Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0969102	(X3) Date Survey Completed 07/09/2025
Name of Provider or Supplier Tennessee Oncology, Pllc	**Street Address, City, State** 776 Weatherly Drive, Ste A, Clarksville, 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
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 a review of the laboratory procedure manual, review of testing personnel records, a review of a patient activity log, and staff interview, the laboratory failed to follow the policy for technical consultant approval of testing personnel training and competency prior to patient testing for one of one new testing persons since the last survey date. The findings include: 1. A review of the laboratory's policy titled "Competency Testing on Laboratory Personnel" revealed the following statement: The competency of each person who performs the duties of a defined test system must be assessed by the Technical Consultant following training before the person performs testing if the person is a new hire or is learning a new test system. 2. A review of one of one new testing persons (TP 3) since the last survey date revealed an initial competency assessment signed by the technical consultant on 05/20/25. 3. A review of a patient activity log revealed that TP 3 performed six patient CBC w/Diff tests prior to the technical consultant's competency assessment approval (patient sample identification numbers 25293892, 25294383, 25295571, 25295947, 25296080-performed on 05/12/25, sample identification number 25308415 performed on 05/16 /25). 4. Technical consultant two confirmed the survey findings during an interview on 07/09/25 at 3:30 p.m.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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 laboratory observation, a review of the laboratory procedure manual, review of instrument maintenance logs, review of validation records, review of a patient activity report and staff interview, the laboratory failed to follow the procedure for technical consultant review and approval of new test systems prior to patient testing for two of two new Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) instruments implemented in April 2024 with approximately 2,757 patient CBC w/Diff results released prior to approval of validation records. The findings include: 1. Laboratory observation on 07/09/25 at 9:15 a.m. revealed the Sysmex XN 430 (serial number 12047) and the Sysmex XN 530 (serial number 12533) used for patient testing for CBC w/Diff. During observations, the lead testing person stated the instruments were new since the last survey date. 2. A review of the laboratory procedure titled "Qualification of Laboratory Equipment" revealed the following statement: "Under no circumstances is it acceptable to result patient testing prior to Medical Director or Technical Consultant (Moderate Complexity) signature release and demonstration of training competency of testing personnel." 3. A review of the instrument maintenance logs revealed that both instruments were put into use for patient testing on approximately 04/24/24. The exact date could not be determined. 4. A review of the validation records for both instruments revealed that they were not approved for use until after patient testing had begun. The approval date for both instruments was 06/11/24. 5. A review of a patient activity report revealed that approximately 2,757 patients were reported after the instruments were used for patient testing, but before the technical consultant and laboratory director approved the validations. 6. Technical consultant number two confirmed the survey findings during an interview on 07/09/25 at 3:30 p.m.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on laboratory observation, review of the laboratory document titled "Hematology Auto-Verification Rules and Actions", review of the laboratory information system auto-verification validation documents, and staff interview, the laboratory failed to provide documentation that supported the validation of auto-verification of CBC w/Diff results into the laboratory information system. The use of auto-verification began in March 2024 and continued until the survey date on July 9, 2025. 1. Laboratory observation on 07/09/25 at 9:15 a.m. revealed the Sysmex XN 430 (serial number 12047) and the Sysmex XN 530 (serial number 12533) used for patient testing for CBC w/Diff. During observations, the lead testing person was

	asked to describe how the results from the instruments are released to the patient's chart. She stated that the laboratory uses auto-verification for many of the results. Certain results are held for review by the testing person before release to the chart. She stated that the use of auto-verification began sometime last year. 2. A review of the document titled "Hematology Auto-Verification Rules and Actions" detailed which results would be excluded from auto-verification and what actions the testing person would take for those results that did not auto-verify. 3. A review of the laboratory information system auto-verification validation documents, with a date of 03/22/24, revealed no approval signatures or dates of the laboratory director, no raw data supporting the verification activity, and no evidence that each criterion for results excluded from auto-verification had been tested. 4. Technical consultant two confirmed the survey findings during an interview on 07/09/25 at 3:30 p.m.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (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. This STANDARD is not met as evidenced by: Based on laboratory observation, document review, lack of documentation, and staff interview, the laboratory director failed to delegate technical consultant duties to two of three persons performing technical consultant duties (technical consultants two and three). The findings include: 1. Laboratory observation on 07/09/25 at 9:00 a.m. revealed two Sysmex CBC w/Diff instruments used for patient testing. 2. A review of laboratory documents revealed that two persons (new since the last survey date) performed technical consultant duties, which included reviewing quality control, reviewing maintenance, and conducting competency assessments of testing personnel. 3. The laboratory director had not delegated the technical consultant duties in writing to technical consultant two or technical consultant three. 4. Technical consultant two confirmed the survey findings during an interview on 07/09/25 at 3:30 p.m.