Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2020900	10/12/2021
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, 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 Dallas Regional Office (RO) 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 2019, 2020 and 2021 and staff interview it was determined the laboratory failed to ensure PT attestations were signed by the laboratory director or designee for 4 of 27 events. The findings were: 1. Review of the CAP PT Attestation form revealed: "The laboratory director or designee and the testing personnel must sign on the result form." 2. Review of the laboratory's CAP PT documents for 2019, 2020 and 2021 revealed the following attestation forms missing the laboratory director's/designee's signature: 2019 Virology event 2 - CHPV-B tested August 2019 2019 Bacteriology event 2 - HC6A-B tested September 2019 2019

	Bacteriology event 3 - HC6A-C tested October 2019 2019 Parasitology event 2 - TVAG-B tested November 2019 3. In an interview on 10/11/2021 at 1130 hours in the conference room the General Supervisor (as described on CMS Form 209 signed by the laboratory director on 10/11/2021) stated that the Attestation forms should have been signed. This confirmed the findings.
D2025	BACTERIOLOGY CFR(s): 493.823(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. 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 2019, 2020 and 2021 and staff interview it was determined the laboratory failed to ensure timely submission of results to the PT agency for 1 of 8 Bacteriology events. The findings were: 1. Review of the laboratory's CAP evaluation documents for its Bacteriology PT participation for 2019, 2020 and 2021 revealed the following event result form was not submitted on time resulting in a score of zero for the event: 2020 Bacteriology event 1 - HC6A-A tested March 2021 2. In an interview on 10/11/2021 at 1130 hours in the conference room the General Supervisor (as described on CMS Form 209 signed by the laboratory director on 10/11/2021) confirmed that the results were not submitted on time.
D2061	VIROLOGY CFR(s): 493.831(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. 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 2019, 2020 and 2021 and staff interview it was determined the laboratory failed to ensure timely submission of results to the PT agency for 2 of 10 Virology events. The findings were: 1. Review of the laboratory's CAP evaluation documents for its Virology PT participation for 2019, 2020 and 2021 revealed the following event result forms were not submitted on time resulting in a score of zero for the event: 2019 Virology event 3 - CHPV-C tested December 2019 2020 Virology event 3 - ID5-C tested December 2020 2. In an interview on 10/11 /2021 at 1130 hours in the conference room the General Supervisor (as described on CMS Form 209 signed by the laboratory director on 10/11/2021) confirmed that the results were not submitted on time.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of performing a competency assessment for 1 of 2 general supervisors. Findings include: 1. A review of the laboratory's policy titled 'Competency Assessment' revealed the following: "Supervisory, technical and clerical staff is evaluated for competency as defined in their job descriptions." 2. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 10/11 /21) revealed the laboratory identified 2 general supervisors. 3. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of performing a competency assessment for: General Supervisor #2 4. An interview with the general supervisor (as indicated on the CMS 209 form) on 10/12/21 at 11:27 a.m. in the conference room revealed the laboratory did not assess the competency of the general supervisor. This confirmed the above findings.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient records for January 2021 and staff interview it was determined the laboratory failed to document notification of amended reports to provider for 1 of 7 patient's reports reviewed. The findings were: 1. Review of the laboratory's policies revealed there was no documentation of notification to provider for amended/corrected reports. 2. Review of the laboratory's patient records for January 2021 revealed the following amended patient report without documentation of notification of the correction to provider: Accession #: G21-00034 Collected: 01/04/2021 Resulted/electronically signed by Pathologist: 01/08/2021 Amended report on: 01/19/2021 Amended result: HPV GT 18 /45 - from NEGATIVE to POSITIVE 3. In an interview on 10/12/2021 at 1000 hours in the conference room the General Supervisor (as described on CMS Form 209 signed by the laboratory director on 10/11/2021) stated that because the pathologist is in constant communication with the provider the laboratory does not document notification of amended reports. This confirmed the findings.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities

	to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, the laboratory's personnel records, and staff interview, it was revealed that the laboratory director failed to have documentation of delegating the responsibility of performing annual competency assessments on the laboratory's testing personnel to the General Supervisor. Findings include 1. A review of the laboratory's policy titled 'Competency Assessment' revealed the following: "The general supervisor or lead cytotechnologist design the competence assessment program and the technical supervisor or designee conducts competence assessment." 2. A review of the laboratory's personnel records revealed no documentation of the laboratory director delegating the responsibility of performing annual competency assessments on the laboratory's testing personnel to the general supervisor. 3. An interview with the general supervisor (as indicated on the CMS 209 form) on 10/12/21 at 10:59 a.m. in the conference room, after review of the records, confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel files, and staff interview, it was revealed that the technical supervisor failed to perform a competency assessment in 2020 on 1 of 5 testing personnel for high complexity testing- Cytology. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 10/11/21) revealed the laboratory identified 5 testing personnel performing high complexity testing- Cytology. 2. A review of the laboratory's personnel records revealed that there was documentation of a competency assessment performed on 10/19/20 for testing person #1 for Cytology testing. Further review of the competency assessment revealed the assessment was performed by testing person #5, who was not designated and did not qualify to be the laboratory's technical supervisor. 3. An interview with the general supervisor on 10/12/21 at 10:59 a.m. in the conference room, after review of the records, confirmed the above findings.