Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2161100	08/28/2025
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 08/28/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) 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. This STANDARD is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to ensure attestation signatures of laboratory director/designee and/or testing personnel were documented for three of five PT events reviewed from 2023, 2024 and 2025. Findings included: 1. Review of laboratory's American Proficiency Institute (API) PT records revealed the following API instructions to laboratories: "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." 2. Further review of laboratory's 2023-2025 PT records revealed the following three of five reviewed API PT events did not have documentation of required attestation signatures: Event: 2023 Microbiology - 3rd Event Tested: November 2023 Missing signature(s): Testing Personnel Event: 2024 Microbiology - 2nd Event Tested: July 2024 Missing signature(s): Testing Personnel Event: 2025 Microbiology - 1st Event Tested: January 2025 Missing signature(s): Laboratory Director/designee and Testing Personnel 3. In an interview on 08/28/2025 at 1010 hours in the open office space, the Testing Person number two (as indicated on submitted Form CMS 209) confirmed the findings.

D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on review of laboratory's temperature/humidity records, policies/procedures and staff interview, the laboratory failed to define and monitor room temperature /humidity to ensure histopathology slides' preservation for one of one room where histopathology slides were stored in 2024 and 2025. Findings included: 1. Review of laboratory's temperature/humidity records revealed there was only one room temperature/humidity monitored in 2024 and 2025, the molecular testing room. There were no temperature/humidity records for the room where histopathology slides were stored. 2. Review of laboratory's policies/procedures revealed the policies/procedures did not define requirements for histopathology slides' storage conditions to ensure slides' preservation. 3. In an interview on 08/28/2025 at 1110 hours in the open office space, the facility's Practice Manager (as indicated on submitted Survey Entrance/Exit Conference document), when asked, stated that histopathology slides were stored in a separate room, but the temperature/humidity was not monitored there. This confirmed the findings.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) 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: This is a repeat deficiency from the survey conducted on 10/02/2023. Based on review of laboratory's proficiency testing (PT) records and staff interview, the laboratory failed to document self-evaluation for one of fifteen "Not Graded" PT results from 2024 and 2025. Findings included: 1. Review of laboratory's PT records revealed the laboratory used American Proficiency Institute (API) as their PT provider. 2. Review of the API instructions to laboratories revealed: "Laboratories are responsible for documenting and performing corrective action for failures 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 API records revealed the laboratory did not document self-evaluation for the following "Not Graded" analyte: 2024 Microbiology - 3rd Event Analyte: Other method-please review/Shigella Sample: GIP-13 Reported Result: Detected Expected Result: See Data Summary Performance: Not Graded 4. In an interview on 08/28/2025 at 1010 hours in the open office space, the Testing Person number two (as indicated on submitted Form CMS 209) confirmed the findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on review of laboratory's personnel records, policies/procedures and staff interview, the laboratory failed to ensure that the laboratory director, upon assumption of duties, reviewed and approved policies and procedures for microbiology testing by molecular methods, one of two testing specialties performed in the laboratory in 2024 and 2025. Findings included: 1. Review of laboratory's personnel records revealed the current Laboratory Director took over as of 05/21/2024. 2. Review of the laboratory's policies/procedures revealed there was no documentation of review/approval of the existing policies/procedures for microbiology testing by molecular methods by the current Laboratory Director. 3. In an interview on 08/28/2025 at 0955 hours in the open office space, the facility's Practice Manager (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, personnel records and staff interview, the laboratory's Technical Consultant failed to document performance of competency assessments for four of six competency assessments reviewed from 2024 and 2025. Findings included: 1. Review of laboratory's policy "Competency Evaluation Program" (policy number G-1, effective December 2018) revealed: "The Administrative Director/ Technical Consultant is responsible for evaluating the competency of testing personnel and assuring that the staff maintains their competency to perform test procedures and report test results promptly, accurately and proficiently" 2. Review of laboratory's personnel records revealed instead of Technical Consultant, Testing Person number two (as indicated on submitted Form CMS 209) documented performance of competency assessment for the following personnel: Testing personnel: Testing Person number 3 (TP3) 2024 Competency assessment date: 04/10/2024 2025 Competency assessment date: 04/25/2025 2024 and 2025 Competency assessed by: TP2 Testing personnel: TP4 2024 Competency assessment date: 08/23/2024 2025 Competency assessment date: 08/22/2025 2024 and 2025 Competency assessed by: TP2 3. In an interview on 08/28/2025 at 0955 hours in the open office space, the Testing Person number two (as indicated on submitted Form CMS 209) confirmed the findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) 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 laboratory's policies/procedures, personnel records and staff interview, the laboratory's Technical Consultant failed to document performance of competency assessments at least semiannually during the first year of employment for one of four testing personnel, Testing Person number 4 (TP4). Findings included: 1. Review of laboratory's policy "Competency Evaluation Program" (policy number G-1, effective December 2018) revealed: "DEVELOPING AND SCHEDULING COMPETENCY TESTING 1. All employees are required to participate in the program annually and new employees semi-annually." 2. Review of laboratory's personnel records revealed TP4 had completion of training and initial competency documented on 08/23/2024. The next competency assessment was documented on 08 /22/2025. There was no documentation of semi-annual competency assessment in February 2025. 3. In an interview on 08/28/2025 at 0955 hours in the open office space, the Testing Person number two (as indicated on submitted Form CMS 209) confirmed the findings.