Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	38D2030331	10/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Salem Gastroenterology Consultants	875 Oak St Se, Suite 3010, Salem, OR	

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
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 review of laboratory temperature records, including room temperature, humidity and refrigerator temperature records and interview with the Lean Lab Specialist on site during survey 10/09/2023, the laboratory failed to ensure that the refigerator storing temperature sensitive reagents was recorded / monitored daily. Findings include: 1. During review of the laboratory temperature records, no record of the temperature recording of the laboratory's refrigerator could be produced. 2. Upon inspection of the contents in the laboratory refrigerator, it was noted that a 500 ml bottle of Schiff's reagent was stored in this refrigerator. 3. Upon inspection of the factory applied label on the Schiff's reagent revealed it must be stored at 2 - 8 degrees Celcius. 4. Schiff's reagent is used in the laboratory to perform the special stain Periodic Acid Schiff (PAS), which is used to aid in diagnosis of such diseases as breast cancer, adenocarcinoma, fungal infection and other significant disease processes. 5. Interview with the Lean Lab Specialist during survey at 11:30 am revealed that no refrigerator temperature monitoring was in place at time of survey. 6. The laboratory reports performing 45,000 total histpathology specimens annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of laboratory instrument maintenance records and interview with the Lean Lab Specialist on site during survey, the laboratory failed to ensure that the histology tissue processor was under contract for annual preventative maintenance (PM) as detailed in the manufacturers users manual. Findings include: 1. Upon review of the laboratory's records for instrument maintenance, no recent record of PM for the tissue processor could be produced. 2. Upon review of the procedure titled "Microwave Hints and Reminders" for this lab, #6 in this procedure states "Have your Processor serviced annually". 3. The Lean Laboratory Specialist on site during survey confirmed through interview at 12:00 pm that no recent records for PM were available for review to her knowledge. 4. The lab reports performing 45,000 histological procedures annually.
D6173	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495 The testing personnel are responsible for specimen processing, test performance and for reporting test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's standard operating procedure (SOP) for specimen processing / grossing and interview with the Lean Laboratory Specialist during survey, the laboratory failed to ensure the grossing performed by the histotechnologist on site was reviewed by a qualified technical supervisor (TS) within 24 hours and documented. Findings include: 1. Upon request for the lab's SOP that details how the lab handles grossing review by a qualified TS within 24 hours, none could be produced. 2. Upon request for evidence of grossing review by a qualified TS, none could be produced. 3. Interview with the Lean Laboratory Specialist on site confirmed that no SOP for grossing review when a qualified TS is not present existed and shared that grossing done on Fridays in this laboratory are not reviewed within the regulatory specifications of 24 hours by personnel at the Arkansas laboratory at 12:30 pm 10/09 /2023. 4. The laboratory reports performing/processing 45,000 histological specimens annually.