

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0992181	(X3) Date Survey Completed 09/04/2024
Name of Provider or Supplier Tennessee Oncology Pllc	Street Address, City, State Russell Plaza 120 Frank Martin Road, Suite 102, Shelbyville, 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
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, review of patient testing records, maintenance records, the laboratory's policies, monthly quality reports, and staff interviews, the laboratory's quality assessment process was ineffective in identifying problems with the refrigerator temperature monitoring system for one of four testing dates reviewed in 2023 and 2024. The findings include: 1. Observation of the laboratory on 09/04/2024 at 9:00 a.m. revealed the laboratory used a Norlake refrigerator (ID: 7080546) to store HN-L Check quality control (Lot: 4181) materials used in hematology testing and patient specimens. The XN-L Check vials state a required storage temperature of 2 - 8 degrees Celsius. A TempTrak sensor (ID: 236252) monitored the refrigerator temperature electronically. 2. A random review of four patient test records revealed the laboratory performed hematology testing on 07/27/2023 (patient ID: 555490), 10/24/2023 (patient ID: 153780), 04/22/2024 (patient ID: 545783), and 09/03/2024 (patient ID: 546254). 3. A review of the laboratory's 2023 and 2024 maintenance records revealed no refrigerator temperatures recorded in the TempTrak system for 07/27/2023. 4. A review of the "Laboratory Maintenance" policy (ID: 12122789) revealed that the laboratory requires refrigerator temperatures to be recorded daily with documentation of corrective actions for any outliers. A review of the "Quality Assurance Program" policy (ID: 13180163) revealed laboratory management will review quality assurance reports monthly for "quality outliers." 5. A review of the</p>

daily maintenance and monthly quality reports for July 2023 revealed that the laboratory failed to identify that the TempTrak system did not record temperatures from 07/26/2024 to 07/27/2024. 6. An interview with the Quality Manager on 09/04/2024 at 2:00 p.m. confirmed that the laboratory's monthly quality assessment process failed to identify a problem with the electronic temperature monitoring system for a two day period in July 2023.