

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2022590	(X3) Date Survey Completed 07/07/2026
Name of Provider or Supplier Avamar Gastroenterology Inc	Street Address, City, State 9225 East Market Street, Warren, OH	
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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review, direct observation and an interview with Testing Personnel (TP) #1, TP#2 and the Inform Diagnostics sales representative (SR), the laboratory failed to label the secondary container of a Sodium Hypochlorite cleaning solution with the strength or concentration, storage requirement, preparation and expiration dates and lot number (pertinent information required for proper use) which was utilized for cleaning procedures in the tissue grossing hood of high complexity tissue biopsy testing procedures in the subspecialty of Histopathology. This deficient practice had the potential to affect 31,976 out of 31,976 patient tissue biopsy specimens from the last CLIA inspection on 04/23/2024 through 07/07/2026. Findings Include: 1. Review of the laboratory's "Accessioning and Grossing Procedure" and "Grossing" policies and procedures, approved via signature and date by the Laboratory Director on 08/22/2025 and provided for inspection review did not find any instructions of the laboratory's labeling policies and procedures for secondary containers of prepared solutions. 2. Direct observation of the Histopathology tissue grossing hood on 07/07/2026 at 2:20 PM found a secondary bottle of Sodium Hypochlorite cleaning solution labeled only with "Sodium Hypochlorite" without any indication of the strength or concentration, storage requirement, preparation and expiration dates and lot number (pertinent information required for proper use). 3. On 07/07/2026 at 2:20 PM the Inspector requested the laboratory's policy and procedure for labeling secondary containers of prepared solutions from TP#1, TP#2 and the SR.

	TP#1, TP#2 and the SR confirmed the laboratory did not establish a policy and procedure for labeling secondary containers of prepared solutions and the laboratory did not label secondary container of the Sodium Hypochlorite cleaning solution as required by CLIA regulation. TP#1, TP#2 and the SR were unable to provide the requested documentation on the date of the inspection. 4. Review of laboratory documentation revealed the laboratory completed 31,976 patient tissue biopsy specimens from the last CLIA inspection on 04/23/2024 through 07/07/2026.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: * This is a repeat deficiency * Based on direct observation and an interview with Testing Personnel (TP) #1, TP#2 and the Inform Diagnostics sales representative (SR), the laboratory failed to ensure solutions were not utilized for Histopathology cleaning procedures when they had expired. This deficient practice had the potential to affect 24,597 out of 24,597 patient tissue biopsy specimens between 10/31/2024 through 07/07/2026. Findings Include: 1. On 07/07/2026 at 2:20 PM, direct observation of the laboratory found two bottles of ParaGard tissue embedder cleaner, lot number 132108, with an expiration date of 10/31/2024 in use. Further observation found three additional unopened bottles of the same lot and expiration in the cupboard. 2. On 07/07/2026 at 2:20 PM TP#1, TP#2 and the SR confirmed the two opened bottles of ParaGard tissue embedder cleaner had been used past the expiration date. 3. Review of laboratory documentation revealed the laboratory completed 24,597 patient tissue biopsy specimens between 10/31/2024 through 07/07/2026.