Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2307956	07/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Cancer Specialists	4 Sheridan Square, Suite 102, Kingsport, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of the laboratory's procedure manual, a review of quality control (QC) records, and a staff interview, the laboratory failed to follow the procedure for hematology analyzer QC frequency in March 2026 when QC was not performed for one of 31 days in March 2026, with 37 patient test results being reported. The findings include: 1. Observation of the laboratory on 07.09.2026 at 8:15 a.m. revealed the Sysmex XN-550 (serial number 28145) hematology analyzer used for Complete Blood Count with automated differential (CBC w/ Diff) patient testing. 2. A review of the laboratory's procedure, "Quality Control," revealed that for hematology, "three levels of assayed controls are run each day." 3. A review of the laboratory's QC records for March 2026 revealed the laboratory did not run level 1, level 2, or level 3 QC on 03.09.2026. 4. An interview with the technical consultant on 07.09.2026 at 12:00 p.m. confirmed the above survey findings and confirmed that 37 patient test results were reported for CBC w/ Diff on 03.09.2026.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on laboratory observation and staff interview, the laboratory failed to ensure that it did not use blood collection tubes for reference laboratory patient testing past their expiration date on the date of the survey, 07.09.2026. The findings include: 1. Laboratory observation on 07.09.2026 at 8:15 a.m. revealed a tray with blood collection supplies, which included one 10 milliliter (mL) Becton Dickinson (BD) Vacutainer serum blood collection tube (lot number: 4022403, expiration date: 01.31.2026) for reference laboratory testing. 2. An interview with the technical consultant at 8:28 a.m. confirmed the above survey findings.
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, a review of 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 4 of 4 randomly reviewed lot numbers of QC for 2025 and 2026. The findings include: 1. Observation of the laboratory on 07.09.2026 at 8:15 a.m. revealed the Sysmex XN-550 (serial number 28145) 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 ranges for randomly reviewed analytes for the following lot numbers; -Lot 5067 (Level 1) Analyte Range RBC 2.18-2.41 10x6/uL HGB 5.6-6.2 g/dL HCT 16.0-18.4% PLT 36-85 10x3/uL WBC 2.10-2.84 10x3/uL (Level 2) Analyte Range RBC 4.13-4.47 10x6/uL HGB 12.2-13.3 g/dL HCT 33.5-37.8% PLT 188-265 10x3/uL WBC 6.33-7.74 10x3/uL (Level 3) Analyte Range RBC 5.06-5.48 10x6/uL HGB 16.2-17.5 g/dL HCT 43.2-48.7% PLT 464-591 10x3/uL WBC 14.77-17.69 10x3/uL -Lot 5235 (Level 1) Analyte Range RBC 2.21-2.45 10x6/uL HGB 5.2-5.8 g/dL HCT 15.1-17.4% PLT 36-85 10x3/uL WBC 1.96-2.66 10x3/uL (Level 2) Analyte Range RBC 4.15-4.49 10x6/uL HGB 11.7-12.7 g/dL HCT 32.1-36.2% PLT 187-264 10x3/uL WBC 6.09-7.44 10x3/uL (Level 3) Analyte Range RBC 4.99-5.41 10x6/uL HGB 15.8-17.1 g/dL HCT 41.7-47.0% PLT 470-598 10x3/uL WBC 15.10-18.09 10x3/uL -Lot 6038 (Level 1) Analyte Range RBC 2.14-2.36 10x6/uL HGB 5.1-5.7 g/dL HCT 14.8-17.0% PLT 36-85 10x3/uL WBC 2.14-2.89 10x3/uL (Level 2) Analyte Range RBC 4.11-4.45 10x6/uL HGB 12.0-13.0 g/dL HCT 32.8-37.0% PLT 184-259 10x3/uL WBC 6.25-7.64 10x3/uL (Level 3) Analyte Range RBC 4.99-5.40 10x6/uL HGB 15.5-16.8 g/dL HCT 41.4-46.7% PLT 469-596 10x3/uL WBC 15.54-18.62 10x3/uL -Lot 6122 (Level 1) Analyte Range RBC 2.17-2.40 10x6/uL HGB 5.3-

	5.9 g/dL HCT 15.3-17.6% PLT 36-86 10x3/uL WBC 2.07-2.80 10x3/uL (Level 2) Analyte Range RBC 4.13-4.47 10x6/uL HGB 11.3-12.3 g/dL HCT 31.2-35.2% PLT 182-256 10x3/uL WBC 6.12-7.49 10x3/uL (Level 3) Analyte Range RBC 5.05-5.48 10x6/uL HGB 15.4-16.7 g/dL HCT 41.0-46.2% PLT 463-590 10x3/uL WBC 14.95-17.91 10x3/uL 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 5067 (Level 1 for April 2025) Analyte Range RBC 2.18-2.42 10x6/uL HGB 5.6-6.2 g/dL HCT 16.2-18.2% PLT 37-83 10x3/uL WBC 2.22-2.72 10x3/uL (Level 2 for April 2025) Analyte Range RBC 4.11-4.49 10x6/uL HGB 12.3-13.1 g/dL HCT 33.7-37.7% PLT 189-263 10x3/uL WBC 6.47-7.61 10x3/uL (Level 3 for April 2025) Analyte Range RBC 5.04-5.50 10x6/uL HGB 16.2-17.4 g/dL HCT 43.6-48.4% PLT 473-583 10x3/uL WBC 15.09-17.37 10x3/uL -Lot 5235 (Level 1 for September 2025) Analyte Range RBC 2.21-2.45 10x6/uL HGB 5.2-5.8 g/dL HCT 15.3-17.3% PLT 37-83 10x3/uL WBC 2.08-2.54 10x3/uL (Level 2 for September 2025) Analyte Range RBC 4.13-4.51 10x6/uL HGB 11.8-12.6 g/dL HCT 32.2-36.0% PLT 189-263 10x3/uL WBC 6.22-7.32 10x3/uL (Level 3 for September 2025) Analyte Range RBC 4.97-5.43 10x6/uL HGB 15.9-17.1 g/dL HCT 42.0-46.8% PLT 478-590 10x3/uL WBC 15.43-17.75 10x3/uL -Lot 6038 (Level 1 for February 2026) Analyte Range RBC 2.11-2.37 10x6/uL HGB 5.0-5.6 g/dL HCT 14.6-16.8% PLT 37-83 10x3/uL WBC 2.22-2.80 10x3/uL (Level 2 for February 2026) Analyte Range RBC 4.08-4.50 10x6/uL HGB 11.8-12.8 g/dL HCT 32.4-36.8% PLT 186-258 10x3/uL WBC 6.28-7.54 10x3/uL (Level 3 for February 2026) Analyte Range RBC 4.96-5.48 10x6/uL HGB 15.4-16.6 g/dL HCT 41.4-46.8% PLT 476-588 10x3/uL WBC 15.61-18.25 10x3/uL -Lot 6122 (Level 1 for May 2026) Analyte Range RBC 2.14-2.40 10x6/uL HGB 5.3-5.9 g/dL HCT 15.2-17.4% PLT 34-84 10x3/uL WBC 2.17-2.73 10x3/uL (Level 2 for May 2026) Analyte Range RBC 4.08-4.50 10x6/uL HGB 11.1-12.1 g/dL HCT 31.0-35.2% PLT 172-250 10x3/uL WBC 6.21-7.45 10x3/uL (Level 3 for May 2026) Analyte Range RBC 5.01-5.53 10x6/uL HGB 15.3-16.5 g/dL HCT 41.2-46.4% PLT 450-570 10x3/uL WBC 15.05-17.61 10x3/uL 4. An interview with the technical consultant on 07.09.2026 at 12:00 p.m. confirmed the above survey findings. Word Key: RBC = Red Blood Count HGB = Hemoglobin HCT = Hematocrit PLT = Platelet WBC = White Blood Count uL = microliter g/dL = grams/deciliter % = percent
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 April 2025, September 2025, February 2026, and May 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 analyzer in 2025 and 2026. The findings include: 1. Review of hematology QC records from the hematology analyzer revealed the QC ranges on the monthly analyzer QC printouts for RBC, HGB, HCT, PLT, and WBC for April 2025 (QC lot 5067), September 2025 (QC lot 5235), February 2026 (QC lot 6038), and May 2026 (QC lot 6122) 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. An interview with the technical consultant on 07.09.2026 at 12:00 p.m. confirmed the above survey findings.