

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2118967	<b>(X3) Date Survey Completed</b> 04/18/2024
<b>Name of Provider or Supplier</b> Texas Surgical Dermatology Pa	<b>Street Address, City, State</b> 21009 Kuykendahl Road Suite A, Spring, 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>	An announced survey of the laboratory was conducted on 04/18/2024. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). STANDARD LEVEL DEFICIENCIES were cited.
<b>D5415</b>	<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 use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observations and staff interview, the laboratory failed to label secondary containers with the content, lot and expiration dates for four of four in-house prepared colored freezing media observed on a shelf in the laboratory. Findings included: 1. Surveyor's observations on 04/18/2025 at 0910 hours in the laboratory revealed 5 bottles (4 with colored solutions and 1 with a clear solution) sitting on a shelf in the laboratory. The containers were labeled 1 through 5 with a marker. The containers were labeled by the manufacturer as follows: Bottle marked number 1 containing a light blue solution: Labeled by Manufacturer as: Subxero Freezing Medium Lot: 85814 Expiration date: 07/21 Bottle marked number 2 containing an orange solution: Labeled by Manufacturer as: Subxero Freezing Medium Lot: 85814 Expiration date: 07/21 Bottle marked number 3 containing a purple solution: Labeled by Manufacturer as: Subxero Freezing Medium Lot: 87145 Expiration date: 09/21 Bottle marked number 4 containing a clear solution: Labeled by Manufacturer as: Subxero Freezing Medium Lot: 45145 Expiration date: 08/2025 Bottle marked number 5 containing a yellow solution: Labeled by Manufacturer as: Polarstat Plus Frozen Embedding Medium Lot: 082330 Expiration date: 2021-06-01 Note:</p>

Manufacturer prepared Subxero Freezing Medium in its original form was a clear solution. 2. In an interview on 04/18/2024 at 0915 hours in the laboratory, the facility's Histo Tech stated that, except for Solution bottle number 4 which was unadulterated or changed in any form, the other colored solution bottles were reused for an in-house preparation of the current lot of clear Subxero Freezing Medium combined with store bought food coloring. She also stated that these colored solutions of Subxero Freezing Medium on the shelf were recently prepared but was not sure of the exact date. No written policy with formula for the preparation of the mixture was available for review. 3. Further surveyor's observations at the time of the above interview revealed the bottles with the colored solutions did not have labels specifying the bottles' mixture content, date of preparation and date of expiration. 4. In an interview on 04/18/2024 at 0915 hours in the laboratory, the facility's Histo Tech (as indicated on submitted Survey Entrance/Exit Document) confirmed the findings.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on surveyor's observations, review of laboratory's Cryostat maintenance records and staff interview, the laboratory failed to document daily and monthly maintenance for two of two Cryostat instruments in use, the Avantik QS and the Thermo Scientific Microm HM520 Cryostats. Findings included: 1. Surveyor's observations on 04/18/2024 at 0905 hours in the laboratory revealed two Cryostat instruments in use: The Avantik QS Cryostat Serial Number: 59730 The Thermo Scientific Microm HM520 Cryostat Serial Number: 4180 2. In an interview at the time of the observation, the facility's Histo Tech stated that the Avantik Cryostat was the instrument used most of the time and the Thermo Scientific Microm HM520 Cryostat was the backup and used sporadically as needed. 3. Review of laboratory's Cryostat maintenance records for October 2023 to March 2024 revealed the laboratory required the following maintenance of the Cryostats: "Interior is cleaned day of surgery while wearing gloves. Air filter is cleaned as part of the maintenance every month." 4. Further review of the laboratory's Cryostat maintenance records revealed:  
a. There was only one log sheet where daily Cryostat maintenance was recorded, but it did not specify which of the two instruments underwent maintenance on the day of record/use. b. There was no documentation of when the monthly air filter cleaning took place for either if the instruments. 5. In an interview on 04/18/2024 at 1000 hours in the laboratory, the facility's Histo Tech (as indicated on submitted Survey Entrance /Exit Document) stated that the cryostats' daily maintenance was performed and documented only on the days of use. She could not state which cryostat was in use on the days of record. This confirmed the findings.