Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0701243	09/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Valley Gastroenterology Assoc	100 Knowlson Avenue, Beaver Falls, PA	

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
D3013	FACILITIES CFR(s): 493.1101(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation. This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, and interview with the histology technician (HT), the laboratory failed to monitor and record the room temperature for paraffin block storage to ensure proper preservation for 727 of 727 days from 09/09/2023 to the day of the survey. Findings include: 1. On the day of the survey, 09/09/2025 at 2:14 pm, during the laboratory tour the surveyor observed that the paraffin blocks were not stored in a temperature monitored area. 2. The laboratory failed to provide the room temperature records for paraffin blocks stored in a building offsite for 727 of 727 days from 09/13/2023 to 09/09/2025. 3. The HT confirmed the findings above on 09/09/2025 at 03:05 pm.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, lack of documentation, and interview with the Practice Administrator (PA), the laboratory failed to establish and follow procedures to assess the competency of 2 of 3 testing personnel (TP) that performed macroscopic histopathology examinations (grossing and inking) in 2024 and 2025.

	Findings include: 1. On the day of survey, 09/09/2025 at 12:50 pm, review of the laboratory procedure manual revealed the laboratory failed to establish a procedure to assess the competency of TP#2 and TP #3 (CMS 209 personnel #2 and #3, dated 08/29 /2025) who performed macroscopic histopathology examinations (grossing and inking) in 2024 and 2025. 2. The laboratory failed to provide competency assessment records for TP#2 for 2024. 3. The laboratory performed 13681 histopathology slide examinations in 2024 (CMS 116, estimated annual volume, dated 08/29/2025). 4. The PA confirmed the above findings on 09/09/2025 at 3:05pm.
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 lack of documentation and interview with the Practice Administrator (PA), the laboratory failed to verify twice annually the accuracy of macroscopic histopathology examinations performed for 2 of 2 years from 09/13/2023 to the day of survey. Findings include: 1. On the day of the survey, 09/09/2025 at 1:31pm, the laboratory failed to provide documentation for the verification of accuracy performed at least twice annually for macroscopic histopathology examinations (grossing and inking) performed from 09/13/2023 to 09/09/2025. 2. The laboratory could not provide a procedure for the verification of accuracy for macroscopic histopathology examinations (grossing and inking). 3. The laboratory performed 13681 histopathology slide examinations in 2024 (CMS 116, estimated annual volume, dated 08/29/2025). 4. The PA confirmed the findings above on 09/09/2025 at 03:05 pm.
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 review of laboratory records, lack of documentation, and interview with the Practice Administrator (PA), the laboratory failed to monitor and document room temperature and humidity to ensure operating conditions were met for 1 of 1 Olympus CX43 microscope (s/n 4044685) used to perform histopathology slide examinations from 09/13/2023 to the date of survey. Findings include: 1. On the date of the survey, 09/09/2025 at 1:18 pm, the laboratory failed to provide documentation for monitoring room temperature (laboratory's acceptable range 60 - 75 degrees Fahrenheit) to ensure operating conditions were met for the 1 of 1 Olympus CX43 microscope (s/n 4044685) used to perform histopathology slide examinations from 09/13/2023 to 09/09 /2025. 2. The laboratory failed to document and define criteria for relative humidity

	(manufacturer's acceptable limit: less than 80%) to ensure operating conditions were met for 1 of 1 Olympus CX43 microscope (s/n 4044685) used to perform histopathology slide examinations from 09/13/2023 to 09/09/2025. 3. The laboratory performed 13681 histopathology slide examinations in 2024 (CMS 116, estimated annual volume, dated 08/29/2025). 4. The PA confirmed the findings above on 09/09 /2025 at 3:05 pm.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Practice Administrator (PA), the Technical Supervisor (TS) failed to evaluate and document the competency of 1 of 3 testing personnel (TP) at least semiannually during the first year, when performing macroscopic histopathology examinations (grossing and inking) in 2024. Findings include: 1. On the day of survey, 09/09/2025 at 12:50 pm, the laboratory failed to provide documentation of the six month competency assessment of TP #2 (CMS 209 personnel #2, dated 08/29/2025) who began performing macroscopic histopathology examinations (grossing and inking) in April of 2024. 2. The laboratory performed 13681 histopathology slide examinations in 2024 (CMS 116, estimated annual volume, dated 08/29/2025). 3. The PA confirmed the above findings on 09/09/2025 at 3:05pm.