

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0726025	(X3) Date Survey Completed 08/30/2023
Name of Provider or Supplier Waco Gastroenterology Associates Pa	Street Address, City, State 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
D0000	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's reagent logs, interview, and pre-survey paperwork, the laboratory failed to retain the open date for the chemicals and stains used in the laboratory for histopathology microscopic interpretation for 22 of 22 months reviewed. Findings follow. A. Review of the Reagent Lot Verification log also used as the reagent log from 10/18/2021 - 08/30/2023 showed no documentation of the open date. B. Interview with the PathLab Supervisor on August 30, 2023 at 1600 hours confirmed they have not retained the open date of chemicals and stains used in the laboratory. C. Review of the CMS Form 116 showed the estimated annual testing volume was 22,960 blocks and special stains.</p>