Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0898621	09/04/2019
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
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Abbreviations- H&E = Haematoxylin and Eosin IHC = Immunohistochemistry Based on review of patient intermediate worksheets and interview with the laboratory director, the laboratory's record system failed to ensure that the intermediate worksheets were retrievable at the time of the survey. Findings: 1. The "H&E/IHC /Special Stain Quality Assurance Log" was reviewed for 2018 and 2019. On 10/22/18 and 10/24/18 the Helicobacter Pylori (HPY) stain was documented as unacceptable. 2. The surveyor asked to review the intermediate worksheets with the original interpretations of the slides reviewed. The laboratory director was not able to locate the intermediate worksheets with the original interpretations. 3. During an interview on 08/02/19 at 3:00 PM, the LD confirmed that the intermediate worksheets with the original interpretations of the slides were not available at the time of the survey.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 06/28/17 for not performing and documenting quality assurance (QA) activities to ensure that problems were identified, monitored, and corrected in the pre-analytic, analytic, and post-analytic phases of testing. The plan of correction stated that the QA documentation would be performed as required. Based on review of the QA summary that was being performed weekly and interview with the laboratory director (LD), the laboratory failed to perform QA activities as required to ensure that problems were identified, monitored, and corrected in the pre-analytic, analytic, and post-analytic phases of testing. Findings: 1. A review of laboratory QA records from 2018 and 2019 showed that there were no QA was documented after 10/12/18. 2. During an interview on 08/02/19 at 3:00 PM, the LD confirmed that QA reviews were not being performed as required after 10/12/18.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of the quality control (QC) worksheet, policy and procedure manuals, and interview with the histotech, the laboratory failed to provide an interpretation of the abbreviations used in the procedure manual and on the worksheets used to document laboratory activities. Findings: 1. The laboratory worksheet used for documenting the stain QC identified stains as H&E, ABPAS, CD-3, and HPY. 2. Neither the worksheet nor the policy and procedure manual identified the meaning of the abbreviations. 3. During the survey on 08/02/19 at 2:00 PM the histotech confirmed that none of the abbreviations used in the laboratory were not identified on the worksheet or in the policy and procedure manuals. II. Based on review of the policy and procedure manuals, slides and interview with the histotech, the laboratory failed to provide a system for identifying the date that the patient and quality control slides were prepared and stained. Findings: 1. Review of the laboratory records for tissue processing show the date the tissue was collected, date received /accessioned and the date reported. The laboratory records do not include the date the patient tissue and quality control materials were actually stained. 2. The histotech stated that the tissue is received in formalin and is stored on the counter until the

	slides are prepared. The staining does not always occur on the date the slides are prepared. 3. During the survey on 08/02/19 at 2:00 PM the histotech confirmed that the laboratory record system did not include the date of preparation and staining of the slides.
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 laboratory records and interview with the histotech, the laboratory failed to perform the method validation on the staining systems used in the laboratory prior to testing patient specimens and reporting results. Findings: 1. The laboratory started to perform in-house slide preparation for Haematoxylin and Eosin (H&E) stains on 10/08/18 and automated slide staining for special stains- Periodic Acid Schiff's (PAS), Alcian Blue stain (AB) and Helicobacter Pylori stain (HP) additional special in April 2019. 2. The laboratory records that were reviewed did not include a procedure for the validation of the new staining processes. There were no defined performance specifications comparable to those established by the manufacturer for accuracy, precision, sensitivity, specificity and any other characteristics that would be appropriate when verifying a new staining system. 3. During an exit phone call on 09/04/19 at 11:50 AM the histotech confirmed that there were no written validation procedures for the staining being performed and no analysis of stain comparisons for each of the new stains performed on the new analyzer prior to reporting patient test results.
D5603	HISTOPATHOLOGY CFR(s): 493.1273(b)(f) (b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (l), or (m). (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the "H&E/IHC/Special Stain Quality Assurance Log", the quality control (QC) slides and interview with the laboratory director (LD), the laboratory failed to ensure that the QC slides were labeled in such a way as to identity which patients were stained with each QC slide. Findings: 1. According to the LD prior to 10/08/18 all the slides that were reviewed in the laboratory were prepared and stained at an off-site licensed facility. They were identified with the date and identification number that could be connected to each batch of slides stained a received for review

	by the pathologists. 2. The laboratory started to perform in-house slide preparation for Haematoxylin and Eosin (H&E) stains on 10/08/18 and automated slide staining for special stains- Periodic Acid Schiff's (PAS), Alcian Blue stain (AB), Cluster of Differentiation 3 (CD3), and Helicobacter Pylori stain (HP or HPY) additional special in April 2019. 3. The QC slides that were prepared in-house did not include an identifier that connected them to a specific batch of slides that were stained until 04/25 /19. The only stained slides that were consistently given identifiers were the HPY slides. The H&E QC slides were given identifiers 3 of 12 days of testing, CD3 QC slides were given identifiers 5 of 12 days of testing and ABPAS QC slides were not given identifiers on any of the worksheets reviewed after 04/25/19. 4. During the survey on 08/02/19 at 3:00 PM the laboratory director confirmed that the QC slides were not consistently given identifiers that connected them to each batch of patients stained.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory director failed to perform a method validation on the staining systems used in the laboratory prior to testing patient specimens and reporting results (D6086); failed to perform and document a root cause analysis when stain quality control was not acceptable (D6093); failed to ensure that the quality assurance reviews was performed and documented (D6094); failed to ensure that all the required function checks were being performed as required (D6095); and failed to perform and document a root cause analysis when stain quality control was not acceptable and patient test results were reported (D6097).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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: The laboratory failed to perform a method validation on the staining systems used in the laboratory prior to testing patient specimens and reporting results. Cross refer to Tag D5421 for details.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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. Based on review of the "H&E/IHC/Special Stain Quality Assurance Log", the "Quality metrics" section of the standard operating and procedure manual and interview with the laboratory director (LD), the LD failed to perform and document a root cause analysis when stain quality control (QC) was not acceptable. Findings: 1. According to the LD prior to 10/08/18 all the slides that were reviewed in the laboratory were prepared and stained at an off-site licensed facility. On 10/08/18 the laboratory started to perform manual staining on-site and automated staining on 04/16 /18. 2. Review of the "H&E/IHC/Special Stain Quality Assurance Log" from 09/07/18 to 07/26/19 showed that specific stains were not acceptable on the following dates: Helicobacter pylori (HPY) 10/22/18, 10/24/18, 11/09/18, 01/11/19, 01/25/19, 02/01 /19, 02/08/19, 03/01/19, 03/08/19, 04/25/19, 04/26/19, 05/10/19, 05/17/19, 06/19/19, 06/28/19 and 07/26/19. 3. The "Specimen integrity & slide/stain acceptability" section of the "Quality metrics" procedure states: "The summary of specimen integrity and slide/stain acceptability issues will include at least a root cause, who was notified (the practice, endoscopy center, and/or Dianon Pathology), corrective action implemented, and subsequent outcome. 4. The "Comment" section of the "H&E/IHC/Special Stain Quality Assurance Log" failed to identify where the root cause analysis of the unacceptable QC results would be documented. 5. The quality metrics procedure states: "When quality metrics indicate the existence of a quality assurance issue, the issue will be described at the top of a pathology quality assurance issue form, signed and dated by the pathologist. The corrective action will be described at the bottom of this same form, signed and dated by the pathologists." Review of the laboratory records showed that there were no quality assurance issues that needed investigation and corrective actions. 6. During the survey on 08/02/19 at 3:00 PM the laboratory director confirmed that there was no documented root cause analysis for the unacceptable QC results identified on the stain QA log. II. Based on review of the "H&E/IHC/Special Stain Quality Assurance Log", patient final reports and interview with the laboratory director (LD), the LD failed to ensure that patient test interpretations were not reported when the stain quality control (QC) was unacceptable. Findings: 1. The "H&E/IHC/Special Stain Quality Assurance Log" showed that on 04/25/19 the Helicobacter Pylori stain (HPY) stain was not acceptable. 2. There were two entries on the worksheet for 04/25/19 labeled HPY 241-272 and HPY 275-294. The QC stain quality was labeled as unacceptable for both QC slides. 3. The LD reviewed the patients final reports that had been interpreted on 04/25/19 and reported on 04/29/19 and found that the "Microscopic description" for three patients had been reported as "Helicobacter immunohistochemical study (controls are satisfactory)." 4. During the survey on 08/02/19 at 3:00 PM the LD confirmed that these results were reported in error since the stain QC was found to be unacceptable and that corrected reports would need to be sent to the physician.
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. Based on review of the quality assurance (QA) records the laboratory director failed to ensure that the monthly QA review was performed and documented. Cross refer to Tag D5291 for details. II. Based on review of the proficiency testing (PT) section of

	the QA policy, PT records and interview with the laboratory director, the laboratory failed to ensure that the PT events were identified with the dates the reviews were performed. Findings: 1. The laboratory was cited during the re-certification survey on 06/28/17 for not ensuring the PT procedure identified the frequency that another pathologist would review slides for accuracy. The plan of correction stated that the procedure would be updated to state that a review would be performed twice a year. 2. Review of the PT records for 2018 and 2019 showed that two reviews were performed in 2018 and as of 08/02/19 there was no PT performed in 2019. 3. The records for 2018 were identified as "2018-1st" and "2018-2nd." The records did not include the date that the reviews were performed. 4. During the survey on 08/02/19 at 3:00 PM the laboratory director confirmed that the reviews for 2018 were not dated to show when the review occurred and that a PT review for 2019 had not been performed yet. III. Based on review of the "Quality metrics" section of the standard operating and procedure manual and interview with the laboratory director (LD) and histotech, the LD failed to implement all the "Procedural steps" defined in the procedure. Findings: 1. "Procedural steps" states: "Quality metrics can also be summarized monthly, every six month, and annually to help identify and document trends." 2. The "H&E/IHC /Special Stain Quality Assurance Log" shows multiple problems over the last 10 months with the Helicobacter pylori stain (See D6093.). The laboratory started to perform the staining in-house on 10/08/18 and failed to document the problems identified, corrective action and subsequent outcome. 3. The "Turnaround time" procedure states: "The pathologist will be on site one day a week. All cases ready for final review on that day will be completed on that day." 4. Sample ID# CEC18-00111 was received on 10/29/18, accessioned on 11/05/18, stained on 11/09/18 and reported on 12/07/18. There was no written investigation defining the problem, the corrective actions, subsequent outcome, and the reason for the delay. 5. When reviewing the received dates, and accessioned dates during October and November 2018 it was noted that several tissue samples were accessioned up to 20 days after they were received into the staining laboratory. The histotech stated that they were having problems with the staining equipment. There were no written investigations defining the problems, the corrective actions and subsequent outcomes. 6. During the survey on 08/02/19 at 3:00 PM the LD director confirmed that there were problems with the turnaround time but there was no documented investigation explaining the problems and the solution. IV. Based on review of the laboratory records the laboratory director failed to ensure that the new staining protocols had been validated and found acceptable prior to testing and releasing patient test results. Cross refer to Tag D5421 for details.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the "Equipment Maintenance and Function Checks" procedure and interview with the histotech, the LD failed to ensure that all the required function checks were being performed as required. Findings: 1. According to the "Equipment Maintenance and Function Checks" procedure the temperature of the embedding center, water bath, drying oven and refrigerator is to be recorded daily. 2. The histotech that uses the equipment listed above stated that the temperatures are checked daily but the value is not recorded each day of use. 3. During the survey on 08/02/19

	at 3:00 PM the LD director confirmed that equipment temperatures were not being recorded by the testing person as required.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: The laboratory director failed to perform and document a root cause analysis when stain quality control was not acceptable and patient test results were reported. Cross refer to Tag D6093 for details.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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. This STANDARD is not met as evidenced by: Based on review of Quality Assurance (QA) section of the policy and procedure manual for the histology department, laboratory records and interview with the laboratory director, the laboratory director acting as the technical supervisor did not ensure that the histology technologist was provided with initial training for the testing performed. Findings: 1. The laboratory started to perform in-house slide preparation for Hematoxylin and Eosin (H&E) stains on 10/08/19 and automated slide staining for additional special stains in April 2019. 2. Section 6. of the QA procedures refers to a "Competency Assessment checklist" to be completed for each lab assistant or histotech. 3. At the time of the survey there were no completed "Competency Assessment checklist" for the histotech that was preparing slides for the laboratory director to review. 4. During the survey on 08/02/19 at 3:00 PM the laboratory director confirmed that he had not documented the initial training and evaluation of the histotech prior to performing the H&E stain and special stains for patient slides.
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 record the temperature of the laboratory equipment on a daily basis as required. Cross refer to Tag D6094 section V. for details.