

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1006416	(X3) Date Survey Completed 07/22/2026
Name of Provider or Supplier Thompson Oncology Group	Street Address, City, State 1915 White Avenue, Knoxville, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on laboratory observations and staff interviews, the facility failed to follow posted safety signage by storing food for human consumption in a freezer designated for biohazards on the survey date (07.22.2026). The findings include: 1. Observation of the laboratory on 07.22.2026 at 9:10 a.m. revealed the Sysmex XN-530 (serial number 12248) Hematology analyzer and the Medica EasyRA (serial number 20423040519) Chemistry analyzer used for patient testing. Also observed, at 9:25 a. m., in the blood collection area, was a refrigerator/freezer with safety signage that read "Biohazard no food or drink to be stored in this refrigerator or freezer." The freezer contained a pint of ice cream for human consumption. 2. An interview on 07.22.2026 at 9:30 a.m. with the two technical consultants confirmed the above survey findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) 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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test

reports.

This STANDARD is not met as evidenced by:

Based on direct observation, a review of the manufacturer's storage requirements, lack of documentation, and staff interviews, the laboratory failed to ensure proper temperature storage for blood collection tubes on the date of the survey (07.22.2026). The findings include: 1. Observation of the blood collection room on 07.22.2026 at 9:10 a.m. revealed the following blood collection tubes stored in the cabinet: -16 Becton Dickinson (BD) Vacutainer 4mL dipotassium Ethylenediaminetetraacetic Acid (K2E) tubes -24 BD Vacutainer 3mL Gel and Lithium Heparin (LH) tubes -60 BD Vacutainer 2.7mL Buffered Sodium Citrate tubes -64 BD Vacutainer 6.0 mL serum tubes -100 BD Vacutainer 6.0 mL K2E tubes -5 BD Vacutainer 6.0 mL Trace Element Serum tubes Observed in a cabinet in the adjoining hallway revealed the following blood collection tubes; -9 packs, containing 100 tubes per pack, BD Vacutainer 4mL K2E tubes -2 packs, containing 100 tubes per pack, BD Vacutainer 3 mL Gel and LH tubes -3 packs, containing 100 tubes per pack, BD Vacutainer 5.0mL Sodium Separator Tube (SST) tubes 2. A review of the BD Vacutainer manufacturer's storage requirements revealed that the acceptable temperature range for tube storage is 4C to 25C. 3. A request for environmental records for the blood collection room and adjoining hallway revealed no records available for surveyor review on the survey date, 07.22.2026. 4. An interview with the two technical consultants on 07.22.2026 at 9:30 a.m. confirmed the above survey findings. Word Key: C = degrees Celsius mL = milliliters