Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0898621	07/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Specialists Of Frederick	85 Thomas Johnson Court Ste B, Frederick, MD	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory director (LD), laboratory staff did not follow established safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. Findings: 1. During a tour of the laboratory at 9:45 AM, it was observed that the histotechnician had placed an open drink can on the counter near where they open biohazard bags containing tissue and biopsy specimens which are stored in jars of formalin preservative. This area also serves as secondary laboratory space and contained a stainer which is used to perform immunohistochemistry staining on tissue and biopsy specimens. 2. The laboratory is required to implement safety policies and procedures to ensure the safety of the testing personnel. The Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) provide guidelines for laboratory safety. Good laboratory practices state that there should be no eating, drinking, or application of cosmetics in the laboratory. 3. During an interview on 07/28/2023 at 3:30 PM, the LD confirmed that laboratory staff did not follow established safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials.
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 procedure manual and quality assurance (QA) review and interview with the laboratory director (LD), the laboratory did not ensure that proficiency testing (PT) was performed at least twice annually. Findings: 1. The laboratory currently has 2 testing personnel (TP) listed on the "Laboratory Personnel Report" (CMS-209). One of one TP interprets stained histology slides. 2. The procedure, Section "6. Quality Assurance," "2.G. Pathologist Proficiency Testing" states that "Twice year these pathologist(s) will provide Peer Review and Consultation on a minimum of 5 cases per pathologist." 3. A review of QA records from 2022 and 2023 showed that the laboratory sent out 10 cases for secondary review from 2022 and five cases from 2023. Fifteen of fifteen cases were reviewed by the second pathologist on 06/25/2023. 4. During an interview on 07/28/2023 at 3:30 PM, the LD confirmed that PT slides were not sent out twice a year in 2022.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on patient slide, laboratory records, and procedure review and interview with the laboratory director (LD) and testing person (TP), the laboratory failed to notify the practice when a patient specimen was missing. Findings: 1. Patient CEC22-00735 was 1 of 4 randomly chosen patients for review of laboratory records, physical slides, and final reports. 2. The patient had 8 biopsies labeled A-H that were collected on 09/21 /2022. 3. The laboratory documented the number of specimens received, the accession date, the grossing date, and the dates read and signed out by the pathologist on the "Specimen Flow Sheet" (flow sheet). 4. The flow sheet for 09/21/2022 showed that 8 specimens for CEC22-00735 were received from the practice. The specimens were not accessioned until 10/01/2023. 5. The slide for specimen E had "No Specimen" written on it by the TP. 6. The laboratory's procedure titled "Section 2. Specimen Handling & Reporting" stated that "For missing specimens, contact the submitting location." 7. There was no documentation that the laboratory contacted the practice to let them know that a specimen was missing. 8. The physician was notified on the final report that was issued on 11/18/2022, 58 days after specimen collection, that "Specimen E: Duodenum, Bulb NO SPECIMEN." 9. During the survey on 07/28 /2023 at 3:30 PM, the LD confirmed that they assumed the TP had notified the practice and the TP confirmed that they had not notified the practice that 1 of 8 specimens for patient CEC22-00735 was missing upon receipt.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or

examining specimens.

This STANDARD is not met as evidenced by:
Based on standard operating procedure manual (SOPM) and record review and interview with the histotechnician, office staff, and the laboratory director (LD), the laboratory failed to have an up-to-date written procedure manual for the specific practices performed in the laboratory. Findings: 1. The laboratory's procedure titled "Section 2. Specimen Handling & Reporting" states that "For missing specimens, contact the submitting location." The laboratory failed to notify the practice when a patient specimen was missing. Cross-refer to D5311 for findings. 2. Section "4. Staining" "1. Hematoxylin and Eosin [H&E] Staining" states to "follow Laboratory H&E Stain Line Quality Control Guidelines located on the Quality Control Sheet." During an interview at 11:15 AM, the histotechnician stated that they filter the hematoxylin stain every 2 weeks. A review of the "Quality Control Sheet" for H&E staining showed that there are no "guidelines" listed on the log and no procedure for this in the SOPM. 3. Section "5. Immunohistochemistry" "1. Manual IHC Procedure" states, "When the Histotech receives a new antibody, the tech must grossly inspect the antibody and complete the Immunohistochemistry Stain Lot Number Quality Control Log [IHC Stain QC Log], prior to using." Record review showed that there were no IHC Stain QC Logs present at the time of the survey. During an interview at 2:30 PM the histotechnician confirmed that the lab did not use the IHC Stain QC Log and that the validation of new lot numbers of antibody were not documented. 4. Section "5. Immunohistochemistry" "2. New Antibody Validation" states, "Prior to staining tissue for diagnosis, any new antibody must be validated with appropriate documentation. This is also true for new lots of the same antibody. The detection system must also be validated when new lots of detection arrive, this validation consists of running a series of six (6) known negatives with appropriate controls." During an interview, the histotechnician stated that they would stain a slide with the old lot number of stain and the new lot number of stain and compare them to validate a new lot number of antibody. Neither the LD nor the histotechnician could explain what "new lots of detection" referred to. 5. Section "6. Quality Assurance" "1. General QA Plan" states that monthly the laboratory will complete a "Monthly Quality Assessment Report (MQAR)" which includes nine quality assurance (QA) topics. QA record review showed that there were no MQAR available at the time of the survey. 6. The QA procedure also states that "Procedure manual reviews will be performed annually or more frequently as needed." The SOPM was signed and approved by the LD on 03/01 /2019. During an interview at 1:10 PM the LD stated that they don't review the SOPM annually and aren't "aware" of all of the procedures in the SOPM. 7. The "Physician Quality Assurance" section of the QA procedure states, "At least twice a year, the lab will send out 2-4 slides for a second opinion (at least 6 months apart)." The laboratory did not ensure that proficiency testing was performed at least twice annually. Cross-refer to D5217 for findings. 8. Section "2.E. Personnel Competency" of the QA procedure states that the competency assessment of the histotechnician will include a "Histology Practical" where the employee will "prepare a practical slide set," cutting slides from "old or sample tissue blocks" "to prepare all the necessary stains (i.e. H&E Stain, Immunostains, and Special Stains)." During an interview at 1:50 PM the histotechnician stated that their competency assessment did not include a "histology practical." This was confirmed by the LD. 9. Section "2.G. Pathologist Proficiency Testing" of the QA procedure refers to the name of the laboratory as the "Center of Digestive Health & Nutrition." This is not the name of the laboratory being surveyed. During an interview at 2:30 PM the histotechnician stated that the SOPM was "borrowed" from another laboratory. 10. Section "7. Computers" "3. Data Integrity"

	provides a procedure for checking 10 patient laboratory reports from the "Data Back-Up File" to "ensure the integrity of data, i.e. patient reports, is maintained during transmission, storage, back-up and retrieval." The procedure states that this is to be performed annually. During an interview at 3:00 PM the office staff stated that this was not performed. 11. During an interview on 07/28/2023 at 3:30 PM, the LD confirmed that the laboratory's SOPM was not updated to reflect the current practice of the laboratory.
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: I. Based on observation, record review, and interview with the laboratory director (LD), the laboratory failed to define and monitor the environmental conditions for histopathology specimen processing and slide preparation. Findings: 1. The laboratory processed histopathology specimens and prepared slides in a room that was not monitored for temperature or humidity. 2. There was no procedure or log that defined the acceptable temperature and humidity requirements for histopathology specimen processing and slide preparation. 3. During the survey on 07/28/2023 at 3:30 PM, the LD confirmed that the laboratory did not have defined acceptability requirements and was not monitoring temperature and humidity for histopathology specimen processing and slide preparation. II. Based on instrument operating manual and temperature log record review and interview with the laboratory director (LD), the laboratory failed to establish a room temperature range for the laboratory which was consistent with the histology slide stainer's manufacturer's instructions. Findings: 1. The laboratory monitored the temperature where they perform immunohistochemistry staining using the StatLab Quantum HDx Slide Stainer. The operating manual for the StatLab Quantum HDx Slide Stainer, under "3.1 Installation Requirements" states, "The work area must be in an environment with an ambient temperature between 18C-26C (64F-79F)." 2. A review of the laboratory's "Daily Room Temp and Humidity Chart" showed that the "Allowable temp range" was "10C to 30C." 3. During an interview on 07/28/2023 at 3:30 PM, the LD confirmed that the laboratory's acceptable room temperature range was not consistent with the manufacturer's instructions.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory director (LD), the laboratory did not ensure that the in-use histology stain reagents were labeled with the date that they were opened. Findings: 1. During a tour of the laboratory at 2:30 PM, it was observed that three bottles of reagents were stored on the floor of the laboratory, under the fume hood. 2. Three of three bottles were opened and in-use: 100% Reagent Alcohol (lot # 174545, expiration date 05/31/2025), 95% Reagent Alcohol (lot # 173684, expiration date 05/31/2025), and xylene (lot # 171623, expiration date 04/30 /2025). 3. None of the opened and in-use bottles of reagents were labeled with the date that they were opened and put in to use. 4. During an interview on 07/28/2023 at 3:30 PM, the LD confirmed that the in-use histology stain reagents were not labeled with the date that they were opened.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the staining reagent log, staining reagent instructions for use (IFU), and Stain Quality Assurance Log and interview with the testing person (TP), the laboratory failed to ensure that staining reagents were not used beyond their expiration date. Findings: 1. The laboratory performed immunohistochemistry (IHC) staining on patient histopathology slides using the Quantum HDx automated staining platform to identify Helicobacter pylori (HPY) and CD3 protein. 2. The reagent kit "Quantum HDx 3 Step HRP Detection Kit" (detection kit) was used for the laboratory's IHC staining. The IFU for this reagent kit stated "Do not use after expiration date printed on vial." 3. The laboratory recorded the lot number, date in use, and expiration date of all staining reagents on the "Lot Numbers" log. 4. The "Lot Numbers" log showed that lot number 211011 of the detection kit expired on 09/30 /2022 and the next lot number, lot 230602, was put into use on 12/12/2022. 5. The Stain Quality Assurance Log documented all slides stained and the dates of staining and showed that 34 slides were stained for HPY on 10/06/2022, 34 slides were stained for HPY on 10/13/2022, 10 slides were stained for HPY on 10/26/2022, 23 slides were stained for HPY on 10/30/2022, and 2 slides were stained for CD3 on 10/30 /2022. 6. During the survey on 07/28/2023 at 3:30 PM, the TP confirmed that the "Lot Numbers" log showed that the IHC reagent detection kit was used beyond its expiration date.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 01/06/2022 for not performing and documenting instrument and equipment

	maintenance as specified by the manufacturer. The plan of correction stated that this would be corrected. I. Based on observation, procedure manual, instrument operating manual, and record review, and interview with the histotechnician and the laboratory director (LD), the laboratory did not perform and document routine preventive maintenance checks on laboratory equipment. Findings: 1. During a tour of the laboratory at 9:45 AM, it was observed that the Leica Auto Stainer XL and Leica RM 2235 Microtome were labeled with stickers stating that maintenance was last performed 12/26/2017 and that the next maintenance was "due 12/2018." The Tissue-Tek VP tissue processor was labeled with a sticker that stated that filter replacement is recommended every six months. Maintenance was last documented on 7/2021. 2. The procedure, "Section 6. Quality Assurance" "4.C. Equipment Maintenance and Function Checks" states that "yearly preventative maintenance" is to be performed on the tissue processor, embedding center, microtome, water bath, drying oven, microscope, and refrigerator. 3. Record review showed that there was no documentation that preventative maintenance was performed as specified in the procedure manual on the above listed laboratory equipment. 4. The operating manual for the StatLab Quantum HDx Slide Stainer, under "7.4 Annual/Semi-Annual Maintenance" states, "Annual/semi-annual maintenance on the whole system must be performed by a trained service technician." During an interview at 2:40 PM on the day of the survey the histotechnician stated that annual/semi-annual maintenance had not been performed by a service technician on the StatLab Quantum HDx Slide Stainer, or at all. 5. The "Quantum HDx Solution Change Schedule" logs were reviewed for June and July, 2022. During an interview, the histotechnician stated that they document the date when new vials are added to the stainer by writing a check mark next to the name of the stain on that date. The review showed that new stain vials were added to the stainer on June 3,10,17, and 23 and July 1,7, and 26. 6. The histotechnician also stated that if the "Quantum HDx Solution Change Schedule" log shows that new vials were added, then the instrument was used to stain patient slides on that day. A review of "Quantum HDx IHC Stainer Maintenance/Pre-run Checklist" logs for June and July, 2022 showed that there was no daily maintenance documented in June 2022, and daily maintenance was not documented on July 1 or July 7, when new vials of stain were added. 7. During an interview on 07/28/2023 at 3:30 PM, the LD confirmed that preventative maintenance was not performed and documented as defined by the manufacturer and with at least the frequency specified by the manufacturer. II. Based on observation, procedure manual and record review, and interview with the histotechnician, the laboratory did not perform and document routine preventive maintenance checks on the laboratory's fume hood. Findings: 1. The procedure, "Section 3. General Histology" "13. Proper Use of the Fume Hood and Fume Adsorber" states under "Safety Features," "The fume hood is equipped with an air flow monitor that is designed to alarm if the face velocity...drops below 60 fpm [feet per minute]. Weekly this alarm should be tested for functionality and quarterly the face velocity of the fume hood should be verified with the use an air flow monitor (vaneometer)." 2. Record review showed that the laboratory did not have a log, documenting that weekly and quarterly safety checks had been performed on the fume hood. This was confirmed during an interview on 07/28/2023 at 2:30 PM with the histotechnician.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
I. The laboratory director failed to ensure that procedures for notifying the submitting surgery center when patient specimens were missing were followed and monitored. Cross-refer to tag D5311 for findings. II. Based on review of the quality assurance (QA) procedure, review of specimen flow sheets, and interview with the laboratory director (LD) and testing person (TP), the LD failed to ensure that turnaround times (TAT) were defined and monitored to ensure the quality of laboratory services provided. Findings: 1. Section "1. General QA Plan" of the QA procedure stated "Once weekly, a review will be made of all outstanding cases to determine if (that is any cases not signed out that have been received more than one week prior) any have not been signed out" and "At the pathologist's request, a courtesy phone call to the clinician will be made explaining any outstanding cases with a proposed date of final report." 2. Section "4.E. Patient History and Information" (4E) of the QA procedure stated, "Test reports will be filed within 7 days of testing." The procedure did not specify if "testing" referred to date of collection, date of specimen processing and slide preparation, or date of pathologist review. 3. Section 4E also stated, "All reports are electronically sent to the originating physician, faxed, or transported by courier service, or a combination of these. This is established through communication with the individual practice sites to assure turn-around time needs are met." The laboratory only processed specimens from a single site which did not have a defined TAT. 4. The laboratory was connected to the surgery site and patient biopsy specimens were brought directly to the laboratory the same day specimens were collected. 5. The laboratory documented the accession date, the grossing date, and the dates the pathologist read and signed out patient specimens on the "Specimen Flow Sheet" (flow sheet). 6. Below are some examples of patient specimens with turnaround times exceeding one month after specimen collection: a. Specimen CEC22-00735 was collected on 09/21/2022, accessioned on 10/01/2022 (10 days after collection), and read and signed out by the pathologist on 11/18/2022 (58 days after collection). The date of grossing was missing from the flow sheet. Cross-refer to tag D5311 for more details. b. Specimens collected on 10/21/2022 were accessioned on 11/08/2022 (18 days after collection), grossed on 11/14/2022, read by the pathologist on 11/25/2022, and signed out by the pathologist on 12/02/2022 (42 days after collection). c. Specimens collected on 11/09/2022 were accessioned on 12/05/2022 (26 days after collection), grossed on 12/15/2022, read by the pathologist on 12/23/2022, and signed out by the pathologist on 01/02/2023 (54 days after collection). d. Specimens collected on 12/30/2022 were accessioned on 02/05/2023 (37 days after collection), grossed on 02/06/2023, read by the pathologist on 02/10/2023, and signed out by the pathologist on 02/22/2023 (54 days after collection). e. Specimens collected on 01/18 /2023 were accessioned on 02/19/2023 (32 days after collection), grossed on 02/21 /2023, read by the pathologist on 03/03/2023, and signed out by the pathologist on 03 /05/2023 (46 days after collection). f. Specimens collected on 04/21/2023 were accessioned on 05/22/2023 (31 days after collection), grossed on 05/30/2023, read by the pathologist on 06/02/2023, and signed out by the pathologist on 06/16/2023 (56 days after collection). g. Specimens collected on 06/09/2023 were accessioned on 07 /10/2023 (31 days after collection), grossed on 07/13/2023, read by the pathologist on 07/14/2023, and signed out by the pathologist on 07/18/2023 (39 days after collection). 7. The LD filled out a form titled "Quality Assurance Summary (issues /trends)" (QA summary) every week which included a section for TAT. The TAT section of the QA summary for the above dates were marked "Acceptable." At 11:39 AM on 07/28/2023, the LD confirmed that the criteria used to complete this section is not a defined TAT, but whether or not the surgery site contacted the LD looking for

	patient results. The TAT was considered "Acceptable" if no one from the surgery site contacted the LD looking for patient results. 8. During the survey on 07/28/2023 at 3: 30 PM, the LD confirmed that the surgery site had no defined TAT for patient results and the laboratory was not monitoring TAT from patient receipt to final results reporting. III. Based on review of patient and weekly quality assurance (QA) logs and interview with the laboratory director (LD), the LD failed to ensure that all laboratory logs were completed with all the required information. Findings: 1. The log titled "Specimen Flow Sheet" (flow sheet) included 12 columns to record the patient name and details regarding the receipt, processing, evaluation, and reporting of patient specimens. 2. Flow sheets from 01/2022 through 07/2023 were reviewed. 3. The "Grossing Complete Date" was missing for all specimens on the flow sheets from specimens collected on 09/16/2022, 09/19/2022, 09/21/2022, and 11/07/2022. 4. The columns for "# Slides Received by Pathologist" and "Date Read by Pathologist Complete" were missing for 6 of 8 patients collected on 10/10/2022. 5. The columns for "# Slides Received by Pathologist", "Date Read by Pathologist Complete", and "Date Signed Out Complete by Pathologist" were missing for 5 of 13 patients collected on 10/14/2023. 6. The "# Slides Received by Pathologist" was missing for all 12 patients on 12/30/2022. 7. The LD filled out a form titled "Quality Assurance Summary (issues/trends)" (QA summary) every week, which included a section for "Errors on Specimen Flow Sheets." There was no documentation of the incomplete flow sheets on the weekly QA summary from the above dates. 8. During the survey on 07/28/2023 at 3:30 PM, the LD confirmed that the weekly QA summaries did not document the incomplete specimen flow sheets. IV. The laboratory did not perform and document routine preventive maintenance checks on laboratory equipment. Cross-refer to D5429 for findings. V. The laboratory did not ensure that proficiency testing was performed at least twice annually. Cross-refer to D5217 for findings.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: The laboratory director failed to have an up-to-date written procedure manual for the specific practices performed in the laboratory. Cross-refer to D5401 for findings.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: The testing person failed to follow laboratory procedures for notifying the submitting surgery center when patient specimens were missing. Cross-refer to tag D5311 for findings.