Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2169722	09/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Gastroenterology Practice Associates	301 Highlander Blvd Suite 121, 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	An entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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: I. 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 11 of 11 patients from August 2021 (random

	sampling). Findings Included: 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 August 2021 (random sampling) 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 August 2021(random sampling). The following is a random sampling of patients that were tested and reported: 08/20/2021 Patient ID: OA21-00210; Patient ID: OA21-00211 08/24/2021 Patient ID: OA21-00212; Patient ID: OA21-00213; Patient ID: OA21-00214 08/25/2021 Patient ID: OA21-00215 08/26 /2021 Patient ID: OA21-00216; Patient ID: OA21-00217; Patient ID: OA21-00218; Patient ID: OA21-00219; Patient ID: OA21-00220 4. According to laboratory records, the laboratory's annual volume was 1130 histology tests. 5. During an interview on 09 /08/2021 at 12:58 pm, the Vice President for Laboratory Services, after presentation of findings, confirmed the above findings. II. 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 Immunohistochemical staining (IHC) to ensure predictable staining characteristics of quality control slides for staining on each day of patient testing for 11 of 11 patients from August 2021 (random sampling). Findings Included: 1. Review of the laboratory policy titled "Evaluating Quality of Control Slides" revealed the laboratory failed to specify the intended reactivity for Immunohistochemical staining (IHC) 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 IHC staining, Hematoxylin and Eosin (H & E) 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 August 2021 (random sampling) revealed the laboratory did not document the intended reactivity for the IHC stains 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 IHC staining on each day of patient testing from August 2021 (random sampling). The following is a random sampling of patients that were tested and reported: 08/20/2021 Patient ID: OA21-00210; Patient ID: OA21-00211 08/24/2021 Patient ID: OA21-00212; Patient ID: OA21-00213; Patient ID: OA21-00214 08/25 /2021 Patient ID: OA21-00215 08/26/2021 Patient ID: OA21-00216; Patient ID: OA21-00217; Patient ID: OA21-00218; Patient ID: OA21-00219; Patient ID: OA21-00220 4. According to laboratory records, the laboratory's annual volume was 1130 histology tests. 5. During an interview on 09/08/2021 at 12:58 pm, the Vice President for Laboratory Services, after presentation of findings, confirmed the above findings.