Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2169720	08/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Arlington Gastroenterology Services	2725 Matlock Road, Arlington, 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	Laboratory representatives were present at the entrance conference. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Health and Human Services Commission, Health Facility Compliance Arlington Group. 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 laboratory procedures, laboratory quality control records, patient records, and confirmed in staff interview, the laboratory failed to define and document the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics of quality control slides for H & E staining on each day of patient testing for 39 of 39 patients from October 2019 to August 2021

	(random sampling). Findings: 1. Review of the laboratory policy titled "Evaluating Quality of Control Slides" revealed the laboratory failed to specify the intended reactivity for Hematoxylin and Eosin (H & E) staining to ensure predictable staining characteristics. 2. Review of laboratory records revealed that all histology specimens for the laboratory were sent to a reference laboratory for grossing and H&E staining, immunohistochemical and special staining. The slides were shipped back to the laboratory for pathological interpretation. 3. A random review of laboratory Technical Quality Assurance Form and Slide Delivery Logs and patient test records from October 2019 to August 2021 revealed the laboratory did not document the intended reactivity for the H & E stain to ensure predictable staining characteristics on each day of patient testing on either the control record or patient test report. The laboratory failed to document the intended reactivity of quality control slides for H & E staining on each day of patient testing from October 2019 to August 2021. The following is a random sampling of patients that were tested and reported: 12/09/2019 Patient ID: HK-19-00017 12/16/2019 Patient IDs: HK-19-00018, HK-19-00019, HK-19-00020, HK-19-00021 12/23/2019 Patient IDs: HK-19-00022, HK-19-00023, HK-19-00024, HK-19-00025 12/12/2020 Patient IDs: HK-20-00190, HK-20-00191 12/21/2021 Patient IDs: HK-20-00193, HK-20-00194, HK-20-00195 12/26/2021 Patient IDs: HK-20-00196, HK-20-00197, HK-20-00198, HK-20-00199, HK-20-00200, HK-20-00201 07/22/2021 Patient IDs: HK-21-00134, HK-21-00135, HK-21-00136, HK-21-00137, HK-21-00138, HK-21-00139 07/24/2021 Patient IDs: HK-21-00140, HK-21-00141, HK-21-00142 08/03/2021 Patient IDs: HK-21-00143, HK-21-00144, HK-21-00145, HK-21-00146, HK-21-00147, HK-21-00148, HK-21-00149, HK-21-00154, HK-21-00155 08/05/2021 Patient ID: HK-21-00157 08/09/2021 Patient ID: HK-21-00156 4. According to laboratory records, the laboratory's annual volume was 900 histology tests. 5. During an interview on 08/12/2021 at 10:37 am, the Vice President for Laboratory Services stated the she had spoken with Testing Person-1 (TP-1) over the telephone and TP-1 communicated that she had failed to document the stain quality on the QC log or on any patient records. This confirmed the above findings.
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 the laboratory policy, laboratory quality control records patient pathology reports, and confirmed in interview, the laboratory failed to check and document the positive and negative reactivity of immunohistochemical (IHC) stains and document reactions of the control slide with special stains each time of use for 4 of 4 patients in 2019 (random review December) and 7 of 7 patients in 2020 (random review December) and 15 of 15 patients in 2021 (random review July, August). Findings: 1. Review of the laboratory policy titled "Evaluating Quality of Control Slides" revealed: "Purpose To establish procedures for review and recording the interpretation of the stained quality control slides provided by the reference laboratory that performs the technical portion of the specimen testing. Procedure 1- The laboratory sends patient specimens to the reference laboratory. The reference

	laboratory processes, embeds, cuts, and stains the patient specimens provided by the physician's office. It is the policy of the reference laboratory that specimens processed at site are submitted to the pathologist for review of and a log (Technical Quality Assurance Form and Slide Log) is maintained ..." 2. A review of laboratory records revealed the laboratory used 3 differential or special stains for histology testing (AB /PAS, AB and Trichrome) and 3 immunochemical stains (H. Pylori, CD3, CD117). 3. A random review of "Technical Quality Assurance Form and Slide Delivery Log" and patient test reports for 2019, 2020 and 2021 revealed the following immunohistochemical stains were performed and interpreted without documentation of positive and negative reactivity and special stain was performed and interpreted without documentation of control slide reactivity: 12/16/2019 - Patient ID HK19-00019, IHC stain was H. Pylori 12/16/2019 - Patient ID HK19-00021, IHC stain were H. Pylori and CD3, special stain was AB/PAS 12/23/2019 - Patient ID HK19-00024, IHC stain was H. Pylori 12/23/2019 - Patient ID HK19-00025, IHC stain was H. Pylori, special stain was AB/PAS 12/12/2020 - Patient ID HK20-00190, IHC stain was H. Pylori, special stain was AB/PAS 12/14/2020 - Patient ID HK20-00192, IHC stain was H. Pylori 12/21/2020 - Patient ID HK20-00195, IHC stain was H. Pylori, special stain was AB/PAS 12/26/2020 - Patient ID HK20-00196, IHC stain were H. Pylori and CD3, special stain was AB/PAS 12/26/2020 - Patient ID HK20-00197, IHC stain was CD3, special stain was AB/PAS 12/26/2020 - Patient ID HK20-00198, IHC stain were H. Pylori and CD3, special stain was AB/PAS 12/26/2020 - Patient ID HK20-00200, IHC stain was H. Pylori, special stain was AB/PAS 07/22/2021 - Patient ID HK20-00134, IHC stain was CD3, special stain was Trichrome 07/22/2021 - Patient ID HK20-00136, IHC stain was CD3, special stain was Trichrome 07/22 /2021 - Patient ID HK20-00137, IHC stain was H. Pylori, special stain was AB/PAS 07/22/2021 - Patient ID HK20-00138, IHC stain was CD3, special stain was Trichrome 07/24/2021 - Patient ID HK20-00140, IHC stain were H. Pylori and CD3, special stain were AB/PAS and Trichrome 07/24/2021 - Patient ID HK20-00142, IHC stain was H. Pylori 08/03/2021 - Patient ID HK20-00145, special stain was AB/PAS 08/03/2021 - Patient ID HK20-00146, IHC stain were H. Pylori and CD3, special stain was AB/PAS 08/03/2021 - Patient ID HK20-00147, IHC stain was CD3, special stain was Trichrome 08/03/2021 - Patient ID HK20-00148, IHC stain was H. Pylori, special stain was AB/PAS 08/03/2021 - Patient ID HK20-00149, IHC stain was H. Pylori, special stain was AB/PAS 08/03/2021 - Patient ID HK20-00150, special stain was AB/PAS 08/03/2021 - Patient ID HK20-00152, special stain was AB/PAS 08/03 /2021 - Patient ID HK20-00154, IHC stain was CD3, special stain was AB/PAS 08/09 /2021 - Patient ID HK20-00157, IHC stain were H. Pylori and CD3, special stain was AB/PAS 4. According to laboratory records, the laboratory's annual volume was 900 histology tests. 5. During an interview on 08/12/2021 at 10:37 am, the Vice President for Laboratory Services stated the she had spoken with Testing Person-1 (TP-1) over the telephone and TP-1 communicated that she had failed to document the stain quality on the QC log or on any patient records. This confirmed the above findings. Word Key: PAS- Periodic Acid-Schiff AB - Alcian Blue