

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0941021	(X3) Date Survey Completed 02/27/2025
Name of Provider or Supplier Oral Pathology Services	Street Address, City, State 610 Professional Drive, Gaithersburg, MD	
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
D5417	<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 reagent log record review, surveyor observation, and interview with the laboratory director (LD), the laboratory failed to document the lot numbers and expiration dates of reagents used for oral histopathology testing, ensuring that they were not used when they had exceeded their expiration date, had deteriorated, or were of substandard quality. Findings: 1. The laboratory performs histopathology testing on oral pathology specimens. 2. Review of "Laboratory Reagents Inventory and Utilization" logs from 2023 to 2025 showed that the laboratory documented the name of the reagent and its manufacturer, the lot number, "Date of Expiration," "Date of Initial Use," "Date Discontinued," and "Review" for two reagents since the last recertification survey on 04/20/2023. 3. The laboratory documented the "XL-Cal" reagent (lot # 2204919, expiration date: 03/2024) which was put into use "05/23" and discontinued "03/2024" and "Cover Seal-X" (lot # 061773, expiration date: 06/2024) which was put into use "02/2023" and discontinued "06/2024." 4. During a tour of the laboratory on 02/27/2025 at 09:50 AM, it was observed that the laboratory stored their histopathology stain reagents in a cabinet in a room next to the laboratory. Nine bottles of different reagents appeared to have been opened, however no opened dates were documented on the bottles. 5. The bottles of opened reagents observed were as follows: two bottles of "Xylene" (lot # 2331406, expiration date: 11/13/2027); two bottles of "Xylene" (lot # 2302301, expiration date: 01/26/2027); and one bottle each of "Zero Xylene" (lot # 2219204, expiration date: 07/11/2026); "Scott ' s Tap Water Substitute" (lot # 2424318, expiration date: 03/13/2026); "Mayer ' s Hematoxylin" (lot # 2329321, expiration date: 11/19/2025); "Reagent Alcohol, 200 Proof" (lot #</p>

2331112, expiration date: 11/07/2027); and "Eosin Y, Alcoholic" (lot # 2413105, expiration date: 05/22/2026). 6. Reagent log review showed that none of the opened reagents observed in the cabinet were documented on the "Laboratory Reagents Inventory and Utilization" log. 7. During an interview on 02/27/2025 at 12:15 PM, the LD confirmed that the laboratory failed to document the lot numbers and expiration dates of reagents used for histopathology testing.