Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2161100	01/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Center For Digestive Disease	129 Vision Park Blvd, Suite 307, Shenandoah, 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. 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of laboratory records, laboratory policy, and confirmed in interview, the laboratory failed to verify twice annually the accuracy of all tests it performed on the Biofire FilmArray Torch Multiplex PCR analyzer. The findings were: 1. A review of the laboratory records revealed the laboratory performed patient testing using the Gastrointestinal panel on the Biofire FilmArray Torch Multiplex PCR analyzer 2. Review of the package insert for the FilmArray Gastrointestinal Panel (CE-IVD) Instruction Booklet (RFIT-PRT-OH3-04, June 2017) revealed under intended use "The [21] following organisms and subtypes are identified using the FilmArray GI Panel: Campylobacter spp. (C. jejuni, C. coli, and C. upsaliensis), Clostridium difficile toxin A/B, Plesiomonas shigelloides, Salmonella spp., Vibrio

	spp. (V. parahaemolyticus, V. vulnificus, and V. cholerae), Yersinia entercolitica, Enteroaggregative E. coli (EAEC), Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC) lt/st, Shiga-like toxin-producing E. coli (STEC) stx1/stx2, E. coli O157, Shigella/Enteroinvasive E. coli (EIEC), Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia, adenovirus F 40/41, astrovirus, norovirus GI/GII, rotavirus A, and sapovirus (I, II, IV, and V)." 3. Review of the 2019 laboratory records revealed no documentation of twice annual accuracy assessment for the above organisms. 4. Review of the laboratory records revealed the laboratory started patient testing on 5/7/2019 with an annual volume of 9240 tests. 5. An interview with the technical consultant on 1/6/2020 at 1100 hours in the office confirmed the above findings.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory requisitions, and confirmed in interview, the laboratory failed to ensure that patient test requisitions included necessary information to ensure accurate interpretation of results for the patient testing for the Gastrointestinal (GI) panel testing on the Biofire Filmarray Torch Multiplex PCR analyzer. Findings were: 1. Review of the laboratory records revealed the laboratory used Copan fecal swabs (171H29 191186100, exp 10/31/20) for GI specimen collection for patient testing on the Biofire Filmarray Torch Multiplex PCR analyzer. 2. Review of the package insert for the Copan fecal swab (HPC021B Rev 02 2016) under specimen collection revealed "proper specimen collection from the patient is extremely critical for successful isolation and identification of infectious organisms. The patient should be cautioned against the use of antacids, barium, bismuth, anti-diarrheal medication, antibiotics, histamine, nonsteroidal anti-inflammatory drug or oily laxatives prior to collection of the specimen." 3. Random review of the laboratory requisitions from 07/2019 to 12/2019 revealed no documentation of soliciting the required information above. 4. An interview with the technical consultant on 1/6/2020 in the office confirmed the above findings. She acknowledged that the laboratory should solicit the above information.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory records, patient test records, and confirmed in interview, the laboratory failed to define and monitor the correct acceptable criteria for accurate and reliable test system operation consistent with the manufacturer's instructions for Gastrointestinal (GI) patient testing on the Biofire Filmarray Torch Multiplex PCR analyzer. Findings were: 1. Review of the laboratory records revealed the laboratory used Copan fecal swabs (171H29 191186100, exp 10/31/20) for GI specimen collection for patient testing on the Biofire Filmarray Torch Multiplex PCR analyzer. 2. Review of the package insert for the Copan fecal swab (HPC021B Rev 02 2016) revealed "specimens should be refrigerated at 2-8C and processed within 72 hours or stored at room temperature (20-25C) and processed within 48 hours." 3. Random review of the environmental laboratory records from May 2019 through December 2019 revealed 6 of 25 days with temperature outside of the acceptable room temperature of 20 - 25 C per the manufacturer's instructions. Date Temperature 07/31/19 19.3 C 08/01/19 19.3 C 09/10 /19 19.2 C 11/04/19 18.6 C 12/10/19 18.5 C 12/13/19 18.0 C 4. Review of the laboratory patient test records from May 2019 - December 2019 revealed the laboratory performed patient testing on the above dates. Refer to the patient alias list. 5. An interview with the technical consultant on 1/6/2020 at 1021 hours in the office confirmed the above findings.
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 review of the manufacturer's instructions, laboratory policies and verification studies, and confirmed in interview, the laboratory failed to document verification studies using the Cary Blair Protocol that evaluated Biofire FilmArray GI (Gastrointestinal Panel) performance when organisms are in a Cary Blair sample matrix. Findings were: 1. Review of the package insert for the FilmArray Gastrointestinal Panel (CE-IVD) Instruction Booklet (RFIT-PRT-OH3-04, June 2017) revealed under intended use "The [21] following organisms and subtypes are identified using the FilmArray GI Panel: Campylobacter spp. (C. jejuni, C. coli, and C. upsaliensis), Clostridium difficile toxin A/B, Plesiomonas shigelloides, Salmonella spp., Vibrio spp. (V. parahaemolyticus, V. vulnificus, and V. cholerae), Yersinia entercolitica, Enteroaggregative E. coli (EAEC), Enteropathogenic E. coli (EPEC),

	Enterotoxigenic E. coli (ETEC) lt/st, Shiga-like toxin-producing E. coli (STEC) stx1 /stx2, E. coli O157, Shigella/Enteroinvasive E. coli (EIEC), Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia, adenovirus F 40/41, astrovirus, norovirus GI/GII, rotavirus A, and sapovirus (I, II, IV, and V). 2. Review of the laboratory policies revealed the laboratory accepted GI specimens in Copan fecal swabs that contain Cary Blair media. 3. Review of the technical note for the FilmArray Gastrointestinal Panel (FLM1-PRT-0151-04) under performance overview revealed a "simple Cary Blair Media protocol that evaluates the performance of each assay on the GI Panel with a stool in Cary Blair sample matrix...a stool sample in Cary Blair media will be used as the organism pool background rather than synthetic stool (Negative)." 4. Review of the laboratory verification studies revealed no documentation of the GI verification studies using the Cary Blair Protocol for the Biofire FilmArray Torch Multiplex PCR analyzer. 5. An interview with the technical consultant on 1/6/2020 at 1050 hours confirmed the above findings. She was unaware the laboratory was required to perform the studies using a different protocol.
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 review of the laboratory records, INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) records, and confirmed in interview, the laboratory failed to document a complete IQCP that included a Risk Assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) plan for Gastrointestinal testing on the Biofire Filmarray Torch Multiplex PCR analyzer. Findings were: 1. Review of the laboratory records revealed the laboratory performed external quality control for the Gastrointestinal testing on the Biofire Filmarray Torch every 30 days or every new lot. 2. Review of the quality control records revealed the laboratory performed a quality control study for Gastrointestinal testing on the Biofire Filmarray Torch. No documentation of the Risk Assessment (RA), a Quality Control Plan (QCP), and a Quality Assessment (QA) plan were available for review by the end of survey date of 1/6/2020. 3. Review of the laboratory records revealed the laboratory started patient testing on 5/7/2019 with an annual volume of 9240 tests. 4. An interview with the technical consultant on 1/6/2020 at 1000 hours in the office confirmed the above findings. She stated that she "overlooked" that portion of the IQCP.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records from May - December 2019, patient test records, and confirmed in interview, the laboratory failed to document external control for 1 of 8 months on the Gastrointestinal testing on the Biofire Filmarray Torch Multiplex PCR analyzer. Findings were: 1. Review of the laboratory quality control records from May - December 2019 revealed the laboratory failed to perform external quality control (QC) for 1 of 8 months (November 2019) on the Gastrointestinal testing on the Biofire Filmarray Torch . 2. Review of the laboratory patient test records revealed the laboratory performed 6 patient testing from 11/29/19 (date QC was due) to 12/6/19 (date prior to QC performed). Refer to patient alias list. 3. An interview with the technical consultant on 1/6/2020 at 0945 hours in the office confirmed the above findings. She acknowledged that QC should have been performed in November.
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 review of quality assessment reports and interview, the laboratory quality assessment policies and procedures failed to identify and correct problems identified in analytical systems. Refer to D5413, D5421, D5445, D5481
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 test reports and confirmed in interview, the laboratory failed to document the name and address of the testing facility where the Gastrointestinal (GI) Panel patient testing were performed on the Biofire FilmArray Torch Multiplex PCR analyzer. Findings were: 1. A random review of the patient reports from May 2019 to December 2019 revealed 10 of 10 test reports with no documentation of the name and address of the testing facility where the GI panel were analyzed on the Biofire FilmArray Torch Multiplex PCR analyzer . Refer to patient alias list. 2. An interview with the technical consultant on 1/6/2020 at 1021 hours in the office confirmed the above findings. She acknowledged that the reports should be updated to reflect the laboratory name and address.

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 a review of the manufacturer's instructions, laboratory's verification records and confirmed in interview, the laboratory director failed to ensure verification studies were complete for Gastrointenstinal panel testing on the BioFire FilmArray before reporting patient test results. (Refer to D5421)
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 review of the facility records and confirmed in interview, the laboratory director failed to ensure a quality assessment plan identified and corrected problems. Refer to D5791
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records and confirmed in interview, the technical consultant failed to ensure that the quality control program had been established and maintained for the Gastrointestinal panel testing on the Biofire Filmarray Torch Multiplex PCR analyzer. Refer to D5445, D5481