

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D1081456	(X3) Date Survey Completed 08/18/2026
Name of Provider or Supplier Priority Care, Llc	Street Address, City, State 5751 Bradford Hicks Dr, Livingston, 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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on laboratory observation, lack of documentation, a review of patient test records, a review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116), and staff interview, the laboratory failed to verify the patient normal/ reference ranges used by the laboratory for Complete Blood Count with Automated White Blood Cell Differential (CBC w/Diff) testing using the Sysmex XQ-320 hematology analyzer, with approximately 3102 patients reported since patient testing began on 11/20/2025. The findings include: 1. Laboratory observation on August 12, 2026, at 10:00 a.m. revealed a Sysmex XQ-320 hematology analyzer (Serial Number 15153) used for CBC w/Diff patient testing. The instrument was new since the last survey date. 2. A review of the instrument validation records revealed no documentation that a normal/ reference range study had been performed to verify the ranges used by the laboratory. 3. A review of patient test records revealed that patient testing for CBC w/Diff began on 11/20/2025 on the new instrument, with patient medical record number 17808. 4. A review of the Form CMS-116 revealed an approximate volume of 3102 patient CBCs w/Diff had been performed since patient testing began on 11/20/2025. 5. The Laboratory Director and Testing Personnel 5 and 8 (TP5 and TP8) confirmed the survey findings in an interview on August 12, 2026, at 12:45 p.m. when they stated that they adopted the

manufacturer's ranges for male and female, adult and pediatric CBC w/Diff but did not perform a verification of these ranges before the analyzer was placed in use on November 20, 2025.

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 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 2 of 3 randomly reviewed lot numbers of QC since patient testing began on this analyzer on November 20, 2025. The findings include: 1. Laboratory observation on August 12, 2026, at 10:00 a.m. revealed a Sysmex XQ-320 hematology analyzer (Serial Number 15153) 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, "EIGHTCHECK-3WP X-TRA HEMATOLOGY CONTROL X-Q SERIES," 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 5357 Expiration Date: 04/01/2026 Level 2 Normal- 53571402 RBC ($10^6/\mu\text{L}$) Package Insert Range: 4.20 - 4.65 Laboratory Range: 4.20 - 4.66 - Lot 6076 Expiration Date: 06/24/26 Level 1 Low Abnormal- 60761401 RBC ($10^6/\mu\text{L}$) Package Insert Range: 2.19 - 2.53 Laboratory Range: 2.18 - 2.56 HCT (%) Package Insert Range: 15.0 - 18.2 Laboratory Range: 15.0 - 18.6 PLT ($10^3/\mu\text{L}$) Package Insert Range: 58 - 106 Laboratory Range: 52 - 114 WBC ($10^3/\mu\text{L}$) Package Insert Range: 3.23 - 3.97 Laboratory Range: 3.06 - 3.98 - Lot 6076 Expiration Date: 06/24/2026 Level 2 Normal- 60761402 RBC ($10^6/\mu\text{L}$) Package Insert Range: 4.29 - 4.75 Laboratory Range: 4.25 - 4.81 HCT (%) Package Insert Range: 33.8 - 39.0 Laboratory Range: 33.9 - 39.5 PLT ($10^3/\mu\text{L}$) Package Insert Range: 193 - 267 Laboratory Range: 182 - 266 WBC ($10^3/\mu\text{L}$) Package Insert Range: 6.57 - 7.91 Laboratory Range: 6.46 - 7.90 - Lot 6076 Expiration Date: 06/24/2026 Level 3 High Abnormal- 60761403 RBC ($10^6/\mu\text{L}$) Package Insert Range: 5.21 - 5.77 Laboratory Range: 5.19 - 5.85 HGB (g/dL) Package Insert Range: 15.8 - 17.6 Laboratory Range: 15.7 - 17.5 HCT (%) Package Insert Range: 43.3 - 50.1 Laboratory Range: 43.8 - 50.8 PLT ($10^3/\mu\text{L}$) Package Insert Range: 470 - 602 Laboratory Range: 444 - 590 WBC ($10^3/\mu\text{L}$) Package Insert Range: 17.59 - 19.83 Laboratory Range: 17.13 - 19.97 3. The Laboratory Director and Testing Personnel 5 and 8 (TP5 and TP8) confirmed the survey findings in an interview on August 12, 2026, at 12:45 p.m. Word Key: RBC =

Red Blood Cell HGB = Hemoglobin HCT = Hematocrit PLT = Platelet WBC = White Blood Cell 10⁶/uL = million/microliter % = percent 10³/uL = thousand/microliter g/dL = grams/deciliter

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 November 2025, January 2026, and May 2026, and staff interview, the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytic performance for QC testing on the hematology analyzer in 2026 for two 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 for January 2026 (lot 5357), and RBC, HGB, HCT, PLT, and WBC for May 2026 (lot 6076) 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 Laboratory Director and Testing Personnel 5 and 8 (TP5 and TP8) confirmed the survey findings in an interview on August 12, 2026, at 12:45 p.m.