

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2161100	<b>(X3) Date Survey Completed</b>  03/11/2022
<b>Name of Provider or Supplier</b>  Center For Digestive Disease	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>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 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 Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records from American Proficiency Institute (API) for 2020 and 2021, review of API instructions and staff interview it was determined the laboratory failed to ensure individuals testing the samples and the laboratory director have attested to the routine integration of the samples into the patient workload for 2 of 6 events reviewed. Findings included: 1. Review of the laboratory's PT records from API for 2020 and 2021 revealed the attestation forms for 2 of 6 reviewed events were not signed by either the testing personnel and/or by the laboratory director as follows: 2021 Microbiology - Event 1 Tested March 2021 Did not contain testing personnel attestation signatures. 2021</p>

Microbiology - Event 2 Tested June 2021 Did not contain testing personnel or laboratory director attestation signatures. 2. Review of API instructions revealed: "SIGNATURES REQUIRED - For all PT results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years." 3. In and interview on 03/11/2022 at 1105 hours in the reception area the testing person number 1, (as described on submitted Form 209, signed by laboratory director on 03/11/2022), after review of the data, confirmed the findings.

**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's Individualized Quality Control Plan (IQCP) for the BioFire Gastrointestinal Panel, review of quality control (QC) records for 2020, 2021 and 2022 for said panel, review of patient test records and staff interview it was determined the laboratory failed to document performance of QC as defined by the IQCP for 4 of 20 IQCP defined intervals reviewed. Findings included: 1. Review of the laboratory's IQCP for the BioFire Gastrointestinal Panel (placed into effect June 12, 2019) 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 of reagents and/or monthly." 2. Review of the BioFire Gastrointestinal Panel QC records for 2020, 2021 and 2022 revealed the following QC intervals exceeding the IQCP defined 30 day maximum: 04/13/2020 to 05/29/2020 Interval of 48 days 06/30/2020 to 08/05/2020 Interval of 37 days 11/17/2020 to 01/08/2021 Interval of 45 days 10/26/2021 to 01/13/2022 Interval of 79 days 3. Review of patient test records for the above intervals revealed the following patients were tested on days the 30 day maximum IQCP defined QC was no longer valid: Tested on Patient ID 05/15/2020 110185 07/31/2020 092101 07/31/2020 082880 08/03/2020 092984 08/04/2020 031775 08/04/2020 070670 08/04/2020 042398 08/04/2020 071685 12/18/2020 080650 12/23/2020 113028 01/04/2021 011048 11/29/2021 070351 12/14/2021 HG 12/31/2021 PL PK 01/10/2022 AP SM 4. In and interview on 03/11/2022 at 1110 hours in the reception area the testing person number 1 (as described on submitted Form 209), after review of the data, confirmed the findings.

**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 the laboratory's quality assessments for 2020, 2021 and 2022 and staff interview it was determined the laboratory's quality assessment processes failed to identify issues with adherence to quality control frequency as per laboratory's Individualized Quality Control Plan (IQCP). Refer to D5445.

**D6047**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's submitted Laboratory Personnel Report (Form 209), review of personnel competency assessment records for 2021 and 2022 and staff interview it was determined the technical consultant failed to document direct observation of testing for 1 of 2 testing personnel. Findings included: 1. Review of the laboratory's submitted Form 209 (signed by the laboratory director on 03/11/2022) revealed the laboratory employed 2 testing personnel. 2. Review of personnel competency assessment records for 2021 and 2022 revealed the 2022 competency assessment form for testing person number 1 did not have direct observation of test performance documented. 3. The laboratory was asked to provide documentation of the 2022 testing person #1 competency assessment for direct observation of testing and no such documentation was available for review. 3. In and interview on 03/11 /2022 at 0925 hours in the reception area the testing person number 1, (as described on submitted Form 209), after review of the data, confirmed the findings.

**D6048**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's submitted Laboratory Personnel Report (Form 209), review of personnel competency assessment records for 2020 and 2021 and staff interview it was determined the technical consultant failed to document monitoring the recording and reporting of test results for 2 of 2 personnel's competency assessments reviewed. Findings included: 1. Review of the laboratory's submitted Form 209 (signed by the laboratory director on 03/11/2022) revealed the laboratory employed 2 testing personnel. 2. Review of personnel competency assessment records for 2020 and 2021 revealed competency assessment forms were missing the required component of monitoring the recording and reporting of test results. 3. The laboratory was asked to provide documentation of competency assessment for monitoring the recording and reporting of test results and no such documentation was available for review. 3. In and interview on 03/11/2022 at 0925 hours in the reception area the testing person number 1, (as described on submitted Form 209), after review of the data, confirmed the findings.

**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 the laboratory's submitted Laboratory Personnel Report (Form 209), review of personnel competency assessment records for 2020 and 2021 and staff interview it was determined the technical consultant failed to document review of preliminary test results, quality control records, proficiency testing results, and preventive maintenance records for 2 of 2 personnel's competency assessments reviewed. Findings included: 1. Review of the laboratory's submitted Form 209 (signed by the laboratory director on 03/11/2022) revealed the laboratory employed 2 testing personnel. 2. Review of personnel competency assessment records for 2020 and 2021 revealed competency assessment forms were missing the required component of preliminary test results, quality control records, proficiency testing results, and preventive maintenance records review. 3. The laboratory was asked to provide documentation of competency assessment for preliminary test results, quality control records, proficiency testing results, and preventive maintenance records review and no such documentation was available for review. 3. In and interview on 03/11/2022 at 0925 hours in the reception area the testing person number 1, (as described on submitted Form 209), after review of the data, confirmed the findings.

**D6050**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(iv)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Laboratory Personnel Report (Form 209), review of personnel competency assessment records for 2020 and 2021 and staff interview it was determined the technical consultant failed to document direct observation of performance of instrument maintenance and function checks for 2 of 2 personnel's competency assessments reviewed. Findings included: 1. Review of the laboratory's submitted Form 209 (signed by the laboratory director on 03/11/2022) revealed the laboratory employed 2 testing personnel. 2. Review of personnel competency assessment records for 2020 and 2021 revealed competency assessment forms were missing the direct observation of performance of instrument maintenance and function checks component. 3. The laboratory was asked to provide documentation of competency assessment for direct observation of performance of instrument maintenance and function checks and no such documentation was available for review. 3. In and interview on 03/11/2022 at 0925 hours in the reception area the testing person number 1, (as described on submitted Form 209), after review of the data, confirmed the findings.

**D6052**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Laboratory Personnel Report (Form 209), review of personnel competency assessment records for 2020 and 2021 and staff interview it was determined the technical consultant failed to document problem solving skills for 2 of 2 personnel's competency assessments reviewed. Findings included: 1. Review of the laboratory's submitted Form 209 (signed by the laboratory director on 03/11/2022) revealed the laboratory employed 2 testing personnel. 2. Review of personnel competency assessment records for 2020 and 2021 revealed competency assessment forms were missing the required component of problem solving skills. 3. The laboratory was asked to provide documentation of competency assessment for problem solving skills and no such documentation was available for review. 3. In and interview on 03/11/2022 at 0925 hours in the reception area the testing person number 1, (as described on submitted Form 209), after review of the data, confirmed the findings.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Laboratory Personnel Report (Form 209), review of personnel competency assessment records for 2020 and 2021 and staff interview it was determined the technical consultant failed to document 2 competency assessments (at least semiannually) within the first year of employment for 1 of 2 testing personnel employed by the facility. Findings included: 1. Review of the laboratory's submitted Form 209 (signed by the laboratory director on 03/11/2022) revealed the laboratory employed 2 testing personnel. 2. Review of personnel competency assessment records for 2020 and 2021 revealed testing person number 1 had only 1 competency assessment the first year of employment as follows: Testing Person #1 Trained on 02/09/2021 Competency assessment performed 02/20/2022 3. In and interview on 03/11/2022 at 0925 hours in the reception area the testing person number 1, (as described on submitted Form 209), after review of the data, confirmed the findings.