Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2161100	10/02/2023
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	An announced survey of the laboratory was conducted on 10/02/2023. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D6063 - 42 C. F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel. .
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of laboratory's Proficiency Testing (PT) documents for the Biofire FilmArray Gastrointestinal (GI) Panel for 2022 and 2023 and staff interview, the laboratory failed to retain all documentation for one of five events reviewed, 2022 Microbiology - 2nd (second) Event. Findings included: 1. Review of laboratory's PT documents for 2022 and 2023 revealed the laboratory used the American Proficiency Institute (API) to perform PT for its Biofire FilmArray GI Panel. 2. Further review of the PT documents for 2022 and 2023 revealed the following documents for 2022 Microbiology - 2nd Event (tested June 2022) were not retained: - Attestation document - Test data entry printouts - API Performance Summary - API Comparative Evaluation - API Participant Data Summary - Documentation of evaluation of laboratory's performance 3. In an interview on 10/02/2023 at 1005 hours in the laboratory, the facility's Testing Person number one (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
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 review of laboratory's Proficiency Testing (PT) documents for the Biofire FilmArray Gastrointestinal Panel (GI) for 2022 and 2023, review of American Proficiency Institute's (API) instructions for evaluation of results and staff interview, the laboratory failed to follow API instructions for documentation of evaluation of "Unacceptable" results for one of five accuracy verification events reviewed. Findings included: 1. Review of laboratory's PT documents for 2022 and 2023 revealed the laboratory used the API to perform PT for its Biofire FilmArray GI Panel. 2. Review of the API instructions for evaluation of results revealed: "Laboratories are responsible for documenting and performing corrective action for failures (unacceptable results) and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 3. Further review of laboratory's PT documents for 2022 and 2023 revealed the laboratory did not follow API's instructions for the following one of five events reviewed: API 2023 Microbiology - 2nd Event (tested June 2023) did not have documentation of corrective action for "Unacceptable" results for the following sample/analyte: Sample: Analyte: GIP-07 Astrovirus 4. In an interview on 10/02/2023 at 1005 hours in the laboratory, the facility's Testing Person number one (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of laboratory's Proficiency Testing (PT) documents for the Biofire FilmArray Gastrointestinal Panel (GI) for 2022 and 2023, review of American Proficiency Institute's (API) instructions for evaluation of results and staff interview, the laboratory failed to follow API instructions for documentation of evaluation of "Not Graded" results for one of five accuracy verification events reviewed. Findings included: 1. Review of laboratory's PT documents for 2022 and 2023 revealed the laboratory used the API to perform PT for its Biofire FilmArray GI Panel. 2. Review of the API instructions for evaluation of results revealed: "Laboratories are responsible for documenting and performing corrective action for failures (unacceptable results) and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 3. Further review of laboratory's PT documents for 2022 and 2023 revealed the laboratory did not follow API's instructions for the following one of five events reviewed: API 2023 Microbiology - 1st Event (tested February 2023) did not have documentation of self-evaluation for "Not Graded" results for the following samples/analytes: Sample: Analyte: GIP-01 Shigella GIP-04 Shiga Toxin 1 GIP-04 Shiga Toxin 2 4. In an interview on 10/02/2023 at 1005 hours in the laboratory, the facility's Testing Person number one (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

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 laboratory's individualized quality control plan (IQCP), quality control (QC) records, patient test records and staff interview the laboratory failed to follow its own policy for performing Biofire FilmArray Gastrointestinal (GI) Panel QC every 30 days for two of eighteen 30-day intervals reviewed from 2022 and 2023. Note: This is a repeat deficiency from the survey conducted on 03/11/2022. Findings included: 1. Review of laboratory's IQCP (established and approved 06/12/2019, last reviewed 12/09/2021) revealed: "The BioFire Array system was evaluated for 30 days to establish QC analysis is not required each day of patient testing." And, "External QC will be performed with each new reagent shipment, new lots numbers of reagents and/ or monthly." 2. Review of laboratory's QC records for 2022 and 2023 revealed the following intervals exceeded the IQCP defined 30-day QC requirements: 08/23 /2022 to 09/27/2022 Interval Days elapsed between QC: 35 07/10/2023 to 08/18/2023 Interval Days elapsed between QC: 39 3. Review of patient test records revealed the following patients' samples were tested beyond the required 30-day QC interval: 08/23 /2022 to 09/27/2022 Interval Date tested: Sample: 09/23/2023 09232022 09/26/2023 01221956 07/10/2023 to 08/18/2023 Interval Date tested: Sample: 08/09/2023 09111956 08/10/2023 03151957 08/14/2023 06301943 08/14/2023 11261947 08/15 /2023 08152023 Note: Refer to Master List attached for patient/sample information. 4. In an interview on 10/02/2023 at 1110 hours in the laboratory, the facility's Testing Person number one (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
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 laboratory's individualized quality control plan (IQCP), quality control (QC)/quality assurance records, patient test records and staff interview the laboratory's quality assurance failed to identify and correct issues with QC performance beyond 30-day IQCP defined intervals for two of eighteen intervals reviewed. Refer to D5445. Note: This is a repeat deficiency from the survey conducted on 03/11/2022.

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 review of laboratory's individualized quality control plan (IQCP), quality control (QC) records, patient test records and staff interview the Laboratory Director failed to ensure Biofire FilmArray Gastrointestinal (GI) Panel QC was maintained as per laboratory's IQCP requirements for two of eighteen 30-day intervals reviewed from 2022 and 2023. 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 review of laboratory's individualized quality control plan (IQCP), quality control/quality assurance records, patient test records and staff interview the Laboratory Director failed to ensure laboratory's quality assurance was maintained and able to identify and correct issues with QC performance beyond 30-day IQCP defined intervals for two of eighteen intervals reviewed for 2022 and 2023. Refer to D5791.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory's personnel records, patient test records and staff interview, the Laboratory Director failed to ensure that prior to testing patients'

	specimens, all personnel have the appropriate education for one of three testing personnel. Refer to D6065.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of laboratory's personnel records and staff interview, the Technical Consultant failed to ensure 2023 personnel competency assessment documentation included review of intermediate test results, proficiency testing results, and maintenance records for one of three testing personnel (TP) employed by the laboratory, TP number one. Note: This is a repeat deficiency from the survey conducted on 03/11/2022. Findings included: 1. Review of laboratory's personnel records revealed 2023 annual competency assessment for TP number one, performed on 08/08/2023, did not have documentation of required review of intermediate test results, proficiency testing results, and maintenance records. Competency assessment form used for the TP's assessment was an old form in use prior to the 3/11/2022 survey, which did not include the required components. 2. In an interview on 10/02 /2023 at 1045 hours in the office, the facility's Testing Person number one (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on review of laboratory's personnel records, patient test records and staff interview, the laboratory failed to ensure it employed personnel who met the qualification requirements for its moderate complexity testing for one of three testing personnel. Findings included: 1. The laboratory failed to ensure one of three testing personnel have met the necessary education requirements. Refer to D6065. .
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at

	least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: . Based on review of laboratory's personnel records, random patient test records from August and September 2023 and staff interview, the laboratory failed to ensure one of three testing personnel have met the necessary education requirements prior to starting patient testing. Findings included: 1. Review of laboratory's personnel records revealed Testing Person number three (employed 02/02/2021, terminated 09/26/2023) did not have the necessary education requirements documented. 2. The laboratory was asked to provide evidence of Testing Person number three meeting educational requirements, and no such evidence was available for review. 3. Review of random patient test records from August and September 2023 revealed Testing Person number three performed testing on the following patients' samples: Date tested: Sample: 08/14 /2023 06302023 08/14/2023 11261947 08/22/2023 08222023 08/24/2023 08242023 09/01/2023 09012023 09/05/2023 09052023-11 09/05/2023 09052023-12 Note: Refer to attached Master List for patient/sample information. 4. In an interview on 10/02 /2023 at 1110 hours in the laboratory, the facility's Testing Person number one (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid