Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2020900	07/18/2019
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 to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of laboratory College of American Pathologists (CAP) laboratory proficiency testing (PT) records and confirmed in interview, the laboratory failed to verify the accuracy of the analytes not graded by the proficiency testing program. Findings were: 1. Review of the CAP Actions Laboratories Should Take When PT Result is not Graded (Rev 9/2018) revealed "your laboratory must identify all analytes with an exception reason code, review and document the acceptability of performance as outlined below and retain documentation of review for at least 2 years. [26] - Review participant summary report for comparative results and document performance accordingly. Evaluation criteria are not established for education challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation. [27] - Lack of participant or referee consensus: Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the participant summary. If

	comparison is not available, perform and document alternative assessment (i.e. split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested. " 2. Review of the laboratory policy PT Molecular Proficiency Testing (Ver 1.1) revealed "document that the laboratory performed a self-evaluation and compared its results to the intended response provided in the participant summary." 3. Review of the 2018-2019 CAP laboratory records revealed 7 of 12 events with no documentation of the self evaluation for the exception codes per the manufacturer's instructions: 2018 1st event TVAG-A Trichomoniasis vaginalis TVAG-01: lab result - positive [26] TVAG-02: lab result - positive [26] TVAG-03: lab result - negative [26] 2018 2nd event TVAG-B Trichomoniasis vaginalis TVAG-04: lab result - positive [26] TVAG-05: lab result - negative [26] TVAG-06: lab result - positive [26] 2018 2nd event HC6-B Chlamydia /GC by NAA HC6-10: lab result - negative [27] 2018 1st event CHPV-A Human Papillomavirus HR HPV [High Risk HPV] CHPVM-01: lab result HPV 16 [26] CHPVM-02: lab result HPV16 [26] CHPVM-03: lab result HR HPV negative [26] CHPVM-04: lab result HPV 18/45 [26] CHPVM-05: lab result HR HPV negative [26] 2018 2nd event CHPV-B Human Papillomavirus HR HPV [High Risk HPV] CHPVM-06: lab result HPV 16 [26] CHPVM-07: lab resullt HR HPV negative [26] CHPVM-08: lab result HPV 18/45 [26] CHPVM-09: lab result HR HPV negative [26] CHPVM-10: lab result HPV 16 [26] 2018 3rd event CHPV-C Human Papillomavirus HR HPV [High Risk HPV] CHPVM-11: lab result HR HPV negative [26] CHPVM-12: lab resullt HPV 16 [26] CHPVM-13: lab result HR HPV negative [26] CHPVM-14: lab result HPV 16 [26] CHPVM-15: lab result HPV 18/45 [26] 2019 1st event CHPV-A Human Papillomavirus HR HPV [High Risk HPV] CHPVM-01: lab result HR HPV negative [26] CHPVM-02: lab result HR HPV negative [26] CHPVM-03: lab result HPV 16 [26] CHPVM-04: lab result HR HPV negative [26] CHPVM-05: lab result HPV 18/45 [26] 4. An interview with the cytology general supervisor on 7/17/19 at 1310 hours in the conference room confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the FDA web site, laboratory records, laboratory establishment studies, laboratory quality control records and patient logs, and confirmed in interview, the laboratory failed to document complete establishment studies for the reagents and controls used in the lab developed testing (LDT) for Bacterial Vaginosis (BV) and Candida Vaginosis (CV) for the Hologic Panther System. Findings were: 1. Review of the FDA web site for test complexity revealed the following tests: Bacterial Vaginosis and Candida Vaginosis were not FDA approved for the Hologic Panther system using ThinPrep Pap specimen vials . 2. Review of the assay reagents in use in

	the laboratory for Bacterial Vaginosis and Candida Vaginosis revealed the following lot numbers of reagents. Master lot # 238774, exp 12/31/2099 Amplification reagent lot 238763, exp 8/9/19 enzyme reagent lot 238770, exp 8/9/19 Target Capture Reagent lot 238767, exp 8/9/19 Probe Reagent lot 238760, exp 8/9/19 3. Review of the laboratory policy Laboratory developed Test for Candida Vaginosis (GL-1011.6, Ver. 1.0) revealed under reagent storage and handling requirements "after reconstitution, the following reagents are stable for 30 days when stored at 2-8 C. -amplification reagent -enzyme reagent -probe reagent working target capture reagent is stable for 30 days when stored at 15 - 30 C. Do not refrigerate. The CV LDT reagents are stable for a cumulative of 72 hours when stored on board the Panther system." 4. Review of the laboratory policy Laboratory developed Test for Bacterial Vaginosis (GL-1011.5, Ver. 1.0) revealed "after reconstitution, the following reagents are stable for 30 days when stored at 2-8 C. -amplification reagent -enzyme reagent -probe reagent working target capture reagent is stable for 30 days when stored at 15 - 30 C. Do not refrigerate. The BV LDT reagents are stable for a cumulative of 72 hours when stored on board the Panther system." 5. Review of the laboratory quality control records revealed the laboratory used the following controls for CV and BV. Candida Albicans positive control Candida Glabrata positive control Gardnerella vaginalis high positive control Gardnerella vaginalis low positive control lactobacillus crispatus positive control 6. Review of the laboratory establishment studies revealed no documentation of the stability studies to verify the laboratory claims for stability for the above reagents and controls. 7. Review of the laboratory CMS116 revealed the laboratory performed 9427 Bacteriology and Mycology testing annually. 8. An interview with the general supervisor of cytology on 7/17/19 at 1350 hours in the conference room confirmed the above findings. She acknowledged that the laboratory should perform those stability studies.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the 2018 to 2019 College of American Pathologists (CAP) proficiency testing records, laboratory records, and confirmed in interview, the laboratory director failed to ensure the laboratory verified the accuracy of the analytes not graded by the proficiency testing program. Refer to D5215
D6127	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the CMS form 209, personnel records and verified by interview, the Technical Supervisor failed to perform the initial competency evaluations for 2 of 3 testing personnel for the high complexity testing in the specialty of cytology (CT).

	Findings were: 1. Review of the laboratory's CMS 209 signed by the laboratory director on 7/16/19 revealed 3 testing personnel and 2 technical supervisors in the cytology section of the laboratory. 2. Review of the facility's personnel files available revealed 1 of 3 Cytology testing personnel (CT#1) had an initial competency assessment for the high complexity testing in the specialty of cytology performed by the general supervisor 1, not the technical supervisor. General supervisor 1 has a bachelor's degree. CT # 1 (hire date 12/3/18) - initial competency performed by GS#1 3. Review of the facility's personnel files available revealed 1 of 3 testing personnel (GS#1) had an initial competency assessment for the high complexity testing in the specialty of cytology performed by the CT#2, not the technical supervisor. CT#2 has a bachelor's degree. GS#1 (hire date 2/13/17) - initial competency performed by CT#2 4. An interview with the general supervisor 1 on 7/17/19 at 1045 hours in the conference room confirmed the above findings.