

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2280099	(X3) Date Survey Completed 07/23/2025
Name of Provider or Supplier Cpa Bailey Square Frozen Room	Street Address, City, State 1111 W . 34th St. Suite 300, Austin, TX	
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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and interview, the laboratory failed to have a staining procedure for the Hematoxylin and Eosin (H&E) used in frozen sections and touch preps for histopathology and oral histopathology surgical specimens for two of two years reviewed. Findings follow. A. Review of the laboratory's policies and procedures did not include a procedure for staining the H&E slides. A policy and procedure was requested on July 23, 2025 at 1500 hours but not provided. B. Interview with the Physician Assistant (PA) Manager by phone on July 23, 2025 at 1455 hours acknowledged they give oral instructions to the gross tech/ PA and confirmed they had no written staining procedure for H&E. Interview with the Clinical Support Service Manager on July 23, 2025 at 1500 hours confirmed there was no written policy and procedure for staining the H&E slides.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p>

(b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, preventive maintenance records, and interview, the laboratory failed to establish and follow a preventive maintenance protocol to ensure the performance of the Leica CM1850 cryostat. Findings follow. A. Review of the laboratory's procedures did not address the frequency of the preventive maintenance of the cryostat. B. Review of the preventive maintenance records for 2023 and 2024 showed no preventive maintenance on the Leica CM1850 cryostat. Preventive maintenance records were requested on July 23, 2025 at 1040 hours but not provided. C. Interview with the Clinical Support Service Manager on July 23, 2025 at 1040 hours confirmed there were no preventive maintenance records for the cryostat in 2023 and 2024 and there was no procedure defining the frequency of preventive maintenance.