

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0659611	<b>(X3) Date Survey Completed</b> 03/24/2025
<b>Name of Provider or Supplier</b> Texas A&M Oral Pathology Services	<b>Street Address, City, State</b> 3302 Gaston Ave, Dallas, TX	
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>D0000</b>	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiency was cited.
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of patient annual volumes, and confirmed in interview, the laboratory failed to ensure expired reagents were not available for use prior to patient testing for five of five tissue marking reagents observed in March 2025. Findings included: 1. During a tour of the laboratory at 11:23 AM, the surveyor observed five tissue marking reagents on the laboratory counter available for use. The surveyor observed the following printed on the inking reagents: a. Lot Number: 111147 Color: Green Expiration: 11/30/2022 b. Lot Number: 109671 Color: yellow Expiration: 11/30/2022 c. Lot Number: 109668 Color: Red Expiration: 11/30/2022 d. Lot Number: 108664 Color: Orange Expiration: 11/30/2022 e. Lot Number: 112652 Color: Black Expiration: 11/30/2022 The surveyor inquired if the expired reagent were currently being used to test patient samples. The laboratory director confirmed the expired reagents were currently in use for patient testing. 2. Review of patient annual volumes from March 2024-March 2025, revealed the laboratory performed 71 patient tests using the expired tissue marking reagent. 3. In an interview on 03/24/2025 at 11:35 AM in the facility conference room, the laboratory director confirmed the above findings.</p>