

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0882942	(X3) Date Survey Completed 05/10/2023
Name of Provider or Supplier Tennessee Oncology Pllc	Street Address, City, State 250 25th Ave N Suite 100, Nashville, 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
D0000	Intakes: TN00062174 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 Tennessee Oncology PLLC 250 25th Ave. N., STE 412 Nashville, TN 37203 Laboratory A 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 (PT) with Medical Laboratory Evaluation (MLE) (Customer #014511) Laboratory B: Complaint & Recertification Survey 44D0882942 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 PT with Medical Laboratory Evaluation (MLE) (Customer #006664) Laboratory C: Complaint Survey 44D2120027 Tennessee Oncology PLLC 4488 Carothers Parkway, STE 310 Franklin, TN 37067 Laboratory C does not perform testing for PT, PTT, Fibrinogen and D-Dimer. Testing Performed: CBC w/Diff Chemistry Endocrinology Immunology Cytogenetics Enrolled in PT with the 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.
D2000	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 proficiency testing records and the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), patient test reports, interviews and review of email communications, the laboratory failed to ensure PT samples from other laboratories were not tested. The reticulocyte proficiency testing (PT) samples for Lab A were sent to Lab B to be performed for three of three PT events in 2022 - six of six retic samples (Refer to D2013 Citation number one) and the coagulation PT samples for Lab C were sent to Lab B to be performed for 2022 event two, 2022 event three, and 2023 event one--- seven samples per PT event for a total of twenty-one PT samples for coagulation testing (Refer to D2013 Citation number two).

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:

Citation Number One: Reticulocyte Count Based on observation of the laboratory, review of the laboratory's proficiency testing (PT) records, the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), staff interviews, review of patient test reports, and review of email communications, laboratory B failed to ensure PT samples assigned under the PT enrollment for Lab A for reticulocyte count were not tested when the samples were sent to their lab for analysis for 2022 events one, two, and three for six of six reticulocyte PT samples. The findings include: 1. Observation of the laboratory on 04/19/23 at 8:50 am revealed the Sysmex XN 550 (serial #17517) in use for performing patient testing for CBC w/Diff and reticulocyte count. 2. Review of the laboratory's Hematology PT records and the Form CMS-209 revealed the following: Documentation provided during survey of this laboratory: The PT attestation statement for 2022 event one for Lab A was in the PT records for Lab B and signed by a testing person who worked in Lab B. The PT attestation statement for 2022 event three for Lab A was in the PT records for Lab B and signed by testing personnel that worked in Lab B. The date the

attestation statement was signed was 09/15/22. The MLE ID number for Lab A (014511) was recorded on the submission form. The instrument printouts for retic count for 2022 event three had the name, address, CLIA number and instrument serial number (17517) of Lab B. Documentation provided during survey of Lab A: 2022 Event A Retic The retic PT instrument printouts for 2022 event one, labeled RT-1 and RT-2, were dated 02/11/2022 and had the name, address, CLIA number and instrument serial number (17517) of the instrument located in Lab B. The attestation statement had an additional signature of a testing person who worked in Lab B. The results were submitted on 02/11/22. The event cutoff date was 02/25/22. The performance evaluation report for 2022 Event A included reporting for retics. 2022 Event B Retic The retic PT instrument printouts for 2022 event two, labeled RT3 and RT4, were dated 05/18/2022 and had the name, address, CLIA number and instrument serial number (17517) of the instrument located in Lab B. The attestation statement had an additional signature of a testing person who worked in Lab B. The results were submitted on 05/19/22. The event cutoff date was 06/03/22. The performance evaluation report for 2022 Event B included reporting for retics. 2022 Event C Retic The retic PT instrument printouts for 2022 event three, labeled RT5 and RT6, were dated 09/15/2022 and had the name, address, CLIA number and instrument serial number of the instrument located in Lab B. The attestation statement had an additional signature of a testing person who worked in Lab B. The results were submitted on 09/15/22. The date of the testing personnel signature on the attestation statement was 09/15/22. The event cutoff date was 09/30/22. The performance evaluation report for 2022 Event C included reporting for retics. PT samples tested on instrument serial #17517, located in Lab B were RT-1 and RT-2 for 2022 event one, RT-3 and RT-4 for 2022 event two and RT-5 and RT-6 for 2022 event three. 3. During an interview with the laboratory lead for Lab A on 04/10/23 at 12:30 pm the following was communicated: CBC instrument serial number 17517 (that performs retic) was moved to the downstairs lab (Lab B) that operates under the CLIA number 44D0882942 on 10/28/21. When the 2022 PT samples for Lab A were delivered, the retic samples were taken to the downstairs lab (Lab B) to be performed since the upstairs lab (Lab A) did not have the capability to perform the retic counts. She stated that she had sent the updated PT change form to her supervisor, but for whatever reason it never got corrected with the PT program. A copy of the 2022 change form completed after the first event of 2022 was provided via subsequent email. 4. Review of patient test reports for testing performed after the move revealed the following: The last retic count performed for Lab A on instrument serial number 17517 was performed on 10/28/21 (patient MRN 425311). The first retic count performed for Lab B was on instrument serial number 17517 performed on 10/29/21 (patient MRN 521528). 5. During a phone interview with the laboratory's PT provider (MLE) on 04/14/23 at 3:20 pm, the customer service representative stated that the PT program did not have a record of any type of communication from Lab B for changes to their 2022 PT enrollment. 6. During an interview on 04/19/23 at 12:43 pm with the testing person who performed the PT testing for retic for 2022 events one and two, the testing person stated that the primary testing person in the Lab A brought the retic PT samples to the downstairs lab (Lab B) to be performed. He performed the testing, but did not enter on the PT provider website since he did not have the authorization for Lab A. 7. During a phone interview on 04/21/23 at 12:30 pm with the primary testing person in Lab A the following was communicated: The testing person was on leave during the transition period. When she came back on 01/27/22 the instrument that performs retic had been moved downstairs (Lab B). When the first PT event for 2022 came in the retic samples were included in the shipment. She stated she contacted the laboratory lead and was instructed to take them downstairs to Lab B to be performed. After the retic testing was complete she picked up the reports and entered them into the MLE data

submission for Lab A. PT samples for the upstairs lab (Lab A) kept coming for 2022 that included the retic samples. She was instructed to take the retic samples downstairs to Lab B and have the testing personnel in Lab B perform the testing. She then entered them on the MLE site under the PT enrollment for Lab A. 8. Review of email communication received on 04/21/2023 at 12:46 pm from the primary testing person in Lab A revealed communication on 02/09/22 at 1:16 pm for 2022 event one with instructions for taking the retic samples to Lab B to be performed. Additional email communication on 09/15/22 at 9:03 am revealed the retic for 2022 event three were also performed by Lab B. 9. During a phone interview on 04/21/23 at 3:08 pm with the testing person from Lab B who performed retic PT testing for 2022 event three, the following was communicated: The retic samples were brought to Lab B from the upstairs lab (Lab A) by the primary testing person. They were instructed to run the retic samples. The results were then put into the MLE website for evaluation by the primary testing person in Lab A. 10. Phone interview with the director of Lab C on 05/10/23 at 2:45 pm confirmed the survey findings related to sharing of PT samples across sites. Citation number two: Coagulation Testing to include PT, PTT, Fibrinogen and D-Dimer Based on observation of the laboratory, review of the laboratory's proficiency testing (PT) records, the Centers for Medicare and Medicaid Casper Report 155 (CMS 155), document request, staff interviews, review of patient test reports, and review of email communications, laboratory B failed to ensure the PT samples assigned to Lab C for coagulation testing were not tested by Lab B for PT, PTT, Fibrinogen and D-Dimer for 2022 event two, 2022 event three, and 2023 event one. Each event included five samples for PT, PTT, and Fibrinogen and two samples for D-Dimer for a total of 21 PT samples in 2022 and 2023. The findings include: 1. Observation of the laboratory on 04/10/23 at 8:50 am revealed the ACLTOP 350 (serial #20072163) in use for performing patient testing for PT, PTT, Fibrinogen and D-Dimer. 2. Review of the laboratory's PT records revealed no proficiency testing records for the coagulation testing. 3. Review of the CMS 155 revealed no proficiency testing scores for the regulated coagulation analytes (PT, PTT and Fibrinogen). 4. A request was made to the technical consultant on 04/19/23 at approximately 10:30 am for the proficiency testing records for coagulation. She stated that the records were at their other lab in Franklin (Lab C) and she would have a courier bring them over. She further stated they were enrolled with CAP. 5. Review of the coagulation proficiency testing records provided during survey of this laboratory and additional documentation provided during the survey of Lab C revealed the following: Documentation provided during survey of this laboratory: 2022 Event B (CGL-B) The name and address of Lab C (Franklin) was on the CAP PT reports. The serial number on the instrument printouts was 20072163. 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 printouts. The attestation statement was signed by a testing person who worked in Lab B and by the technical consultant for Lab A, Lab B, and Lab C. The event cutoff date was 05/31/22. 2022 Event C (CGL-C) The name and address of Lab C (Franklin) was on the CAP PT reports. The serial number on the instrument printouts was 20072163. 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 printouts. The results transaction history had the name of a testing person who did not work in this laboratory for the "approved" status dated 09/28/22. Attestation signed by testing person who worked at Lab B and by the technical consultant for Lab A, Lab B, and Lab C. The event cutoff date was 10/07/22. 2023 Event A (CGL-A) The name and address of Lab C (Franklin) was on the CAP PT reports. Documentation provided

during survey of Lab C: 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 (instrument observed in use on the date of the survey - 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 printouts. 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 (instrument observed on the date of the survey - 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 approval to CAP was performed by a testing person who works in Lab C on 09/28/22. The event cut-off date was 10/07/22. 2023 Event A (CGL-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 (instrument observed on the date of the survey - 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 CAP was performed by a testing person who works at Lab C on 02/07/23. The event cut-off date was 02/14/23. 6. Interview with the technical consultant on 04/19/23 at approximately 12:15 pm revealed the following: Lab C was enrolled in PT for coagulation testing. The ACLTOP 350 coagulation instrument was moved to Lab B "about a year ago." The proficiency testing samples for coagulation were sent by courier from Lab C to Lab B to be performed since that was where the instrument was located. She stated Lab C no longer performed PT, PTT, Fibrinogen and D-Dimer. She communicated that she did not understand that the CAP number was associated with a specific CLIA number. 7. Review of patient test records revealed the first patient testing for PT and PTT was performed on 10/18/21 in Lab B (patient MRN 421127). 8. Interview on 04/19/23 at 5 pm with the technical consultant and laboratory supervisor for Lab B confirmed that the coagulation PT samples for Lab C were received and tested in Lab B for 2022 events two and three, and 2023 event one. 9. Phone interview on 04/21/23 at 3:08 pm with the testing person who performed the coagulation PT for 2022 event two revealed the following: A courier brought the coagulation PT samples to them to be run since they had the instrument used for performing coagulation testing. The samples received were assigned to Lab C, but they were performed at Lab B. She further stated that she then entered the results on the CAP website. 10. Phone interview with the director of Lab C on 05/10/23 at 2:45 pm confirmed the survey findings related to sharing of PT samples across laboratory sites A, B, and C.

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 proficiency testing policy, the laboratory's proficiency testing records, and staff interviews, the laboratory director for Lab A failed to ensure the laboratory did not test PT samples from other laboratories. (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 proficiency testing policy, review of proficiency testing records and staff interviews, the laboratory director failed to ensure reticulocyte and coagulation PT samples were not tested when received from other laboratories in 2022 and 2023. The findings include: 1. Review of the laboratory's proficiency testing policy revealed the following statements: "Samples CANNOT be shared" 2. Review of proficiency testing records and staff interviews revealed following: The retic PT samples assigned to Lab A were sent to Lab B to be performed and then submitted under the PT enrollment for Lab A. (Refer to D2013 Citation One) The coagulation PT samples assigned to Lab C were sent to Lab B to be performed and then submitted under the PT enrollment for Lab C. (Refer to D2013 Citation Two) 3. Interview with the director of Lab C on 05/10/23 at 2:45 pm confirmed the survey findings.