Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0861111	01/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Adult Gastroenterology Assoc Inc	4200 East Skelly Drive, Suite 310, Tulsa, OK	

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 initial survey was performed on 01/14/2020. The findings were reviewed with the laboratory director and testing person #2 during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, observation, and interview with the laboratory director and testing person #2, the laboratory failed to ensure Tissue Marking Dyes had been stored according to manufacturer's instructions for 6 of 6 bottles. Findings include: (1) At the beginning of the survey, the laboratory director and testing person #2 stated: (a) The laboratory performed grossing of gastrointestinal specimens, including marking of the margins with Shandon Tissue Marking Dyes. (2) Later during the survey, the surveyor observed the following 6 bottles of Shandon Tissue Marking Dyes in the laboratory refrigerator 2-8 degrees C (Celsius): (a) 2 bottles of Blue - Lot# 716695 (b) 1 bottle of Black - Lot# 717032 (c) 1 bottle of Blue - Lot# A772938 (d) 1 bottle of Yellow- Lot# A772195 (e) 1 bottle of Red - Lot# 714046 (3) The surveyor reviewed the manufacturer's storage instructions which was

	15 -30 degrees C; (4) The surveyor reviewed the findings with the laboratory director and testing person #2. Both stated the Shandon Tissue Marking Dyes had not be stored according to manufacturer's instructions.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on an observation and interview with the laboratory director and testing person #2, the laboratory failed to ensure containers of staining materials had been labeled with lot numbers and expiration dates. Findings include: (1) At the beginning of the survey, the laboratory director and testing person #2 stated: (a) The laboratory performed grossing of gastrointestinal specimens, including H&E (Hematoxylin & Eosin) staining. (2) Later during the survey, the surveyor observed the current staining materials with the laboratory director and testing person #2. The following was identified: (a) The copeland jar containing the Hematoxylin stain and the copeland jar containing the Eosin stain were not labeled with the manufacturer's lot numbers and expiration dates; (3) The surveyor explained to the laboratory director and testing person #2 that the bottles must be labeled with the lot numbers and expiration dates of the materials.