

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2314698	(X3) Date Survey Completed 05/08/2025
Name of Provider or Supplier Tennessee Oncology, Pllc	Street Address, City, State 121 Bear Crossing Suite 200, Mount Juliet, 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
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory procedure, review of laboratory records, lack of documentation, and staff interview, the laboratory failed to document corrective action for an inter-instrument comparison of results when they did not meet their established criteria for 4 of 18 analytes performed on two Sysmex XN-430 analyzers in 2025. The findings include: 1) Observation of the laboratory on 05/08/2025 at 12:30 p.m. revealed two Sysmex XN-430 instruments (Serial Numbers 11301 and 12038) in use for complete blood count (CBC) patient testing. 2) A review of the procedure titled "Intra-Instrument Comparison" revealed the following protocol for "Result/Acceptance": 1. Compare the calculated mean percent difference for each parameter to ensure they are within the recommended limits from Sysmex America as listed in the below table. 2. CBC Parameter % Allowable Difference WBC +/- 7.5% RBC +/- 3.0% HGB +/- 3.5% HCT +/- 3.0% MCV +/- 3.0% PLT +/- 12.5% RET % +/- 30.0% 3. If any results fail the comparison, further investigation will be required. If all results are within the allowable limits, the comparison is acceptable. - Review of quality control runs for each analyzer - Review recent calibration and maintenance for each analyzer - Contact manufacturer for troubleshooting Once all necessary</p>

investigation and corrective action is completed, the method comparison will be repeated. 3) A review of the laboratory "Inter Instrument Comparison LOG" that was reviewed and signed by the technical consultant on 03/20/2025, revealed 18 CBC parameters were analyzed, with passing results indicated for all 18. Further review of the analyzer comparison data revealed the following four analytes that did not meet the expected criteria. RBC -3.29% Pass +/- 3.0% HCT -3.32% Pass +/- 3.0% IG# -43.75% Pass +/- 20% IG% -52.94% Pass +/- 20% 4) A review of the laboratory records revealed no investigation or corrective actions for the failed results. 5) An interview on 05/08/2025 at 12:45 p.m. with the technical consultant and the laboratory operations manager confirmed the findings. Word Key: WBC- White Blood Cells RBC- Red Blood Cells HGB- Hemoglobin HCT- Hematocrit MCV- Mean Corpuscular Volume PLT- Platelets RET %- Reticulocyte Percent IG#- Immature Granulocyte Number IG%- Immature Granulocyte Percent