supervisor number 2 (as described on submitted Form 209), after review of the data, confirmed the findings.