

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2022590	<b>(X3) Date Survey Completed</b>  04/23/2024
<b>Name of Provider or Supplier</b>  Avamar Gastroenterology Inc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the sole Testing Personnel (TP), the laboratory failed to ensure the Quick Dip #2 and Quick Dip #3 stains, utilized for high complexity tissue biopsy testing procedures performed in the subspecialty of Histopathology, were not used when they had exceeded their expiration dates. This deficient practice had the potential to affect 662 out of 662 tissue biopsy testing procedures performed between 12/09/2022 through 03/20/2023, Findings Include: 1. Review of the laboratory's "Histology Procedure Manual", approved by the Laboratory Director via signature and date on 08/20/2021 and provided on the date of the inspection, found a policy and procedure titled "Reagents" which revealed the following statement: "6. All expired reagents should be discarded..." 2. Review of the laboratory's 2022, 2023 and 2024 "Reagent Log In Form: revealed the Quick Dip #2 and Quick Dip #3 stains were used beyond their expiration dates as listed below: Quick Dip #2 Lot Opened Expiration Last Used Number Date Date Date 2033853 01/28/22 12/08/22 02/01/23 Quick Dip #3 Lot Opened Expiration Last Used Number Date Date Date 2102917 03/15/22 02/04/23 03/20/23 3. The sole TP stated they were unaware of what may have happened at the time of the documentation and confirmed the Quick Dip #2 and #3 stains were utilized for patient tissue biopsy testing procedures when they had exceeded their expiration dates. The interview occurred on 04/23/2024 at 9:50 AM.</p>