

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2274543	(X3) Date Survey Completed 11/13/2024
Name of Provider or Supplier Tennessee Oncology, Pllc	Street Address, City, State 315 Washington Ave Ste 230, Cookeville, TN	
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
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, a review of laboratory policy, review of temperature records, and staff interview, the laboratory failed to follow its own policy for maintaining proper freezer temperatures for storage of referral specimens on 12 of 27 days in September 2023 and March 2024. The findings include: 1. Observation of the laboratory on November 13, 2024, at 10:15 a.m. revealed an American BioTech Supply (Serial Number- ABS5222033023038) refrigerator/freezer in use for storage of patient specimens. 2. A review of the laboratory policy titled "Laboratory Maintenance" revealed the following requirement: -"7. TEMPERATURE CHECK - 3. Check and record freezer temperature if separate from refrigerator daily: - A. Daily temperature will be taken at the beginning of each day for every freezer that is external from the refrigerator and recorded on the Temperature and Humidity Log. - a. Freezer temperature range: -15C to -25C (5 to -13F) - b. All out of range temperatures will be documented as such on the log. - c. All corrective actions to bring temperature back into an acceptable operating range will be documented on the log." 3. A review of the laboratory temperature records revealed out of range freezer temperatures for 4 of 6 days in September 2023 and 8 of 21 days in March 2024 with no corrective action noted. 4. An interview with the Regional Laboratory Operations Manager and the Laboratory Clinical Operations Manager on November 13, 2024 at 11:30 a.m. confirmed the findings.</p>