Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2329276	07/27/2026
Name of Provider or Supplier	**Street Address, City, State**	
Alpha Gi Pathology Pllc	902 Preskitt Rd Suite 300, Decatur, 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 onsite initial certification survey was conducted on 07/27/2026. The laboratory was found to be in compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, manufacturer's instructions, and confirmed in staff interview, the laboratory failed to monitor the room temperature and humidity of the laboratory for two of two months in 2025 (November - December) and seven of seven months in 2026 (January - July). Findings included: 1. During a tour of the laboratory on 07/27/2026 at 12:02 PM, the surveyor observed the following: 1 Tissue-Tek VIP 5 Vacuum Infiltration Processor, Model VIP 5AF1, Serial # 52150298 The following reagents were stored in a cabinet: 3 bottles 1% Acid Alcohol, lot #: 263938, expiration date: 06/30/2028, storage: 15C - 30C 4 bottles Giemsa Stain, lot #: 264070, expiration date: 12/31/2027, storage: 15C - 30C 1 bottle 0.5% Periodic Acid, lot #: 244506, expiration date: 03/31/2027, storage: 15C - 30C 1 bottle Modified Mayer's Hematoxylin, lot #: 231570, expiration date: 07/31/2026, storage: 15C - 30C 2. Review of the Tissue-Tek VIP 5 Vacuum Infiltration Processor operator's manual page 1.8 stated: "Operating Conditions: Temperature - 10 C to 40 C (50 F to 104 F)

	Relative Humidity - 30% to 85% RH" 3. During an interview in the laboratory on 07 /27/2026 at 12:13 PM, the laboratory director was asked if the room temperature and humidity were monitored in the laboratory. The laboratory director stated that room temperature and humidity were not monitored, confirming laboratory failed to monitor the room temperature and humidity of the laboratory for two of two months in 2025 (November - December) and seven of seven months in 2026 (January - July). Word Key: C - Celsius F - Fahrenheit RH - Relative Humidity
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, QC logs, patient records, annual volume documentation, and confirmed in interview, the laboratory failed to document the intended reactivity for staining material each day of use to ensure predictable staining characteristics for three of three stains (H&E, AB/PAS, Giemsa) for two of two days in December 2025 and six of six days in 2026 (random review January, February, June and July). Findings included: 1. Review of the laboratory's policy "Specimen Processing Procedure Histology Lab", approved by the laboratory director 11/10 /2025, stated: "7. Staining ... Step 3: Stain the tissue using Hematoxylin and Eosin (H&E) or any required special stain (e.g., periodic acid-Schiff (PAS) for mucin, Giemsa for Helicobacter pylori). Hematoxylin: Stains the nuclei blue. Eosin: Stains the cytoplasm pink ... 9. Documentation and Reporting Step 1: Document all specimen processing steps in the laboratory system or logbook. Step 2: Ensure that the slides are ready for examination by the pathologist, who will provide a detailed diagnostic report." Review of the laboratory's policy "Alcian Blue PAS Staining Procedure", approved by the laboratory director 11/10/2025, stated: "Principle of Staining Neutral Mucin: Stains pink/magenta due to the Periodic Acid-Schiff (PAS) component. Acid Mucin: Stains blue due to the Alcian Blue component ... Quality Control (QC) A known positive control tissue (e.g., small intestine or colon tissue) must be included in each staining run to ensure reagent efficacy. The results of the staining run must be documented in the Special Stain Control Log." Review of the laboratory's policy "Giemsa Stain", approved by the laboratory director 11/10/2025, stated: "QUALITY CONTROL: 1. Diluted Giemsa stain deteriorates easily and checking the staining results is critical when it is not made up fresh each time. 2. A thorough water wash is essential after the Giemsa stain since a differentiation of the of the slides is not performed to enhance the bacteria/helicobacter ... RESULTS: Bacteria, Rickettsia, Helicobacter blue to violet" 2. Review of the "WEEKLY HISTOLOGY/CYTOLOGY QUALITY REVIEW RECORD" revealed the following: The log had columns for each weekday with corresponding rows for the documentation of the following items: Histology Slide Quality Histology Timeliness Histology Special Stains/Controls Frozens (Prior Day) Cytology Slide Prep Cross Contamination (gross, proc, emb, cut, stain) Pathologist Date Each day histology slide quality and histology special stains/controls were documented under the day of the week column with the word "OK" or "ditto marks". The log failed to specify what the word "OK" or the "ditto marks" indicated. The following is a random sampling of patients from 2025 and 2026 that were tested and reported when QC was documented as "OK", with "ditto marks", or not at all: 12/17/2025 QC log: histology slide quality:

	documented "OK" histology special stains/controls: documented "OK" Patient ID: AGI25-00152 Stains performed: H&E 12/18/2025 QC log: histology slide quality: documented with a line crossing out the log histology special stains/controls: documented with a line crossing out the log Patient ID: AGI25-00161 Stains performed: H&E, AB/PAS, Giemsa 01/14/2026 QC log: histology slide quality: documented "OK" histology special stains/controls: documented "OK" Patient ID: AGI26-00036 Stains performed: H&E, AB/PAS, Giemsa 01/18/2026 QC log: histology slide quality: no date documented on the log histology special stains /controls: no date documented on the log Patient ID: AGI26-00050 Stains performed: H&E, AB/PAS, Giemsa Patient ID: AGI26-00066 Stains performed: H&E 02/21 /2026 QC log: histology slide quality: no date documented on the log histology special stains/controls: no date documented on the log Patient ID: AGI26-00179 Stains performed: H&E, AB/PAS, Giemsa 06/06/2026 QC log: histology slide quality: no date documented on the log histology special stains/controls: no date documented on the log Patient ID: AGI26-00626 Stains performed: H&E, AB/PAS, Giemsa 07/16/2026 QC log: histology slide quality: documented with "ditto marks" histology special stains/controls: documented with "ditto marks" Patient ID: AGI26-00847 Stains performed: H&E Patient ID: AGI26-00848 Stains performed: H&E Patient ID: AGI26-00854 Stains performed: H&E 07/20/2026 QC log: histology slide quality: documented "OK" histology special stains/controls: documented "OK" Patient ID: AGI26-00855 Stains performed: H&E Patient ID: AGI26-00859 Stains performed: H&E The laboratory failed to document the intended reactivity of quality control slides for the H&E, AB/PAS and Giemsa stains on dates were tested and reported. 3. The laboratory had an annual volume of 1500 histology patients. 4. During an interview on 07/27/2026 at 11:14 AM in the office, the laboratory director, after a review of records, confirmed the laboratory failed to document the intended reactivity for staining material each day of use to ensure predictable staining characteristics for three of three stains (H&E, Giemsa, AB/PAS) for two of two days in December 2025 and six of six days in 2026 (random review January, February, June and July). Word Key: QC - quality control H&E - Hematoxylin and Eosin AB /PAS - Alcian Blue/Periodic Acid Schiff proc - processing emb - embedding