Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0726025	02/21/2020
Name of Provider or Supplier	**Street Address, City, State**	
Waco Gastroenterology Associates Pa	364 Richland West Circle Suite A, Waco, 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
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of policies and procedure, quality control records, patient reports, review of the CMS 116 application and interview of facility personnel, the laboratory failed to define intended reactivity to ensure predictable staining characteristics of Hematoxylin & Eosin (H&E) stain for each day of patient testing in 2018 and 2019. Findings included: 1. Review of the laboratory's written procedure titled Quality control found on pp 2-3 under the heading "QC of Histology Staining: 2. H&E: Is the nuclear and cytoplasm material clearly discernible? Is the chromatin hazy or clear? 2. Review of Daily QA Sheets(used to record acceptability of stains) found no definition of intended reactivity for H&E staining to ensure predictable staining characteristics. The laboratory recorded QC in the appropriate boxes as: October 9, 2018 Eosin ; Lab QC - A Pathologist QC - A Hematoxylin - Lab QC - A Pathologist QC - A October 11, 2018 Eosin ; Lab QC - A Pathologist QC - + Hematoxylin - Lab QC - A Pathologist QC - + October 23, 2018 Eosin ; Lab QC - A Pathologist QC - 3+ Hematoxylin - Lab QC - A Pathologist QC - 3+ September 9, 2019 Eosin ; Lab QC - A Pathologist QC - + Hematoxylin - Lab QC - A Pathologist QC - + September 10, 2018 Eosin ; Lab QC - (Check mark) Pathologist QC - + Hematoxylin - Lab QC - (Check mark) Pathologist QC - + September 23, 2019 Eosin ; Lab QC - A Pathologist QC - A Hematoxylin - Lab QC - A Pathologist QC - A A key at the bottom of the Daily QA sheet designated A= Acceptable, U= Unacceptable, += Positive. 3. Review of laboratory reports found under microscopic description: :Slide quality, stains and

	controls are satisfactory. 4. Review of the CMS 116 application provided during the inspection found the laboratory reported an annual volume of 15,131 histology tests. 5. Interview of testing person 6 on the CMS report 209 Laboratory Personnel Report confirmed the laboratory did not define the predictable staining characteristics of the H&E stain in their policy, documentation of quality control performance or the patient final reports
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (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 policies and procedure, quality control records, patient reports, review of the CMS 116 application and interview of facility personnel, the laboratory failed to define intended reactivity to ensure predictable staining characteristics of the Giemsa and Alc Blue /PAS stains for each day of patient testing in 2018 and 2019. Findings included: 1. Review of the laboratory's written procedures found: a. Quality Control (revision 12/29/2019) - on pp 2-3 under the heading "QC of Histology Staining: 4. Special Stains: Is the +ve control slide clearly discernable? Is the counter stain too light/dark? Stain on label? Type of stain done clearly labeled? b. AB/PAS (Revision 12/29/2019) - page 4 under the heading Quality Control and Quality Assurance: 1. Control materials to be used: a. A Candida Albicans control along with a known positive patient tissue is used for control. 2. Instructions for preparing and handling control materials: a. A 3 micron paraffin embedded section of the known control is made, cut and placed on Candida Albicans Control. b. WGA Path Lab will perform one positive control slide every day that AB/PAS slides are stained. 3. Establishment of tolerance limits for controls: a. Stain as expected. 4. Corrective actions to be taken when tolerance limits are exceeded: a. Stain is repeated. 5. Recording and Storage of QA data. a. A daily QA sheet is completed by the pathologist. The control slide is filed by date. b. Any issues that arise with the performance of special stains are documented." Further review found on page 5 under Interpretation: "Acid mucopolysaccharides (Acid Mucins) stain blue. Sulfated mucopolysaccharides (Neutral mucins) and other PAS- positive tissue elements stain pink to red. Mixtures carbohydrates (acid and neutral mucins) stain bluish to reddish purple." b. Giemsa (revision 12/29/2019) - page 2 under the heading Quality Control and Quality Assurance: 1. Control materials to be used: a. A known positive control section is used. 2. Instructions for preparing and handling control materials: a. A 3 micron paraffin embedded section of the known control is made, cut and placed on Candida Albicans Control. b. WGA Path Lab will perform one positive control slide each day a Giemsa is stained. 3. Establishment of tolerance limits for controls: a. Stain as expected. 4. Corrective actions to be taken when tolerance limits are exceeded: a. Stain is repeated. 5. Recording and Storage of QA data. a. A daily QA sheet is completed by the pathologist. The control slide is filed by date. b. Any issues that arise with the performance of special stains are documented." Further review found on page 3 under Interpretation: "Erythrocytes stain pale ink. Eosinophilic Granules stain reddish orange. Leukocyte nuclei stain purple. Helicobacter pylori stain deep blue." 2.

	Review of Daily QA Sheets(used to record acceptability of stains) found no definition of intended reactivity for Giemsa and PAS staining to ensure predictable staining characteristics. The laboratory recorded QC in the appropriate boxes as: October 9, 2018 Giemsa ; Lab QC - + Pathologist QC - + Alc Blu/PAS- Lab QC - + Pathologist QC - + October 11, 2018 Giemsa ; Lab QC - + Pathologist QC - + Alc Blu/PAS- Lab QC - + Pathologist QC - + October 23, 2018 Giemsa ; Lab QC - + Pathologist QC - 3+ Alc Blu/PAS- Lab QC - + Pathologist QC - 3+ September 9, 2019 Giemsa ; Lab QC - + Pathologist QC - + Alc Blu/PAS- Lab QC - + Pathologist QC - + September 10, 2018 Giemsa ; Lab QC - + Pathologist QC - + Alc Blu/PAS- Lab QC - + Pathologist QC - + September 23, 2019 Giemsa ; Lab QC - + Pathologist QC - + Alc Blu/PAS- Lab QC - + Pathologist QC - + A key at the bottom of the Daily QA sheet designated A= Acceptable, U= Unacceptable, += Positive. 3. Review of laboratory reports found under microscopic description: Accession WG19-003832-WG - Slides, stains and controls (positive and negative) react appropriately and are satisfactory. Accession WG18-003409-WG - Slide quality, stains and controls are satisfactory. Accession WG19-003636-WG - Slide quality, stains and controls are satisfactory. 4. Review of the CMS 116 application provided during the inspection found the laboratory reported an annual volume of 15,131 histology tests. 5. Interview of testing person 6 on the CMS report 209 Laboratory Personnel Report confirmed the laboratory did not document the staining reactions of the Giemsa and PAS stains as defined in their policy.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high 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 testing personnel files, and interview of facility personnel, the Technical Supervisor failed to evaluate and document personnel competency at least semiannually during the first year the individual tests patient specimens for one of seven testing personnel performing histopathology procedures. The findings included: 1. Review of personnel files found testing person 4 (hired January 2019) had no record of semiannual competency evaluations during the first year of testing. 2. Interview of the testing person 6 conducted on February 21, 2020 at 09:47 AM confirmed that competency assessments had not been performed and documented at least semiannually for the first year of testing for testing person 4.