

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2097493	(X3) Date Survey Completed 12/05/2024
Name of Provider or Supplier Brenham Dermatology	Street Address, City, State 1910 Neibuhr Street, Brenham, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observations, review of manufacturer's instructions and interview of facility personnel, the laboratory failed to store 4 of 4 bottles of StatLab Treosin stain (used in histopathology for staining of tissues) as defined by the manufacturer. The findings included: 1. observations made in the laboratory found 4 of 4 bottles of Treosin stored in the cabinet above the automated stainer. 2 bottles each of lots 203270 expiration 2026-01-31 and lot 189836 expiration 2025-7-31. 2. Review of storage instructions found on the labels of the Treosin stain found under the heading STORAGE: "Store in a fireproof dry, cool and well ventilated place". 3. During interview of the histotechnologist conducted by phone on December 5, 2024 at 2:26 PM, she confirmed she did not store the Treosin stain as defined by the manufacturer.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper</p>

use.

This STANDARD is not met as evidenced by:

Based upon observations and interview of facility personnel the laboratory failed to label 4 of 4 secondary containers used for storage of tissue dyes (used for marking tissues) with the contents, preparation and expiration dates. The findings included: 1. Observations made in the laboratory found 4 unlabeled screw top containers filled with substances colored yellow, red, purple and black. 2. During interview of the office manager conducted December 5, 2024 at 2:41 PM, she confirmed the containers were not labeled and contained tissue marking dye.