

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1029009	(X3) Date Survey Completed 08/24/2026
Name of Provider or Supplier Tennessee Oncology Pllc	Street Address, City, State 103 Natchez Park Dr, Suite 103, Dickson, 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: A. Based on laboratory observation, a review of the laboratory's policy titled "POL-Competency Testing on Laboratory Personnel", a review of testing personnel (TP) competency assessment records, and staff interview, the laboratory failed to include blind test performance evaluation in the Sysmex XN 430 Complete Blood Count with automated White Blood Cell differential (CBC w/Diff) competency assessments in two of ten competency assessments reviewed from 2025 and 2026. The findings include: 1. Laboratory observation on 08/18/26 at approximately 8:25 a.m. revealed two Sysmex XN-430 instruments used for performing patient testing for CBC w/Diff. 2. A review of the laboratory's TP competency assessment policy revealed that "Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples" would be included in the competency assessment. 3. A review of testing personnel competency assessments revealed that assessment of test performance using previously analyzed specimens, internal blind samples, or external proficiency testing samples was not performed for the 2025 interim competency assessment (dated 10/27/25) for TP2, or the 2026 annual competency (dated 05/29/26) for TP4. The section for blind testing was marked off as competent without assessing the performance. 4. Technical consultant (TC) 1 confirmed the survey findings during an interview on 08/18/26 at 10 a.m. B. Based on laboratory observations, a review of a patient test report, a review of TP competency assessment documents, and staff interviews, the laboratory failed to ensure that competency assessments were performed for peripheral smear slide reviews for five of five testing personnel in 2025 and 2026. The findings include: 1.

	Laboratory observation on 08/18/26 at approximately 8:25 a.m. revealed a microscope and stains on the counter. During the observation, TP1 stated that the microscope was used to scan slides for platelet clumping in samples flagged by the CBC w/Diff instrument. 2. A review of a patient test report (patient number one) revealed the following, reported on 01/15/26 by TP1: "Slide reviewed, no platelet clumps seen." 3. A review of testing personnel competency assessments revealed that peripheral smear slide review competency was not assessed for five of five testing personnel in 2025 or 2026. 4. TC1 confirmed the survey findings during an interview on 08/18/26 at approximately 11:30 a.m.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) (c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on laboratory observation, a review of a patient test report, a lack of documentation, and a staff interview, the laboratory failed to verify the accuracy of the peripheral smear slide review for platelet clumping in 2025 and 2026. The findings include: 1. Laboratory observation on 08/18/26 at approximately 8:25 a.m. revealed a microscope and stains on the counter. During the observation, TP1 stated that the microscope was used to scan slides for platelet clumping in samples flagged by the CBC w/Diff instrument. 2. A review of a patient test report (patient number one) revealed the following, reported on 01/15/26 by TP1: "Slide reviewed, no platelet clumps seen." 3. There was no documentation that the laboratory had verified the accuracy of the peripheral smear slide reviews in 2025 or 2026. 4. TC1 confirmed the survey findings during an interview on 08/18/26 at approximately 11:30 a.m.
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 Sysmex XN 430 CBC w /Diff quality control (QC) records, and a staff interview, the laboratory failed to ensure that the manufacturer's package insert QC ranges were maintained and used for evaluation of QC for three of three master lots (nine of nine individual lots) reviewed from 2025 and 2026. The findings include: 1. Laboratory observation on 08/18/26 at approximately 8:25 a.m. revealed two Sysmex XN-430 instruments used for performing patient testing for CBC w/Diff (serial number 11991-primary and 12033-

	backup instrument). 2. A review of the Sysmex XN 430 CBC w/Diff QC records revealed the following: The laboratory used the peer-based Sysmex Beyond Care system to manage the QC limits for master lot numbers 5057 (Levels One, Two, and Three - dated 03/21/25 to 06/17/25) and 5319 (Levels One, Two, and Three - dated 11/19/25 to 02/24/26). Instrument records were not available on the survey date. Master lot number 6207 was put into use on 08/10/26. The QC ranges for both instruments were the same. Selected parameters revealed the following: 62071401 (Level One): RBC ($10^6/\mu\text{L}$) Package insert = 2.15 - 2.37 Laboratory range = 2.12 - 2.38 HGB (gm/dL) Package insert = 5.5 - 6.1 Laboratory range = 5.4 - 6.0 HCT % Package insert = 15.1 - 17.3 Laboratory range = 15.3 - 17.5 PLT ($10^3/\mu\text{L}$) Package insert = 36 - 87 Laboratory range = 34 - 84 WBC ($10^3/\mu\text{L}$) Package insert = 2.14 - 2.89 Laboratory range = 2.23 - 2.79 62071402 (Level Two) RBC ($10^6/\mu\text{L}$) Package insert = 3.93 - 4.26 Laboratory range = 3.88 - 4.28 HGB g/dL Package insert = 11.5 - 12.5 Laboratory range = 11.4 - 12.4 HCT % Package insert = 30.9 - 34.8 Laboratory range = 31.1 - 35.3 PLT ($10^3/\mu\text{L}$) Package insert = 187 - 263 Laboratory range = 176 - 256 WBC ($10^3/\mu\text{L}$) Package insert = 6.04 - 7.38 Laboratory range = 6.10 - 7.24 62071403 (Level Three) RBC ($10^6/\mu\text{L}$) Package insert = 5.05 - 5.47 Laboratory range = 5.00 - 5.52 HGB g/dL Package insert = 15.8 - 17.1 Laboratory range = 15.7 - 16.9 HCT % Package insert = 41.4 - 46.7 Laboratory range = 42.2 - 47.6 PLT ($10^3/\mu\text{L}$) Package insert = 469 - 596 Laboratory range = 458 - 580 WBC ($10^3/\mu\text{L}$) Package insert = 14.97 - 17.94 Laboratory range = 15.1 - 17.48 Word Key: HGB=Hemoglobin PLT=Platelet Count RBC= Red Blood Cell WBC=White Blood Cell $10^6/\mu\text{L}$= million/microliter g/dL= grams/deciliter %=percent pg=picograms 3. TC1 confirmed the survey findings during an interview on 08/18/26 at approximately 2:00 p.m.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on laboratory observation, a review of a patient test report, a review of TP competency assessment documents, and staff interviews, the TC failed to ensure that competency assessments were performed for peripheral smear slide reviews for 5 of 5 testing personnel in 2025 and 2026. Refer to D5209B.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) (b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy titled "POL-Competency Testing on Laboratory Personnel," a review of testing personnel competency assessment records,

and staff interview, TC2 failed to include blind test performance evaluation in the Sysmex XN 430 CBC w/Diff competency assessments in two of ten competency assessments reviewed from 2025 and 2026. Refer to D5209A.