Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0460367	02/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Group Amc	131 B Cherokee Rose Lane, Covington, LA	

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	A Certification survey was performed at Gastroenterology Group AMC-CLIA # 19D0460367 on February 26, 2021. Gastroenterology Group AMC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director
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 review of the laboratory's policies, personnel records, and interview with personnel, the laboratory failed to follow their established competency assessment policy for one (1) of two (2) testing personnel reviewed. Findings: 1. Review of the laboratory's "Competency Testing" policy revealed "Competency Testing is required after 6 months of intial training and once a year thereafter." 2. Review of personnel records revealed Testing Personnel 2 did not have a semi-annual competency assessment performed. 3. In interview on February 26, 2021 at 10:11 am, the Laboratory Director stated Testing Personnel 2 was hired August 2018. The Laboratory Director stated the semi-annual competency assessment for Testing Personnel 2 was not done.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to document the review of the performance evaluation for one (1) of six (6) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's 2019 and and 2020 American Proficiency Institute (API) results for Microbiology revealed the Laboratory Director did not evaluate the results for the 2020 Microbiology 3rd event. 2. In interview on February 26, 2021 at 10:26 am, the Laboratory Director stated she did not sign the evaluation for the identified event.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to establish complete policies and procedures. Refer to D5401. 2. The laboratory failed to have complete performance verification studies for the BioFire FilmArray Torch for gastrointestinal (GI) panel testing. Refer to D5421. 3. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control for the BioFire FilmArray Gastrointestinal (GI) Panel testing. Refer to D5445. 4. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 the laboratory's procedures and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policies revealed the laboratory did not include written policies for the following: a) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run variation, as well as operator variance), reportable and reference range studies, acceptability criteria for studies, and actions to take when data from the studies fail to meet acceptability

	criteria b) Individualized Quality Control Plan (IQCP) to include not limited to the required three (3) parts 2. In interview on February 26, 2021 at 11:02 am, the Laboratory Director confirmed the identified procedures were not included.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory's policies, validation records, test menu, and interview with personnel, the laboratory failed to have complete performance verification studies for the BioFire FilmArray Torch for gastrointestinal (GI) panel testing. Findings: 1. Observation by surveyor during laboratory tour February 26, 2021 at 9:20 am revealed the laboratory utilizes the BioFire FilmArray Torch for gastrointestinal panel testing that includes: Campylobacter, Clostridium difficile toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio, Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative E. coli (EAEC), Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC) It/st, Shiga-like toxin-producing E. coli (STEC) stx1/stx2, Shigella/Enteroinvasive E.coli (EIEC), Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia, Adenovirus F 40 /41, Astrovirus, Norovirus GI/GII, Rotavirus A, and Sapovirus. 2. In interview on February 26, 2021 at 9:12 am, the Laboratory Director stated the laboratory started patient testing on the BioFire on August 28, 2018. 3. Review of the laboratory's policies and procedures revealed the laboratory did not have a written policy and procedure for performance specification studies. 4. Review of the laboratory's "BioFire Validation/Verification July 25-August 23, 2018" records revealed "22 positive and 22 negative external control runs" were performed. 5. Further review of the laboratory's "BioFire Validation/Verification July 25-August 23, 2018" records revealed the laboratory did not include the following: a) Raw data to support accuracy and precision studies b) Acceptability criteria c) Laboratory Director's approval /signature of validation studies 6. In interview on February 26, 2021 at 11:02 am, the Laboratory Director confirmed the raw data for the accuracy and precision studies was not included. 7. Review of the laboratory's test menu revealed the laboratory performs 500 GI panel tests annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The

	laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's policies, records, and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control for the BioFire FilmArray Gastrointestinal (GI) Panel testing. Findings: 1. Observation by surveyor during laboratory tour February 26, 2021 at 9:20 am revealed the laboratory utilizes the BioFire FilmArray Torch for gastrointestinal panel testing that includes: Campylobacter, Clostridium difficile toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio, Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative E. coli (EAEC), Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC) It/st, Shiga-like toxin-producing E. coli (STEC) stx1/stx2, Shigella /Enteroinvasive E.coli (EIEC), Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia, Adenovirus F 40/41, Astrovirus, Norovirus GI /GII, Rotavirus A, and Sapovirus. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a written policy for IQCP. 3. Review of the laboratory's "IQCP-BioFire FilmArray Gastrointestinal Panel" records revealed "The plan will be based on the risk assessments determined by the medical director and lab personnel at Gasto Group AMC. It will include data of 22 positive and 22 negative external control runs on the FilmArray instrument over 22 days to prove the method and validate the test. External QC will be completed on any new shipment or lot numbers of FilmArray Pouches and reagents. Initial positive targets will be Zeptometrix NATrol GI Controls." 4. Further review of the laboratory's "IQCP-BioFire FilmArray Gastrointestinal Panel" records revealed the laboratory did not include the following: a) Environmental conditions were not included in the risk assessment b) In-house data to support the reduction in frequency of external quality control (QC) c) Quality Assessment plan 5. In interview on February 26, 2021 at 11: 02 am, the Laboratory Director confirmed the laboratory did not include the identified items.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to establish complete policies and procedures. Refer to D5401. 2. The laboratory failed to have complete performance verification studies for the BioFire FilmArray Torch for gastrointestinal (GI) panel testing. Refer to D5421. 3. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) to support the reduction in frequency of quality control for the BioFire FilmArray Gastrointestinal (GI) Panel testing. Refer to D5445.
D5805	TEST REPORT

	CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient final reports, test menu, and interview with personnel, the laboratory failed to include the laboratory's address on patient final reports for Gastrointestinal (GI) Panel testing. Findings: 1. Review of random selection of the following seven (7) patient final test reports from January 2019 through September 2020 for the GI Panel testing revealed the address of the laboratory performing the testing was not included: January 8, 2019: Patient 433967 July 24, 2019: Patient 324488 December 13, 2019: Patient 437708 January 29, 2020: Patient 439448 September 24, 2020: Patient 386034 December 23, 2020: Patient 446523 January 28, 2021: Patient 326535 2. In interview on February 26, 2021 at 11:17 am, the Laboratory Director confirmed the patient final reports for GI panel testing did not include the laboratory's address. 3. Review of the laboratory's test menu revealed the laboratory performs 500 GI panel tests annually.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor during laboratory tour, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure performance verification studies were complete. Refer to D6013. 2. The Laboratory Director failed to 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. Refer to D6018. 3. The Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6021. 5. The Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D6026. 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)

	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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that 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 record review and interview with personnel, the Laboratory Director failed to 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. Refer to D5211.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D5445.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5791.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, patient final test reports, and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Refer to D5209.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5401.