

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0886211	(X3) Date Survey Completed 09/04/2026
Name of Provider or Supplier Tennessee Oncology Pllc	Street Address, City, State 225 Big Station Camp Blvd Ste 201, Gallatin, 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
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10) (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of the laboratory's procedures, manufacturer's quality control (QC) package inserts, a review of the laboratory's instrument QC records, and staff interviews, the laboratory failed to ensure that the hematology instrument QC ranges matched the manufacturer's QC package insert ranges for randomly reviewed analytes for two of two lots reviewed in 2026. 1. Observation of the laboratory on 09/04/2026 at 9:45 a.m. revealed the Sysmex XN-430 (Serial number 12007) instrument used for Complete Blood Count with automated differential (CBC w/Diff) patient testing. 2. A review of the laboratory's procedure titled "QUA Quality Control Plan" revealed, "The AC is monitored with Sysmex remotely through BCQM (Beyond Care Quality Monitoring), peer reporting, as well as internally checking the instrument." 3. A review of the manufacturer's QC package inserts labeled "XN-L CHECK Hematology Control for Sysmex XN-L Analyzers" and the laboratory's Sysmex XN-430 instrument QC printouts revealed the following: Lot 61221401 (Level 1) 07/24/2026-08/11/2026 RBC (10^6/uL) Package Insert: 2.17-2.40 Instrument: 2.14-2.40 HCT % Package Insert: 15.3-17.6 Instrument: 15.5-17.9 PLT (10^3/uL) Package Insert: 36-86 Instrument: 34-84 WBC (10^3/uL)

	Package Insert: 2.07-2.80 Instrument: 2.16-2.72 Lot 61221402 (Level 2) 07/24/2026-08/11/2026 RBC ($10^6/\mu\text{L}$) Package Insert: 4.13-4.47 Instrument: 4.07-4.49 HCT % Package Insert: 31.2-35.2 Instrument: 31.5-35.9 PLT ($10^3/\mu\text{L}$) Package Insert: 182-256 Instrument: 174-252 WBC ($10^3/\mu\text{L}$) Package Insert: 6.12-7.49 Instrument: 6.23-7.39 Lot 61221403 (Level 3) 07/24/2026-08/11/2026 RBC ($10^6/\mu\text{L}$) Package Insert: 5.05-5.48 Instrument: 5.00-5.52 HCT % Package Insert: 41.0-46.2 Instrument: 41.8-47.2 PLT ($10^3/\mu\text{L}$) Package Insert: 463-590 Instrument: 454-576 WBC ($10^3/\mu\text{L}$) Package Insert: 14.95-17.91 Instrument: 15.11-17.51 Lot 62071401 (Level 1) 07/30/2026-09/04/2026 RBC ($10^6/\mu\text{L}$) Package Insert: 2.15-2.37 Instrument: 2.12-2.38 HCT % Package Insert: 15.1-17.3 Instrument: 15.4-17.6 PLT ($10^3/\mu\text{L}$) Package Insert: 36-87 Instrument: 35-85 WBC ($10^3/\mu\text{L}$) Package Insert: 2.14-2.89 Instrument: 2.23-2.79 Lot 62071402 (Level 2) 07/30/2026-09/04/2026 RBC ($10^6/\mu\text{L}$) Package Insert: 3.93-4.26 Instrument: 3.88-4.28 HCT % Package Insert: 30.9-34.8 Instrument: 31.2-35.6 PLT ($10^3/\mu\text{L}$) Package Insert: 187-263 Instrument: 177-257 WBC ($10^3/\mu\text{L}$) Package Insert: 6.04-7.38 Instrument: 6.10-7.24 Lot 62071403 (Level 3) 07/30/2026-09/04/2026 RBC ($10^6/\mu\text{L}$) Package Insert: 5.05-5.47 Instrument: 4.99-5.51 HCT % Package Insert: 41.4-46.7 Instrument: 42.4-48.0 PLT ($10^3/\mu\text{L}$) Package Insert: 469-596 Instrument: 459-581 WBC ($10^3/\mu\text{L}$) Package Insert: 14.97-17.94 Instrument: 15.10-17.48 4. An interview with the technical consultant one on 09/04/2026 at 1:15 pm confirmed the survey findings. Word Key: RBC= Red Blood Cell $10^6/\mu\text{L}$= million/microliter HCT= Hematocrit %= percent PLT=Platelet Count $10^3/\mu\text{L}$=thousand/microliter WBC=White Blood Cell
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on a review of the laboratory's hematology quality control (QC) records for July, August, and September 2026, and an interview with the technical consultant, the director failed to ensure the establishment and maintenance of acceptable levels of analytic performance for QC testing on the hematology instrument used for Complete Blood Count with automated differential (CBC w/Diff) patient testing in 2026. Refer to D5469. The findings include: 1. Review of the laboratory's QC records from the hematology instrument revealed that the QC ranges on the instrument QC printouts for RBC, HCT, PLT, and WBC for July, August, and September 2026 (two of two lots reviewed) differed from those stated in the manufacturer's QC package insert. No documentation was available to show how the laboratory established the QC ranges in use or how staff evaluated daily QC runs for acceptability. 2. An interview with the technical consultant on 09/04/2026 at 1:15 p.m. confirmed the above survey findings