

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D2120027	<b>(X3) Date Survey Completed</b> 05/10/2023
<b>Name of Provider or Supplier</b> Tennessee Oncology, Pllc	<b>Street Address, City, State</b> 4488 Carothers Parkway Suite 310, Franklin, TN	
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>D0000</b>	Intakes: TN00062373 The laboratory was found to NOT be in compliance with the following 42 CFR PART 493, Requirements for Laboratories for the specialties /subspecialties for which it was surveyed: CFR 493.801 Condition: Enrollment and testing of samples CFR 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director Surveys were performed on the following laboratories: Laboratory A: Recertification Survey CLIA #44D1066106 Survey started on 04/10/23 and completed on 05/10/23 Tennessee Oncology PLLC 250 25th Ave. N., STE 412 Nashville, TN 37203 Laboratory does not perform testing for reticulocyte count. Testing performed: Complete Blood Count with automated White Blood Cell Differential (CBC w/Diff) Enrolled in Proficiency Testing with Medical Laboratory Evaluation (MLE) (Customer #014511) Laboratory B: Complaint & Recertification Survey 44D0882942 Survey started on 04/19/23 and completed on 05/10/23 Tennessee Oncology PLLC 250 25th Ave. N. STE 100 Nashville, TN 37203 Testing performed: CBC w/Diff Reticulocyte Count (Retic) Protime (PT) Activated Partial Thromboplastin Time (PTT) Fibrinogen Fibrin Degradation Products (D-Dimer) General Chemistry Testing Enrolled in Proficiency Testing with Medical Laboratory Evaluation (MLE) (Customer #006664) Laboratory C: Complaint Survey 44D2120027 Survey was started on 05/03/23 and completed on 05/10/23 Tennessee Oncology PLLC 4488 Carothers Parkway, STE 310 Franklin, TN 37067 Laboratory does not perform testing for PT, PTT, Fibrinogen and D-Dimer Testing Performed: CBC w/Diff Chemistry Endocrinology Immunology Cytogenetics Enrolled in Proficiency Testing with College of American Pathologists (CAP) (Customer #8095230-01) All three laboratories have the same technical consultant. Laboratory A and Laboratory B have the same laboratory director.
<b>D2000</b>	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801  Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for

which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

This CONDITION is not met as evidenced by:

Based on observation of the laboratory, review of the laboratory's CAP proficiency testing records, Centers for Medicare and Medicaid Casper Report 155 (CMS 155), and staff interviews, the laboratory failed to ensure proficiency testing samples were not sent to another laboratory for testing. The laboratory enrolled in PT with CAP for coagulation testing in 2022 and 2023 and then sent the PT samples to Lab B to be performed for three PT events (2022 event two, 2022 event three, and 2023 event one). Lab C then submitted the PT, PTT, Fibrinogen and D-Dimer results performed by Lab B to the CAP proficiency testing program for evaluation. (Refer to D2013)

**D2013**

**TESTING OF PROFICIENCY TESTING SAMPLES**

CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory, review of the laboratory's proficiency testing records, CMS 155, and staff interviews, the laboratory failed to ensure PT samples assigned to Lab C were not sent to Lab B for testing for two PT events in 2022 and one PT event in 2023. A total of 21 samples were sent from Lab C to Lab B to be performed. The findings include: 1. Observation of the laboratory on 05/03/23 at 8:45 am revealed no instrument in the laboratory for performing coagulation tests to include PT, PTT, Fibrinogen and D-Dimer. 2. Review of the laboratory C CAP PT records revealed the following for the coagulation testing: 2022 Event B (CGL-B) Attestation signed by testing person who worked at Lab B and by the technical consultant for Lab A, Lab B, and Lab C. The serial number on the instrument printouts was 20072163 (this instrument was noted to be located at Lab B during a survey performed at Lab B on 04/19/23). The PT instrument printouts (dated 05/18/22) were labeled as CG-DD3 and CG-DD4 for D-Dimer; CGL-6, CGL-7, CGL-8, CGL-9, CGL-10 for PT, PTT and Fibrinogen with "Tennessee Oncology Core Laboratory" on the printout. The transaction history report for 2022 event two

indicated the upload to CAP was performed by a testing person who works at Lab C on 05/31/22. The event cut-off date was 05/31/22. 2022 Event C (CGL-C) Attestation signed by testing person who worked at Lab B and by the technical consultant for Lab A, Lab B, and Lab C. The serial number on the instrument printouts was 20072163 (this instrument was noted to be located at Lab B during a survey performed at Lab B on 04/19/23). The PT instrument printouts (dated 09/21/2022 for D-Dimer and 09/14/2022 for PT, PTT and Fibrinogen) were labeled as CG DD5 and CGDD6 for D-Dimer; CGL-11, CGL-12, CGL-13, CGL-14, CGL-15 for PT, PTT and Fibrinogen, with "Tennessee Oncology Core Laboratory" on the printout. The transaction history report for 2022 event three indicated the upload to CAP was 'approved' by a testing person who works at Lab C on 09/28/22. The event cut-off date was 10/07/22. 2023 Event A-Attestation signed by testing person who worked at Lab B and the technical consultant for Lab A, Lab B, and Lab C. The serial number on the instrument printouts was 20072163 (this instrument was noted to be located at Lab B during a survey performed on 04/19/23). The PT instrument printouts (dated 01/30/2023) were labeled as CG-DD1 and CG-DD2 for D-Dimer; CGL-01, CGL-02, CGL-03, CGL-04, CGL-05 for PT, PTT and Fibrinogen, with "Tennessee Oncology Core Laboratory" on the printout. The transaction history report for 2023 event one indicated the upload to CP was performed by a testing person who works at Lab C on 02/07/23. The event cut-off date was 02/14/23. 3. Review of the CMS 155 for Laboratory B and Laboratory C revealed PT scores for PT, PTT and Fibrinogen on the report for Lab C; no scores for PT, PTT and Fibrinogen on the report for Lab B. 4. During an interview with the technical consultant on 05/03/23 at 11:45 am the following was communicated: Lab C was enrolled in PT for D-Dimer, Fibrinogen, PT and PTT with CAP. The PT samples came to Lab C and were then sent by courier to Lab B to be performed since Lab C no longer had the coagulation instrument. 5. Interview with Lab C chemistry supervisor on 05/03/23 at 12 pm confirmed the CAP PT samples for Lab C were sent to Lab B to be performed for 2022 events two and three, and 2023 event one and the results were then submitted under the PT enrollment for Lab C. 6. Phone interview with the Laboratory Director on 05/10/23 at 2:45 pm confirmed the survey findings.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of the laboratory's procedure manual, the laboratory's PT records and interview with the laboratory director, the laboratory director failed to ensure the laboratory did not send coagulation PT samples to another laboratory for testing in 2022 and 2023. (Refer to D6016)

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedure manual, the laboratory's PT records and interview with the laboratory director, the laboratory director failed to ensure PT samples were not sent to another laboratory for testing for 2022 events two and three and 2023 event three. A total of 21 PT samples that were under the enrollment for Lab C were sent to Lab B to be performed. The findings include: 1. Review of the laboratory's proficiency testing policy revealed that PT samples were to be treated as a patient sample, PT samples were not to be sent to another lab for referral or reference. It also stated that "Sending PT samples to another for testing is considered PT referral and will cause serious action to be taken against your laboratory." 2. Review of the laboratory's PT records revealed that the coagulation CAP PT samples for Lab C were sent to Lab B to be performed for 2022 events two and three and 2023 event one, and then submitted to CAP for evaluation. 3. Interview with the laboratory director on 05/10/23 at 2:45 pm confirmed the survey findings.