

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2192407	(X3) Date Survey Completed 07/28/2026
Name of Provider or Supplier Tennessee Oncology, Pllc	Street Address, City, State 1208 Pointe Centre Drive, Suite 110, Chattanooga, 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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on laboratory observation, review of laboratory policy, the Department of Health and Human Services Centers for Medicare and Medicaid Services Laboratory Personnel Report (CLIA) (Form CMS-209), American Proficiency Institute (API) proficiency testing (PT) records, and staff interviews, the laboratory failed to ensure that one of two testing personnel (TP) who performed hematology patient testing also participated in PT testing in 2024, 2025, and 2026. (six of six events reviewed) The findings include: 1. Laboratory observation on 07/28/26 at 10:10 a.m. revealed a Sysmex XN-430 (Serial Number 22290) hematology analyzer used for Complete Blood Count with automated differential (CBC w/ Diff) patient testing. 2. A review of the laboratory policy titled "SOP Proficiency Testing" revealed a requirement that "Proficiency samples will be assigned each year in a manner that allows all trained employees to perform a minimum of one proficiency test per year whenever possible." 3. A review of the Form CMS-209 revealed a total of two testing personnel (TP1 and TP2) who routinely perform moderately complex hematology patient testing. 4. A review of the laboratory's API proficiency testing records revealed that TP2 did not participate in any hematology PT events (0 of 6 events reviewed) in 2024, 2025, and 2026. 5. Technical consultants one and two (TC1 and TC2) confirmed the survey findings in an interview on 07/28/2026 at 1:00 p.m.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based on laboratory observation, a review of the manufacturer's quality control (QC) package inserts, the laboratory's QC records, and staff interview, the laboratory failed to verify QC ranges when the ranges listed on the manufacturer's QC package inserts for randomly reviewed analytes did not match the hematology analyzer's monthly QC reports for 3 of 3 randomly reviewed lot numbers of QC for 2025 and 2026. The findings include: 1. Laboratory observation on 07/28/26 at 10:10 a.m. revealed a Sysmex XN-430 (Serial Number 22290) hematology analyzer used for Complete Blood Count with automated differential (CBC w/ Diff) patient testing. 2. A review of the manufacturer's quality control (QC) package inserts labeled, "XN-L Check Hematology Control for Sysmex XN-L Analyzers" revealed the following expected QC means and ranges for randomly reviewed analytes for the following lot numbers: - Lot 5235, Expiration Date 12/02/2025 - (Level 1) Analyte Mean Range RBC 2.33 2.21 - 2.45 ($10^6/\mu\text{L}$) HGB 5.5 5.2 - 5.8 (g/dL) HCT 16.3 15.1 - 17.4 (%) PLT 60 36 - 85 ($10^3/\mu\text{L}$) WBC 2.31 1.96 - 2.66 ($10^3/\mu\text{L}$) - (Level 2) Analyte Mean Range RBC 4.32 4.15 - 4.49 ($10^6/\mu\text{L}$) HGB 12.2 11.7 - 12.7 (g/dL) HCT 34.1 32.1 - 36.2 (%) PLT 226 187 - 264 ($10^3/\mu\text{L}$) WBC 6.77 6.09 - 7.44 ($10^3/\mu\text{L}$) - (Level 3) Analyte Mean Range RBC 5.20 4.99 - 5.41 ($10^6/\mu\text{L}$) HGB 16.5 15.8 - 17.1 (g/dL) HCT 44.4 41.7 - 47.0 (%) PLT 534 470 - 598 ($10^3/\mu\text{L}$) WBC 16.59 15.10 - 18.09 ($10^3/\mu\text{L}$) - Lot 5319, Expiration Date 02/24/2026 - (Level 1) Analyte Mean Range RBC 2.28 2.16 - 2.39 ($10^6/\mu\text{L}$) HGB 5.4 5.1 - 5.7 (g/dL) HCT 15.9 14.8 - 17.0 (%) PLT 64 38 - 90 ($10^3/\mu\text{L}$) WBC 2.60 2.21 - 2.99 ($10^3/\mu\text{L}$) - (Level 2) Analyte Mean Range RBC 4.33 4.15 - 4.50 ($10^6/\mu\text{L}$) HGB 12.1 11.6 - 12.6 (g/dL) HCT 34.2 32.1 - 36.2 (%) PLT 223 185 - 261 ($10^3/\mu\text{L}$) WBC 6.42 5.78 - 7.06 ($10^3/\mu\text{L}$) - (Level 3) Analyte Mean Range RBC 5.21 5.00 - 5.42 ($10^6/\mu\text{L}$) HGB 16.1 15.5 - 16.8 (g/dL) HCT 44.0 41.3 - 46.6 (%) PLT 518 456 - 580 ($10^3/\mu\text{L}$) WBC 16.50 15.01 - 17.98 ($10^3/\mu\text{L}$) - Lot 6038, Expiration Date 05/19/2026 - (Level 1) Analyte Mean Range RBC 2.25 2.14 - 2.36 ($10^6/\mu\text{L}$) HGB 5.4 5.1 - 5.7 (g/dL) HCT 15.9 14.8 - 17.0 (%) PLT 60 36 - 85 ($10^3/\mu\text{L}$) WBC 2.52 2.14 - 2.89 ($10^3/\mu\text{L}$) - (Level 2) Analyte Mean Range RBC 4.28 4.11 - 4.45 ($10^6/\mu\text{L}$) HGB 12.5 12.0 - 13.0 (g/dL) HCT 34.9 32.8 - 37.0 (%) PLT 222 184 - 259 ($10^3/\mu\text{L}$) WBC 6.95 6.25 - 7.64 ($10^3/\mu\text{L}$) - (Level 3) Analyte Mean Range RBC 5.19 4.99 - 5.40 ($10^6/\mu\text{L}$) HGB 16.2 15.5 - 16.8 (g/dL) HCT 44.0 41.4 - 46.7 (%) PLT 532 469 - 596 ($10^3/\mu\text{L}$) WBC 17.08 15.54 - 18.62 ($10^3/\mu\text{L}$) 3. A review of the laboratory's QC records revealed the following acceptable ranges for randomly reviewed analytes for the following lot numbers and months: - Lot 5235 for September 2025 (Level 1) Analyte Mean SD Calculated Range RBC 2.319 .03 2.259 - 2.379 ($10^6/\mu\text{L}$) HGB 5.49 .05 5.39 - 5.59 (g/dL) HCT 16.16 .22 15.72 - 16.60 (%) PLT 59 3.99 51.02 - 66.98 ($10^3/\mu\text{L}$) WBC 2.352 .05 2.252 - 2.452 ($10^3/\mu\text{L}$) - Lot 5235 for September 2025 (Level 2) Analyte Mean SD Calculated Range RBC 4.337 .03 4.277 - 4.397 ($10^6/\mu\text{L}$) HGB 12.16 .06 12.04 - 12.28 (g/dL) HCT 34.00 .31 33.38 - 34.62 (%) PLT 224 5.77 212.46 - 235.54 ($10^3/\mu\text{L}$) WBC 6.837 .10 6.637 - 7.037

(10³/uL) - Lot 5235 for September 2025 (Level 3) Analyte Mean SD Calculated Range RBC 5.250 .04 5.170 - 5.330 (10⁶/uL) HGB 16.43 .07 16.29 - 16.57 (g/dL) HCT 44.87 .44 43.99 - 45.75 (%) PLT 535 8.58 517.84 - 552.16 (10³/uL) WBC 16.745 .21 16.325 - 17.165 (10³/uL) - Lot 5319 for February 2026 (Level 1) Analyte Mean SD Calculated Range RBC 2.270 .02 2.230 - 2.310 (10⁶/uL) HGB 5.35 .06 5.23 - 5.47 (g/dL) HCT 15.87 .20 15.47 - 16.27 (%) PLT 62 4.04 53.92 - 70.08 (10³/uL) WBC 2.631 .06 2.511 - 2.751 (10³/uL) - Lot 5319 for February 2026 (Level 2) Analyte Mean SD Calculated Range RBC 4.334 .02 4.294 - 4.374 (10⁶/uL) HGB 11.98 .05 11.88 - 12.08 (g/dL) HCT 34.03 .43 33.17 - 34.89 (%) PLT 222 7.04 207.92 - 236.08 (10³/uL) WBC 6.486 .09 6.306 - 6.666 (10³/uL) - Lot 5319 for February 2026 (Level 3) Analyte Mean SD Calculated Range RBC 5.233 .03 5.173 - 5.293 (10⁶/uL) HGB 16.05 .06 15.93 - 16.17 (g/dL) HCT 44.08 .53 43.02 - 45.14 (%) PLT 521 8.87 503.26 - 538.74 (10³/uL) WBC 16.536 .15 16.236 - 16.836 (10³/uL) - Lot 6038 for May 2026 (Level 1) Analyte Mean SD Calculated Range RBC 2.225 .021 2.183 - 2.267 (10⁶/uL) HGB 5.32 .04 5.24 - 5.40 (g/dL) HCT 15.74 .18 15.38 - 16.10 (%) PLT 57 5.10 46.80 - 67.20 (10³/uL) WBC 2.513 .055 2.403 - 2.623 (10³/uL) - Lot 6038 for May 2026 (Level 2) Analyte Mean SD Calculated Range RBC 4.268 .028 4.212 - 4.324 (10⁶/uL) HGB 12.37 .05 12.27 - 12.47 (g/dL) HCT 34.64 .34 33.96 - 35.32 (%) PLT 218.4 8.3 201.8 - 235.0 (10³/uL) WBC 6.958 .094 6.770 - 7.146 (10³/uL) - Lot 6038 for May 2026 (Level 3) Analyte Mean SD Calculated Range RBC 5.201 .035 5.131 - 5.271 (10⁶/uL) HGB 16.05 .07 15.91 - 16.19 (g/dL) HCT 44.19 .43 43.33 - 45.05 (%) PLT 530.4 9.6 511.2 - 549.6 (10³/uL) WBC 17.152 .193 16.766 - 17.538 (10³/uL) 4. Technical consultants one and two (TC1 and TC2) confirmed the survey findings in an interview on 07/28/2026 at 1:00 p.m.

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 hematology quality control (QC) records for September 2025, February 2026, and May 2026, and an interview with the technical consultants, the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytic performance for QC testing on the hematology analyzer in 2025 and 2026. The findings include: 1. A review of hematology QC records from the hematology analyzer revealed the QC ranges calculated from mean and standard deviation (SD) data on the monthly hematology QC printouts for RBC, HGB, HCT, PLT, and WBC for September 2025 (QC lot 5235), February 2026 (QC lot 5319), and May 2026 (QC lot 6038) were disparate 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. Technical consultants one and two (TC1 and TC2) confirmed the survey findings in an interview on 07/28/2026 at 1:00 p.m. Word Key: RBC = Red Blood Count HGB = Hemoglobin HCT = Hematocrit PLT = Platelet WBC = White Blood Count uL = microliter g/dL = grams/deciliter % = percent