

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0958076	(X3) Date Survey Completed 08/27/2026
Name of Provider or Supplier Cancer Center At Cookeville Regional Medical Ctr	Street Address, City, State 1 Medical Center Blvd, Cookeville, 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
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 and the laboratory's QC records, and staff interviews, 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 in 2025 and 2026. The findings include: 1. Laboratory observation on August 27, 2026, at 11:00 a. m. revealed a Sysmex XN-20 hematology analyzer (Serial Number 80238) used for Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) patient testing. 2. A review of the manufacturer's quality control (QC) package inserts labeled, "XN CHECK HEMATOLOGY CONTROL FOR SYSMEX XN-SERIES (XN-10, XN-20 ANALYZERS)," and the laboratory's printed instrument QC data records revealed that the instrument QC ranges differed from the manufacturer's package insert ranges for randomly selected analytes as follows: - Lot 4337 Expiration Date: 02/23/25 Level 1 Low Abnormal- 43371401 RBC (10⁶/uL) Package Insert Range: 2.24 - 2.48 Laboratory Range: 2.26 - 2.50 HGB (g/dL) Package Insert Range: 5.5 - 6.1 Laboratory Range: 5.6 - 6.2 HCT (%) Package Insert Range: 16.0 - 18.4

Laboratory Range: 16.7 - 18.9 PLT ($10^3/\mu\text{L}$) Package Insert Range: 57 - 126
 Laboratory Range: 63 - 119 WBC ($10^3/\mu\text{L}$) Package Insert Range: 2.77 - 3.38
 Laboratory Range: 2.76 - 3.34 - Lot 4337 Expiration Date: 02/23/2025 Level 2
 Normal- 43371402 RBC ($10^6/\mu\text{L}$) Package Insert Range: 4.14 - 4.48 Laboratory
 Range: 4.12 - 4.50 HGB (g/dL) Package Insert Range: 11.4 - 12.4 Laboratory Range:
 11.5 - 12.3 HCT (%) Package Insert Range: 32.7 - 36.9 Laboratory Range: 33.3 - 37.3
 PLT ($10^3/\mu\text{L}$) Package Insert Range: 193 - 266 Laboratory Range: 201 - 253 WBC
 ($10^3/\mu\text{L}$) Package Insert Range: 6.49 - 7.47 Laboratory Range: 6.45 - 7.47 - Lot 4337
 Expiration Date: 02/23/2025 Level 3 High Abnormal- 43371403 RBC ($10^6/\mu\text{L}$)
 Package Insert Range: 4.87 - 5.28 Laboratory Range: 4.86 - 5.30 HGB (g/dL) Package
 Insert Range: 14.7 - 15.9 Laboratory Range: 14.8 - 15.8 HCT (%) Package Insert
 Range: 40.9 - 46.2 Laboratory Range: 42.0 - 46.6 PLT ($10^3/\mu\text{L}$) Package Insert
 Range: 459 - 596 Laboratory Range: 469 - 563 WBC ($10^3/\mu\text{L}$) Package Insert
 Range: 16.39 - 18.49 Laboratory Range: 16.28 - 18.36 - Lot 5363 Expiration Date: 03
 /22/2026 Level 1 Low Abnormal- 53631401 RBC ($10^6/\mu\text{L}$) Package Insert Range:
 2.21 - 2.44 Laboratory Range: 2.17 - 2.43 HGB (g/dL) Package Insert Range: 5.2 - 5.7
 Laboratory Range: 5.1 - 5.7 HCT (%) Package Insert Range: 15.2 - 17.5 Laboratory
 Range: 15.1 - 17.3 PLT ($10^3/\mu\text{L}$) Package Insert Range: 53 - 118 Laboratory Range:
 56 - 110 WBC ($10^3/\mu\text{L}$) Package Insert Range: 2.75 - 3.37 Laboratory Range: 2.72 -
 3.38 - Lot 5363 Expiration Date: 03/22/2026 Level 2 Normal- 53631402 RBC (10^6
 $/\mu\text{L}$) Package Insert Range: 4.16 - 4.51 Laboratory Range: 4.09 - 4.51 HGB (g/dL)
 Package Insert Range: 11.7 - 12.7 Laboratory Range: 11.6 - 12.6 HCT (%) Package
 Insert Range: 33.3 - 37.5 Laboratory Range: 33.0 - 37.6 PLT ($10^3/\mu\text{L}$) Package
 Insert Range: 197 - 272 Laboratory Range: 198 - 258 WBC ($10^3/\mu\text{L}$) Package Insert
 Range: 6.54 - 7.53 Laboratory Range: 6.42 - 7.58 - Lot 5363 Expiration Date: 03/22
 /2026 Level 3 High Abnormal- 53631403 RBC ($10^6/\mu\text{L}$) Package Insert Range: 5.06
 - 5.48 Laboratory Range: 4.96 - 5.48 HGB (g/dL) Package Insert Range: 15.1 - 16.3
 Laboratory Range: 14.9 - 16.1 PLT ($10^3/\mu\text{L}$) Package Insert Range: 476 - 619
 Laboratory Range: 475 - 583 WBC ($10^3/\mu\text{L}$) Package Insert Range: 15.65 - 17.65
 Laboratory Range: 15.36 - 17.62 - Lot 6054 Expiration Date: 05/17/2026 Level 1 Low
 Abnormal- 60541401 RBC ($10^6/\mu\text{L}$) Package Insert Range: 2.23 - 2.47 Laboratory
 Range: 2.18 - 2.44 HGB (g/dL) Package Insert Range: 5.3 - 5.9 Laboratory Range: 5.2
 - 5.8 HCT (%) Package Insert Range: 15.7 - 18.0 Laboratory Range: 15.4 - 17.8 PLT
 ($10^3/\mu\text{L}$) Package Insert Range: 55 - 123 Laboratory Range: 57 - 115 WBC (10^3
 $/\mu\text{L}$) Package Insert Range: 2.68 - 3.28 Laboratory Range: 2.64 - 3.28 - Lot 6054
 Expiration Date: 05/17/2026 Level 2 Normal- 60541402 RBC ($10^6/\mu\text{L}$) Package
 Insert Range: 4.14 - 4.49 Laboratory Range: 4.06 - 4.48 HGB (g/dL) Package Insert
 Range: 11.6 - 12.6 Laboratory Range: 11.4 - 12.4 HCT (%) Package Insert Range:
 33.3 - 37.5 Laboratory Range: 32.8 - 37.4 PLT ($10^3/\mu\text{L}$) Package Insert Range: 197 -
 273 Laboratory Range: 195 - 257 WBC ($10^3/\mu\text{L}$) Package Insert Range: 6.33 - 7.28
 Laboratory Range: 6.17 - 7.29 - Lot 6054 Expiration Date: 05/17/2026 Level 3 High
 Abnormal- 60541403 RBC ($10^6/\mu\text{L}$) Package Insert Range: 4.89 - 5.30 Laboratory
 Range: 4.78 - 5.28 HGB (g/dL) Package Insert Range: 14.5 - 15.7 Laboratory Range:
 14.3 - 15.5 HCT (%) Package Insert Range: 41.1 - 46.3 Laboratory Range: 40.9 - 46.3
 PLT ($10^3/\mu\text{L}$) Package Insert Range: 470 - 610 Laboratory Range: 463 - 571 WBC
 ($10^3/\mu\text{L}$) Package Insert Range: 15.88 - 17.91 Laboratory Range: 15.60 - 17.88 3.
 The Administrative Director, the Oncology Clinic Director, and the Laboratory Lead
 Tech confirmed the survey findings in an interview on August 27, 2026, at 2:45 p.m.
 Word Key: RBC = Red Blood Cell HCT = Hematocrit HGB = Hemoglobin PLT =
 Platelet WBC = White Blood Cell $10^6/\mu\text{L}$ = million/microliter % = percent g/dL =
 grams/deciliter $10^3/\mu\text{L}$ = thousand/microliter .

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 February 2025, January 2026, and May 2026, and staff interviews, 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 for three of three months reviewed. The findings include: 1. A review of hematology QC records from the hematology instrument revealed QC ranges on the monthly QC printouts for RBC, HGB, HCT, PLT, and WBC for February 2025 (lot 4337); RBC, HGB, HCT, PLT, and WBC for January 2026 (lot 5363); and RBC, HGB, HCT, PLT, and WBC for May 2026 (lot 6054) 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 the daily QC runs for acceptability. 2. The Administrative Director, the Oncology Clinic Director, and the Laboratory Lead Tech confirmed the survey findings in an interview on August 27, 2026, at 2:45 p.m.