Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0882942	04/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Oncology Pllc	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	A recertification survey was conducted with an onsite exit date of 04/19/23, but additional information was being gathered through 04/21/23. The facility was found NOT to be in compliance with the following 42 CFR Part 493, Requirements for Laboratories for the specialties/subspecialties for which it was surveyed: 493.801 Proficiency Testing 493.1215 Hematology 493.1403 Laboratory Director 493.1409 Technical Consultant
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 patient test reports, staff interview, phone interview with the laboratory's proficiency testing provider, and email communications, the laboratory failed to enroll in proficiency testing for the regulated coagulation analytes for Prothrombin Time (PT), Activated Partial Thromboplastin Time (PTT) and Fibrinogen from the time the laboratory began patient testing on 10 /18/21 until the date of the survey on 04/19/23 with a total of 27,550 regulated coagulation tests reported. The findings include: 1. Observation of the laboratory on 04 /19/23 at 8:45 am revealed the Instrumentation Laboratories ACLTOP350 coagulation instrument on the counter in use for patient testing for regulated coagulation analytes (PT, PTT, and Fibrinogen). 2. Review of patient test reports revealed the first patient

	for PT, PTT was reported on 10/18/21 (MRN 421127) and the first patient for fibrinogen was reported on 10/19/21 (MRN 331556). 3. In an interview with the technical consultant on the date of the survey (04/19/23) at 5 pm the technical consultant confirmed the laboratory had not been enrolled in proficiency testing for the regulated coagulation analytes in 2022 and 2023. 4. During a phone interview with the laboratory's proficiency testing provider (American Association of Bioanalysts Medical Laboratory Evaluation (AAB/MLE)) on 04/21/23 at 2:40 pm, the customer service representative stated there was no enrollment with AAB/MLE for coagulation modules. 5. An email received from the AAB/MLE proficiency testing program on 04 /21/23 at 3:29 pm with a copy of the order verification for the laboratory revealed no enrollment for coagulation testing for year 2023. 6. Email received from the technical consultant on 04/21/23 at 3:18 pm revealed the following patient test counts since testing began on 10/18/21. PT/INR 16005 PTT 9365 Fibrinogen 2180
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, manufacturer reagent package inserts, PT reagent lot history records, lack of documentation, patient test reports, staff interviews, email communications, and phone interviews, the laboratory failed to meet the condition of hematology. The laboratory failed to follow the policy for use of platelet poor plasma for frozen coagulation analytes (Refer to D5401), and failed to follow manufacturer instructions for establishing the Patient Normal Mean (used in the calculation of patient International Normalized Ratio(INR)) for new lots of Prothrombin Time (PT) reagent (Refer to D5411), resulting in IMMEDIATE JEOPARDY.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, personnel policy, and staff interview, the laboratory personnel policy did not include assessing technical consultant (TC) competency, as required. The findings include: 1. Review of the laboratory personnel records revealed the following: Delegation of technical consultant duties by the lab director to one TC. There were no records for documentation of technical consultant competency by the director of the lab for 2021, 2022, and 2023. 2. Review of the laboratory personnel competency policy revealed no requirement for assessment of technical consultant competency. 3. Phone interview with the technical consultant on 04/25/23 at 2:20 pm confirmed the laboratory personnel competency policy did not include a requirement for technical consultant competency assessment performed by the lab director.

D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, review of patient test reports, phone interview with the laboratory lead, and email communication, the laboratory failed to ensure the frozen plasma used for performing patient coagulation testing was platelet poor as required by their own procedure since patient testing began on 10/18/21 with a total of approximately 204 patients performed since testing began. 1. Observation of the laboratory on 04/19/23 at 8:45 am revealed the Instrumentation Laboratories ACLTOP350 instrument in use for performing patient coagulation testing to include Prothrombin Time (PT) with INR calculation, Activated Partial Thromboplastin Time (PTT), Fibrinogen, and Fibrin Degradation Products (D-Dimer). Also observed was a centrifuge used for processing coagulation samples for testing (Beckman Coulter Allegra X30). 2. Review of the laboratory procedure manual revealed the following: "If testing is delayed by >24 hours centrifuge the sample and freeze platelet poor plasma at -20C." 3. Review of patient test reports revealed patient coagulation testing began on 10/18/21 (patient 421127). 4. During a phone interview with the laboratory lead on 04/21/23 at 11:40 am the following was discussed and confirmed: The laboratory receives frozen samples for coagulation testing if testing is delayed. A request was made for records of centrifuge validations for platelet poor plasma. The laboratory does not have a process in place to ensure the plasma is platelet poor. The centrifuge in use had not been validated to ensure platelet poor plasma is produced. The laboratory lead confirmed the laboratory failed to ensure the frozen plasma used for performing patient coagulation testing was platelet poor from the time testing began on 10/18/21 until the date of the survey on 04/19/23. 5. Email communication received from the technical consultant on 04/21/23 at 03:18 pm revealed an estimated total 204 patients tested from frozen plasma since testing began on 10/25/21.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer package insert, reagent lot history record, document request, patient test results, staff interview, email communication and phone interview with the technical consultant, the laboratory failed to perform Patient Normal Mean determination for two of two new lots of RecombiPlasTin 2G Prothrombin Time reagent before placing into use beginning 05 /02/22 until the date of the survey on 04/19/23 according to the manufacturer's requirements. The findings include: 1. Observation of the laboratory on 04/19/23 at 8:

	45 am revealed the Instrumentation Laboratories ACLTOP350 instrument in use for performing patient coagulation testing to include Prothrombin Time (PT) with INR calculation, Activated Partial Thromboplastin Time (PTT), Fibrinogen, and Fibrin Degradation Product (D-Dimer). The current lot of RecombiPlasTin 2G PT reagent observed in use was N0824895. 2. Review of the manufacturer package insert revealed the following statement: "Enter the ISI value from the insert and establish the Mean of the PT Normal Range with each new lot." 3. Review of the RecombiPlasTin 2G PT reagent lot history records revealed the following: Lot N1218411 activated /placed into use on 05/02/22 Lot N0824895 activated/placed into use on 11/29/22 4. Request made to the laboratory lead on 04/19/23 at 2:45 pm for the Patient Normal Mean study for lot N1218411 and lot N0824895 revealed no documentation was available. 5. Review of patient test results revealed patient number 479210 had PT /INRs reported on 11/7/22, 12/5/22, 12/19/22, 01/03/23, and 01/17/23 during the period when the lots were in use without a Patient Normal Mean determination study performed to use in the calculation of the INR. 6. Interview with the laboratory lead and the technical consultant on 04/19/23 at 5:00 pm confirmed the laboratory failed to establish the Patient Normal Mean for two new lot numbers of RecombiPlasTin 2G Prothrombin Time reagent beginning 05/02/22 until the date of the survey. 7. Email communication received on 04/20/23 at 6:33 am from the laboratory technical consultant revealed a total of 502 patient PT/INR results have been reported since 05 /02/22. 8. Phone interview with the technical consultant on 04/21/23 at 9:15 am confirmed the laboratory primarily performs the PT/INRs for monitoring of patient coumadin therapy.
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 observation of the laboratory, review of coagulation lot validation studies, and staff interviews, the laboratory director failed to ensure patient testing was performed in a manner to ensure accurate patient test results (Refer to D6007).
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure manual, manufacturer package inserts, patient test reports, phone interviews, and email

	communications,the laboratory director failed to ensure the procedure for the use of platelet poor plasma was followed when frozen specimens were tested (Refer to D5401), and failed to ensure accurate analytic performance was maintained for the calculated INR used for monitoring patient coumadin therapy for two of two reagent lots from 05/02/22 until the date of the survey on 04/19/23 with a total of 502 patient PT/INR results reported since the new lots were started on 05/02/22. (Refer to D5411)
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on observation of the laboratory, review of patient test records, technical consultant delegation of duties list, review of Casper report 0155D (Individual Laboratory Profile of proficiency testing scores) (CMS 155), the laboratory's proficiency testing records, and staff interview, the technical consultant failed to ensure enrollment and participation in proficiency testing for regulated analytes. (Refer to D6041)
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of patient test records, the list of duties delegated to the technical consultant by the lab director, the report CMS 155 and interview with the technical consultant, the technical consultant failed to ensure the laboratory was enrolled in proficiency testing for regulated analytes for coagulation and chemistry tests in 2021, 2022 and 2023. The findings include: 1. Observation of the laboratory on 04/19/23 at 8:45 am revealed instruments in use for patient testing for general chemistry, coagulation, and hematology. Testing performed included regulated analytes for all test systems. 2. Review of patient test records revealed the following: Chemistry testing began on 05/24/21 (patient MRN 520887) Coagulation testing began on 10/18/2021 (patient MRN 421127) 3. Review of the technical consultant delegation of duties list revealed the following as delegated by the laboratory director: "Enrollment of the laboratory in a CMS-approved proficiency testing (PT) program for the test performed." 4. Review of the CMS 155 revealed no proficiency testing scores for the regulated coagulation tests or the regulated chemistry tests. 5. Review of the laboratory's proficiency testing records revealed the following: No enrollment in proficiency testing for the regulated coagulation tests to include Prothrombin Time (PT), activated Partial Thromboplastin Time (PTT) and Fibrinogen in 2022 or 2023. No enrollment in proficiency testing for regulated chemistry analytes in 2021 or 2022 to include Glucose, Blood Urea Nitrogen, Sodium, Potassium, Chloride, Total Bilirubin, Aspartate Aminotransferase (AST/SGOT), Alanine Aminotransferase (ALT/SGPT), Total Protein, Calcium, Alkaline

	Phosphatase, Albumin, Lactate Dehydrogenase (LDH), Magnesium, and Uric Acid. 6. Interview with the technical consultant on 04/19/23 at 5:00 pm confirmed the technical consultant failed to ensure the laboratory was enrolled in proficiency testing for regulated analytes for coagulation in 2022 and 2023 and for regulated chemistry analytes in 2021 and 2022.