Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0864483	09/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Of The East Bay	2510 Webster St, 2nd Flr, Berkeley, CA	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of CLIA records and laboratory documents for the Biofire test system using the GI Panel to test for 22 microorganisms, the lack of proficiency testing records, and interview with a laboratory person, it was determined that the Laboratory failed to meet the CONDITION of enrollment in proficiency testing. Findings included: 1. Testing in the Microbiology specialties was added to the laboratory's CLIA record on 10/12/17, on the condition that the laboratory enroll in proficiency testing. 2. Laboratory equipment records documented the Biofire analyzer (serial number 2FAC832F) was verified for use with the GI Panel in 2017 to detect 13 types of Bacteria, 4 types of Parasites, and 5 types of Virus. 3. Laboratory records sampled at random for this survey documented patients specimen were each tested for 22 gastrointestinal organisms and pathogens, as follows: Year, Month Number of specimen ---------- 2018 - March 20 " November 16 " December 16 2019 - July 16 " October 22 2020 - January 1 " August 3 ---------- Total = 94 specimen tested; 2,068 results reported 4. For the aforementioned random sampling of 2,068 results and all other results reported in 2018 - 2020, the laboratory failed to provide proficiency testing records for review. 5. A laboratory person affirmed (10/08/21 at 3:06pm) that

	the laboratory had failed to enroll in proficiency testing for the Biofire in 2017, 2018, 2019, and 2020. 6. The reliability and quality of Biofire results reported could not be assured. Based on the laboratory estimated annual test volume of 66 specimen, the laboratory reported approximately 4,356 results annually. .
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 the cumulative nature of deficiencies cited, it was determined that the Condition for the laboratory's analytic systems required in 493.1251 through 493.1283 and 493.1289 was not met. Findings included: 1. The laboratory failed to have supplemental written policy/procedure related to reporting results. See D5405. 2. The laboratory failed to test positive and negative quality control materials. See D5449. 3. The laboratory failed to monitor for proficiency testing and quality control to assess for problems and apply corrective actions. See D5791. .
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on review of manufacturer's test procedure for the Biofire GI Panel and laboratory test records, the lack of a laboratory document, and interview with a laboratory person, it was determined the laboratory had failed to provide a written policy/procedure to report test results suggestive of diseases of public health importance to the public health department as stated in California Code of Regulations, Title 17, Section 2505. Findings included: 1. The Biofire GI Panel tested for organisms suggestive of diseases of public health importance, as follows: Shiga-like Toxin producing E. coli O157 (STEC) Shigella / Enteroinvasive E. coli (EIEC) Salmonella Yersinia Vibrio Giardia lamblia Cryptosporium Cyclospora Entamoeba histolytica 2. Laboratory test records documented Yersinia enterolytica was detected on 7/04/19, but there was no record of reporting the result to the public health department. 3. A laboratory person affirmed (9/22/21 at 2:30pm and 10/08/21 at 3: 10pm) the laboratory didn't have a written policy/procedure or records of reporting test results to Public Health. 4. The number of reportable diseases informed to public health was not assured. .
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory test records, the lack of quality control records, and interview with a laboratory person, it was determined that the laboratory failed to test negative and positive control material each day patients specimen were tested using the Biofire GI Panel. Findings included: 1. Laboratory records documented patients specimen were tested and Biofire results reported until 2020 (as stated at D2000). 2. The laboratory failed to have Biofire Quality Control records for review. 3. A laboratory person affirmed (9/22/21 at 5pm) the aforementioned lack of Biofire QC records. 4. The reliability and quality of Biofire results reported each day could not be assured. Based on the reported annual test volume of 66 specimens, the laboratory reported approximately 4,356 results each year. .
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 the lack of laboratory records/documents for proficiency testing and Quality Controls, it was determined that the laboratory failed to establish policies or practice for ongoing monitoring of the analytic systems to assess for problems and implement activities for corrections. Findings included: 1. The laboratory failed to monitor for proficiency testing, assess, and identify the problem of not enrolling in proficiency testing for 2017, 2018, 2019, and 2020. 2. The laboratory failed to monitor Quality Control, assess, and identify the problem of not testing QC materials in 2017, 2018, 2019, and 2020.
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 the serious and cumulative nature of deficiencies cited, the Condition for the Laboratory Director to provide overall management of moderate complexity testing was not met. Findings included: 1. See D6015, D6020 and D6021. .
D6015	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the lack of laboratory documents of enrollment in proficiency testing and deficiency cited, the Laboratory Director is herein cited for deficient practice in providing overall administration to ensure the laboratory enrolled in proficiency testing for the Biofire GI Panel. Findings included: 1. Under the Laboratory Director's administration and lack of a written policy and lack of monitoring for quality assessment, the laboratory failed to enroll in proficiency testing. 2. See D2000. .
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 the deficiency cited (D5449), the Laboratory Director is herein cited for deficient practice in overall administration to ensure testing of Quality Control materials is established and maintained. .
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 the deficiency cited (D5791), the Laboratory Director is herein cited for deficient practice in administering over the laboratory to ensure policies are established and maintained to monitor the laboratory, assess for problems, and make corrections to assure the quality and reliability of the laboratory.