Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2030389	(X3) Date Survey Completed 03/14/2025
Name of Provider or Supplier Gastroenterology Associates Of Fredericksburg	**Street Address, City, State** 8709 B Professional Place, Manassas, VA	

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 announced CLIA validation survey was conducted at Gastro Associates of Fredericksburg-Maya Laboratories on March 14, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on a tour, review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), procedures, chemical vapor analysis reports, lack of documentation, and interviews, the laboratory failed to ensure approved safety protocols were documented for grossing stations utilized to process /prepare tissue histopathology samples during twenty-four (24) of 24 months of review (timeframe March 2023 to the date of the validation survey on March 14, 2025). Findings include: 1. During a tour of the histopathology laboratory on 3/14/25 at 10 AM, the inspector noted distinct fume smell and open formalin containers in grossing station while fume hood was not engaged/utilized. 2. An entrance interview, that included a review of the CMS 209 form with the facilities director on 3/14/25 at 10:30 AM, revealed three (3) testing personnel (TP A-C) identified as performing histopathology grossing procedures during the review timeframe and that TP A was a new TP. *See Personnel Code Sheet. 3. Review of the laboratory procedures revealed a written/approved safety protocol (titled: Laboratory Safety/Chemical Hygiene Plan, SP1.0002.V006). The inspector noted instructions under the Safety/Chemical Plan's Section 5.8 Formalin/Formaldehyde Monitoring that stated, "All employees who come in contact with Formalin are required to wear a formalin/formaldehyde monitor

	to assess acceptable levels. The monitor is sent to testing center where exposure levels are evaluated. If monitor report shows unacceptable levels, the filters on the grossing hood must be replaced. Monitoring must be repeated two consecutive times at least 7 days apart." 4. The inspector requested to review vapor analysis reports for the grossing station hoods as outlined per protocol above for the timeframe of March 2023 to the date of the validation on 3/14/25. The inspector was provided a vapor analysis conducted for TP A that reported concentration reading of 0.88 ppm (dated 1 /17/25, exposure monitor for 8 hours). The Advanced Chemical Sensors Formaldehyde report included the statement "result outside of OSHA permissible limit of 0.75 ppm based on personal exposure for an 8 hour period." The inspector requested to review corrective action repeat vapor analysis reports for monitoring TP A and the grossing station per the Safety/Chemical Hygiene Plan after the abnormal 1 /17/25 report noted above. The inspector also requested to review available vapor analysis reports for TP B and C during the 24 months of review. No additional reports or corrective action follow up analysis were available for review. 5. An interview with the facility director on 3/14/25 at 12:30 PM confirmed the above findings.