

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2280099	<b>(X3) Date Survey Completed</b>  01/24/2024
<b>Name of Provider or Supplier</b>  Cpa Bailey Square Frozen Room	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	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.
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on review of the laboratory's records, interview, and pre-survey paperwork, the laboratory failed to retain the chemical name and concentration (if applicable), manufacturer, lot number, received date, and open date of the chemicals and stains used in the frozen section histopathology laboratory for the Hematoxylin and Eosin (H&amp;E) and Diff Quik stains for 11 of 11 months reviewed. Findings follow. A. Review of the Frozen Section Lab QA and Supply Check List reviewed from March 2023 - January 2024 listed reagents and expiration dates. A reagent log with the manufacturer, lot number, received date, and open date of the chemicals and stains was requested on January 24, 2024 at 1550 hours but not provided. B. Interview with the Clinical Service Manager on January 24, 2024 at 1550 hours confirmed the laboratory did not maintain a reagent log. C. Review of the CMS Form 116 showed approximately 14 cases were reported in 2023. II. Based on review of the temperature logs, interview, and patient logs, the laboratory failed to retain the room temperature log for four of 10 months reviewed. Findings follow. A. Review of the Cryostat &amp; Room Temperature Monitor logs from April 2023 - January 2024 showed missing logs from April 2023 - July 2023. The logs stated, "Room temp should remain between 18 degrees Celsius and 30 degrees Celsius (62 degrees Fahrenheit to 86 degrees Fahrenheit." B. Interview with the Clinical Service Manager on January 24,</p>

2024 at 1545 hours confirmed the logs were missing. C. Review of the patient log showed 4 cases were reported from 04/18/2023 - 07/18/2023. III. Based on review of the temperature logs, interview, and patient logs, the laboratory failed to retain the humidity log for four of 10 months reviewed. Findings follow. A. Review of the Cryostat & Room Temperature Monitor logs from April 2023 - January 2024 showed missing logs from April 2023 - July 2023. The logs stated, "% Humidity should remain below 60%." B. Review of the Leica CM1850 Instruction Manual, 12/2003, at Chapter 3. Technical Data stated, "Operating temperature range (ambient temperature): 18 degrees Celsius to 40 degrees Celsius." C. Interview with the Clinical Service Manager on January 24, 2024 at 1545 hours confirmed the logs were missing. D. Review of the patient log showed 4 cases were reported from 04/18/2023 - 07/18/2023.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient test reports, interview, and pre-survey paperwork, the laboratory failed to include the name and address of the facility where the macroscopic examination (grossing), frozen sections, and touch preps were performed for 10 of 10 reports reviewed. Findings follow. A. Review of 10 test reports showed 10 were missing the name and address of the facility where the testing occurred: Date of Service Accession # Reported 1. 04/18/2023 AT23-002657 Macroscopic examination and frozen section diagnosis 2. 04/21/2023 AT23-002800 Macroscopic examination 3. 05/01/2023 AT23-003135 Macroscopic examination and touch preps interpretation 4. 05/19/2023 AT23-003855 Macroscopic examination 5. 05/30/2023 AT23-004170 Macroscopic examination and frozen section diagnosis 6. 07/18/2023 AT23-005863 4 Macroscopic examinations and 4 frozen section diagnosis 7. 08/25/2023 AT23-007160 Macroscopic examination and touch preps interpretation 8. 09/27/2023 AT23-008205 Macroscopic examination and frozen section diagnosis 9. 09/29/2023 AT23-008300 Macroscopic examination and touch prep interpretation 10. 11/30/2023 AT23-010350 Macroscopic examination and 4 frozen sections diagnosis B. Interview with the Clinical Service Manager on January 24, 2024 at 1605 hours confirmed the test reports did not have the name and address of the facility for testing performed at the surgery center. C. Review of the CMS Form 116 showed approximately 14 cases were reported in 2023.