Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D2058075	07/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Associates Pc	1441 Wilkins Circle, Casper, WY	

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
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 proficiency testing records review, lack of documentation, and interview with staff, the laboratory failed to ensure bacteriology, parasitology, and virology proficiency test results were reviewed to identify problems in the Biofire test system for 3 of 3 proficiency testing events reviewed from 2018 to 2019. Findings include: 1. The proficiency testing graded result reports reviewed for College of American Pathologists proficiency module GIP - Events A and B in 2018, and in 2019 module GIP - Event A failed to include the signature or the initials and date of the Laboratory Director (also the Technical Consultant) documenting review of the test results. 2. In an interview on 07/30/2019 at approximately 2:45 P.M., the director confirmed the reports lacked the signature and date of the director as documentation of review.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in

	493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on procedure manual review and direct observation of gross analysis testing, and interview with the director, the laboratory procedure manual failed to include the step by step procedure for measuring endoscopy and coloscopy specimens. The laboratory performed approximately 25,000 specimens per year. Findings include: 1. The laboratory procedure manual failed to include instruction for testing personnel for measuring specimen length, width and depth for the formalin fixed specimens grossed by testing personnel. 2. Direct observation of grossing on 07/30/2019 at approximately 8:45 A.M. staff explained the process for measuring the specimen by length, width, and depth of the specimen or aggregate of specimens. 3. In an interview with the director on 07/30/2019 at approximately 2:50 P.M. the director agreed the measurement method for gross analysis was not detailed with a step by step instructions for testing personnel to follow especially for the specimen depth for aggregate specimens.
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 patient test reports, direct observation, and interview with the laboratory director, the laboratory failed to ensure the laboratory test report included its name and address on 7 of 7 test reports reviewed for Bacteriology, Parasitology and Virology tests performed using the Biofire molecular testing assay. Findings include: 1. Patient test reports for patients #03131948 (test date 10/23/2018), 01181939 (test date 11/12/2018), 01011960(12/28/2018), 10041988 (test date 01/18/2019), 05301954 (test date 01/18/2019), 05121973 (test date 05/13/2019), and 09211949 (test date 09/21 /2019) failed to include the name and address of the laboratory where testing was performed. 2. Testing was observed on 07/30/2019 at approximately 9:12 A.M. The test completed and the report was printed by staff at approximately 10:30 A.M. then the same report was scanned into the laboratory information system. The report observed did not include the name and address of the laboratory. 3. In an interview

	with staff and the laboratory director on 07/30/2019 at approximately 2:50 P.M. The director confirmed they had not revised their Biofire manufacturer generated report to include the name and address of their laboratory. THIS IS A REPEAT DEFICIENCY.