

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0717554	(X3) Date Survey Completed 08/17/2026
Name of Provider or Supplier Holston Medical Group-Fort Henry	Street Address, City, State 4848 Fort Henry Drive, 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
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 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. Observation of the laboratory on 08/17/2026 at 9:40 a.m. revealed the Sysmex XN330 (serial number 14356) analyzer used for Complete Blood Count with automated differential (CBC w/Diff) patient testing. 2. A review of the manufacturer's QC package inserts labeled "XN-L Check Hematology Controls for Sysmex XN-L Analyzers" and the laboratory's printed analyzer QC chart records revealed that the analyzer QC ranges differed from the manufacturer's package insert for randomly selected analytes as follows: Lot 5067 Expiration Date: 06.17.2025. Used during June 2025 Level 1 (50671401) RBC (10⁶/uL) Package insert: 2.18-2.41 Analyzer range: 2.18-2.42 HCT (%) Package insert: 16.0-18.4 Analyzer range: 16.2-18.2 HGB (g/dL) Package insert: 5.6-6.2 Analyzer range: 5.6-6.2 PLT (10³/uL) Package insert: 36-85 Analyzer range: 37-83 WBC (10³/uL)

Package insert: 2.10-2.84 Analyzer range: 2.22-2.72 Level 2 (50671402) RBC (10^6 /uL) Package insert: 4.13-4.47 Analyzer range: 4.11-4.49 HCT (%) Package insert: 33.5-37.8 Analyzer range: 33.7-37.7 HGB (g/dL) Package insert: 12.2-13.3 Analyzer range: 12.3-13.1 PLT (10^3 /uL) Package insert: 188-265 Analyzer range: 189-263 WBC (10^3 /uL) Package insert: 6.33-7.74 Analyzer range: 6.47-7.61 Level 3 (50671403) RBC (10^6 /uL) Package insert: 5.06-5.48 Analyzer range: 5.04-5.50 HCT (%) Package insert: 43.2-48.7 Analyzer range: 43.6-48.4 HGB (g/dL) Package insert: 16.2-17.5 Analyzer range: 16.2-17.4 PLT (10^3 /uL) Package insert: 464-591 Analyzer range: 473-583 WBC (10^3 /uL) Package insert: 14.77-17.69 Analyzer range: 15.09-17.37 Lot 5319 Expiration Date: 02.24.2026. Used during December 2025 Level 1 (53191401) RBC (10^6 /uL) Package insert: 2.16-2.39 Analyzer range: 2.16-2.40 HCT (%) Package insert: 14.8-17.0 Analyzer range: 14.9-16.9 HGB (g/dL) Package insert: 5.1-5.7 Analyzer range: 5.1-5.7 PLT (10^3 /uL) Package insert: 38-90 Analyzer range: 39-89 WBC (10^3 /uL) Package insert: 2.21-2.99 Analyzer range: 2.34-2.86 Level 2 (53191402) RBC (10^6 /uL) Package insert: 4.15-4.50 Analyzer range: 4.14-4.52 HCT (%) Package insert: 32.1-36.2 Analyzer range: 32.2-36.2 HGB (g/dL) Package insert: 11.6-12.6 Analyzer range: 11.7-12.5 PLT (10^3 /uL) Package insert: 185-261 Analyzer range: 187-259 WBC (10^3 /uL) Package insert: 5.78-7.06 Analyzer range: 5.90-6.94 Level 3 (53191403) RBC (10^6 /uL) Package insert: 5.00-5.42 Analyzer range: 4.98-5.44 HCT (%) Package insert: 41.3-46.6 Analyzer range: 41.7-46.3 HGB (g/dL) Package insert: 15.5-16.8 Analyzer range: 15.5-16.7 PLT (10^3 /uL) Package insert: 456-580 Analyzer range: 464-572 WBC (10^3 /uL) Package insert: 15.01-17.98 Analyzer range: 15.34-17.66 Lot 6038 Expiration Date: 05.19.2026. Used during May 2026 Level 1 (60381401) RBC (10^6 /uL) Package insert: 2.14-2.36 Analyzer range: 2.11-2.37 HCT (%) Package insert: 14.8-17.0 Analyzer range: 15.0-17.2 HGB (g/dL) Package insert: 5.1-5.7 Analyzer range: 5.0-5.6 PLT (10^3 /uL) Package insert: 36-85 Analyzer range: 33-83 WBC (10^3 /uL) Package insert: 2.14-2.89 Analyzer range: 2.23-2.81 Level 2 (60381402) RBC (10^6 /uL) Package insert: 4.11-4.45 Analyzer range: 4.07-4.49 HCT (%) Package insert: 32.8-37.0 Analyzer range: 33.1-37.7 HGB (g/dL) Package insert: 12.0-13.0 Analyzer range: 11.8-12.8 PLT (10^3 /uL) Package insert: 184-259 Analyzer range: 177-257 WBC (10^3 /uL) Package insert: 6.25-7.64 Analyzer range: 6.30-7.56 Level 3 (60381403) RBC (10^6 /uL) Package insert: 4.99-5.40 Analyzer range: 4.95-5.47 HCT (%) Package insert: 41.4-46.7 Analyzer range: 42.3-47.9 HGB (g/dL) Package insert: 15.5-16.8 Analyzer range: 15.4-16.6 PLT (10^3 /uL) Package insert: 469-596 Analyzer range: 465-591 WBC (10^3 /uL) Package insert: 15.54-18.62 Analyzer range: 15.63-18.29 3. An interview with technical consultant (TC) one and two on 08/17/2026 at 12:00 p.m. confirmed the above survey findings. Word Key: RBC = Red Blood Cell HCT = Hematocrit HGB = Hemoglobin PLT = Platelet WBC = White Blood Cell 10^6 /uL = million/microliter % = percent g/dL = grams/deciliter 10^3 /uL = 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 the hematology quality control (QC) records for June 2025, December 2025 and May 2026 and an interview with technical consultant (TC) one and two, the laboratory director failed to ensure the establishment and maintenance of

acceptable levels of analytical performance for QC testing on the hematology analyzer used to perform complete blood count with automated differential (CBC w/Diff) patient testing in 2025 and 2026. The findings include: 1. A review of the hematology QC records from the hematology analyzer revealed QC ranges on the monthly analyzer QC printouts for RBC, HCT, HGB, PLT, and WBC for June 2025 (lot 5067), December 2025 (lot 5319), and May 2026 (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. An interview with TC one and two on 08/17/2026 at 12:00 p. m. confirmed the above survey findings.