Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2291009	11/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Oncology, Pllc	808 S James Campbell Blvd, Suite A, Columbia, 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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records and staff interviews, the laboratory failed to evaluate the complete blood count with differential (CBC w/Diff) PT results for one of four events reviewed in 2025. The findings include: 1. A review of the laboratory's API PT records revealed no documented review of the performance evaluation for the 2025 Hematology/Coagulation Event One for the CBC w/Diff analytes. 2. An interview with Technical Consultants One and Two on 11/13/2025 at 12:15 p.m. confirmed the survey findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the laboratory procedure, instrument comparison records, lack of records, and staff interviews, the laboratory failed to document corrective action for one of three method comparison results that did not meet the laboratory's established criteria for one of eighteen analytes on the Sysmex instruments used for complete blood count with differential (CBC w/Diff) patient testing in 2025. The findings include: 1. Observation of the laboratory on 11/13 /2025 at 10:00 a.m. revealed that the laboratory used the Sysmex XN-550 (Serial 12541) and the Sysmex XN-430 (Serial 11898) for CBC w/Diff patient testing. 2. A review of the laboratory procedure titled "Quality-Inter-Instrument Comparison", section five, "Result/Acceptance," revealed the following: 5.4 If any results failed the comparison, further investigation was required, which included a review of quality controls, calibration records, and maintenance records for each instrument and consultation with the manufacturer for troubleshooting. 5.5 Once the laboratory had completed the corrective action, a repeat method comparison would be performed. 3. A review of the comparison records reviewed by the laboratory director on 02/07 /2025 for the Sysmex XN-550 and Sysmex XN-430 instruments revealed that the immature granulocyte percent (IG%) analyte expected criteria was +/- 20% and the result was 22.06, which exceeded the laboratory's established criteria. 4. Documentation of corrective actions or investigation for the failed IG% analyte was not available on the date of the survey (11/13/2025). 5. An interview with technical consultant one on 11/13/2025 at 11:00 a.m. confirmed the survey findings.