Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D2075642	**(X3) Date Survey Completed** 04/07/2025
Name of Provider or Supplier Gastroenterology Consultants Of Central Florida Pa	**Street Address, City, State** 10800 Dylan Loren Cir Ste 102, Orlando, FL	
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 announced CLIA recertification survey was conducted at Gastroenterology Consultants of Central Florida on April 7, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
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 review of the procedure manual, peer review records, and interview, the laboratory failed to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain, Alcian Blue/Periodic Acid-Schiff stain (AB /PAS), and Helicobacter pylori (H. pylori) stain at least twice annually in 2023. Findings: Review of the Clinical Laboratory Improvement Amendments Application for Certificated signed by the Laboratory Director on 04/07/2025, listed the following stains on the test menu: H&E, AB/PAS, and H. pylori. Review of the policy titled Retrospective Quality Assessment showed, "Retrospective quality assurance will be performed biannually by a Florida licensed pathologist and documented on a quality assessment evaluation chart (GF-QM.0002 Attachment 1)." Review of the peer review documents revealed there were no peer review records for 2023. During an interview on 04/07/2024 at 11:00 AM, the Laboratory Director stated she did not do any peer reviews in 2023.
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. This STANDARD is not met as evidenced by: Based on record review, observations, and interview, the Laboratory Director failed to document the acceptability of the differential stain, special stain, and Immunohistochemical stain (IHC) for four (#1, #3, #4, #5) of six (#1 - #6) patients' test reports and slides reviewed; and the laboratory failed to have a separate negative control for the IHC stain for five (#1 - #5) of six (#1 - #6) patients' slides reviewed. Findings 1. Review of the Clinical Laboratory Improvement Amendments Application for Certificated signed by the Laboratory Director on 04/07/2025, noted the following stains were evaluated: Hematoxylin and Eosin stain (differential stain), the Alcian Blue/Periodic Acid-Schiff stain (special stain), and Helicobacter pylori (H. pylori) stain (IHC Stain). 2. Review of the policy titled, Quality Management Plan noted, "Stained quality control slides provided by the reference laboratory should be reviewed and recorded." 3. Review of the Send Out Log Quality Assurance log, showed the log contained a place for the Director Laboratory to sign off on the quality of the stains. Review of the logs showed the stain quality was not documented for the patients on the following dates: Patient #1 on 01/13/2025, Patient #3 on 03/20/2024, Patient #4 on 07/31/2025, and Patient #5 on 10/02/2024. 4. During an interview on 04 /07/2024 at 11:00 AM, the Laboratory Director acknowledged she had not signed the logs. B 1. Review of the patient Pathology Report showed Patients #1 - #5 all had documentation of a H. pylori stained slide results reported. 2. Review of the Send Out Log Quality Assurance log, showed only one IHC control slide was sent by the laboratory performing the technical component for the patients on the following dates: Patient #1 on 01/13/2025, Patient #2 on 02/03/2025, Patient #3 on 03/20/2024, Patient #4 on 07/31/2025, and Patient #5 on 10/02/2024. 3. Observations on 04/07/2025 at 11: 40 AM, showed there were no negative IHC control slides for Patients #1 - #5. 4. During an interview on 04/07/2024 at 11:56 AM, the Laboratory Director stated the laboratory performing the technical component only sent a positive IHC control slide.