

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2055124	(X3) Date Survey Completed 01/15/2025
Name of Provider or Supplier Tennessee Oncology Pllc	Street Address, City, State Spring Hill Medical Plaza, Spring Hill, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, Centers for Medicare & Medicaid Services Laboratory Personnel Report (FORM CMS-209), and staff interviews, the laboratory failed to ensure that routine testing personnel performed one of three hematology PT events in 2024. The findings include: 1. A review of the laboratory's API PT records revealed that the operations manager signed the attestation page for the "2024 Hematology / Coagulation 2nd Event" as the testing person on 07/26/2024. 2. A review of the FORM CMS-209 revealed that the laboratory did not list the operations manager as a testing person for the clinic. 3. An interview with the Regional Laboratory Operations Manager on 01/15/2025 at 12:30 p.m. confirmed that the operations manager did not perform patient testing at the clinic.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p> <p>(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.</p>

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's Centers for Medicare & Medicaid Services Laboratory Personnel Report (FORM CMS-209), personnel records, and staff interviews, the laboratory director failed to define the duties and responsibilities of the Regional Operations Manager (one of two technical consultants). The findings include: 1. A review of the FORM CMS-209 revealed the Regional Operations Manager is one of two technical consultants. 2. A review of the laboratory's personnel records revealed no job description or list of duties and responsibilities defined for the Regional Operations Manager. 3. An interview with the Regional Laboratory Operations Manager on 01/15/2025 at 12:30 p.m. confirmed that the Lab Director did not specify their duties and responsibilities in writing.