

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2258312	<b>(X3) Date Survey Completed</b> 01/03/2023
<b>Name of Provider or Supplier</b> Clear Creek Dermatology	<b>Street Address, City, State</b> 904 Ford St, Llano, 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>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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 upon observations and interview of facility personnel, the laboratory failed to ensure that expired Tissue Marking Dyes were not used in testing the 185 histopathology specimens as recorded on the CMS 116. The findings included: 1. Observations made during the tour of the laboratory found two bottles of expired Cancer Diagnostics, Inc. (CDI) Tissue Marker Dyes (Orange and Violet) in the cabinet. Expiration dates for the two dyes ( as labeled) was 2021-09-30. Testing Person one listed on the CMS 209 Laboratory Personnel report was observed using the expired CDI Tissue Marking Dye to mark tissues at 11:35 AM on January 3, 2023. 2. During interview of the histotechnician conducted January 3, 2023 at 11:37AM confirmed that the expired tissue marking dyes were currently being used in patient testing.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based upon review of the Operating instructions, maintenance records, and interview</p>

of facility personal, the laboratory failed to perform and document monthly maintenance procedures for the Tanner Scientific Cryostat TN50 seven of seven months in 2022. The findings included: 1. Review of the Tanner Scientific Cryostat TN50 Operating instructions (2020-03-008.00) found in section 10.3 under the heading RECOMMENDED MAINTENANCE AND SERVICE SCHEDULE: Daily - Remove frozen section waste from the cryostat chamber after every day of usage. Disinfection if necessary. Weekly - Cleaning of the blade holder. Cleaning of the window. Monthly - Check of Temperature sensor in cryochamber. Cleaning of cryostat ventilation. 2. Review of the Maintenance Records for Cryostat for June - December 2022 (7 months) found no documentation of performing the Clean Air Filter maintenance procedure documented. 3. During interview of the histotechnician conducted January 3, 2023 at 11:22 AM, she confirmed she had not performed the monthly maintenance procedures as defined by the manufacturer.