| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 44D0308253 | 08/10/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Heritage Medical Associates, Pc | 222 22nd Avenue North, Suite 100, Nashville, 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 |
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| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the laboratory, a review of the laboratory's procedures, calibration records, lack of records, and staff interviews, the laboratory failed to perform calibration verification every six months for the hemoglobin A1c analyte in 2024, 2025, and 2026. The findings include: 1. Observation of the laboratory on 08/10/2026 at 10:00 a.m. revealed the Bio-Rad D-100 instrument (Serial # DT5L107114) used to perform hemoglobin A1c patient testing. 2. A review of the laboratory's procedure titled "Hemoglobin A1c (Bio-Rad D-100)" revealed the following: Section "Preparation of Reagents": The laboratory used a two-point calibrator pack and two levels of Diabetes Control. Section "Quality Control": The laboratory used Levels |

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| | One and Two of the Diabetes Control each day of patient testing. Section "Calibration": The laboratory performed calibrations with each new analytical cartridge. 3. A review of the laboratory's hemoglobin A1c calibration report performed on 07/13/2026 revealed a two-point calibration. 4. No documentation of calibration verification studies with three or more points was available on the date of the survey (08/10/2026) for 2024, 2025, or 2026. 5. An interview with technical consultants one and two on 08/10/2026 at 3:00 p.m. confirmed the survey findings. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>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 2 of 2 randomly reviewed lot numbers of QC in 2026. The findings include: 1. Observation of the laboratory on 08/10/2026 at 9:30 a. m. revealed two Sysmex XN2000 (Serial #'s 14341/41481) instruments used for complete blood count with automated differential (CBC w/Diff) and reticulocyte (Retic) patient testing. 2. A review of the manufacturer's QC package inserts labeled "XN Check Hematology Controls for Sysmex XN-L Analyzers" and the laboratory's printed instrument QC chart records revealed that the instrument QC ranges differed from the manufacturer's package insert for randomly selected analytes as follows: Lot 6139 Expiration Date: 08/09/2026 (06/01/2026-06/30/2026) Level 1- 61391101 RBC (10^6/uL) Package insert: 2.18-2.41 Laboratory (Nickname XN-2000-1-R): 2.17-2.43 HCT (%) Package insert: 14.8-17.0 Laboratory (Nickname XN-2000-1-R): 15.0-17.2 HGB (g/dL) Package insert: 5.2-5.7 Laboratory (Nickname XN-2000-1-R): 5.1-5.7 PLT (10^3/uL) Package insert: 58-107 Laboratory (Nickname XN-2000-1-R): 51-103 Laboratory (Nickname XN-2000-1-L): 51-103 WBC (10^3/uL) Package insert: 2.86-3.72 Laboratory (Nickname XN-2000-1-R): 2.70-3.36 Laboratory (Nickname XN-2000-1-L): 2.69-3.35 Retic (%) Package insert: 5.32-9.05 Laboratory (Nickname XN-2000-1-R): 4.79-6.75 Level 2 (61391102) RBC (10^6/uL) Package insert: 4.07-4.40 Laboratory (Nickname XN-2000-1-R): 4.00-4.42 HCT (%) Package insert: 31.4-35.4 Laboratory (Nickname XN-2000-1-R): 31.4-35.8 HGB (g/dL) Package insert: 11.2-12.2 Laboratory (Nickname XN-2000-1-R): 11.0-12.0 PLT (10^3/uL) Package insert: 206-273 Laboratory (Nickname XN-2000-1-R): 198-258 Laboratory (Nickname XN-2000-1-L): 199-259 WBC (10^3/uL) Package insert: 6.91-8.44 Laboratory (Nickname XN-2000-1-R): 6.30-7.44 Laboratory (Nickname XN-2000-1-L): 6.30-7.44 Retic (%) Package insert: 2.22-3.78 Laboratory (Nickname XN-2000-1-R): 1.98-2.88 Level 3 (61391103) RBC (10^6/uL) Package insert: 4.81-5.21 Laboratory (Nickname XN-2000-1-R): 4.72-5.20 HGB (g/dL) Package insert: 14.8-16.1 Laboratory (Nickname |

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| | XN-2000-1-R): 14.6-15.8 PLT (10^3/uL) Package insert: 476-594 Laboratory (Nickname XN-2000-1-R): 459-565 Laboratory (Nickname XN-2000-1-L): 462-568 WBC (10^3/uL) Package insert: 16.83-19.75 Laboratory (Nickname XN-2000-1-R): 15.28-17.52 Laboratory (Nickname XN-2000-1-L): 15.27-17.51 Retic (%) Package insert: 0.96-1.95 Laboratory (Nickname XN-2000-1-R): 0.85-1.65 Lot 6083 Expiration Date: 06/14/2026 (06/01/2026-06/12/2026) Level 1 (60831101) RBC (10^6 /uL) Package insert: 2.15-2.37 Laboratory (Nickname XN-2000-1-R): 2.12-2.38 HCT (%) Package insert: 15.1-17.4 Laboratory (Nickname XN-2000-1-R): 15.2-17.4 HGB (g/dL) Package insert: 5.2-5.8 Laboratory (Nickname XN-2000-1-R): 5.1-5.7 PLT (10^3/uL) Package insert: 53-119 Laboratory (Nickname XN-2000-1-R): 53-109 WBC (10^3/uL) Package insert: 2.66-3.25 Laboratory (Nickname XN-2000-1-R): 2.61-3.25 Retic (%) Package insert: 4.83-7.10 Laboratory (Nickname XN-2000-1-R): 4.98-7.00 Level 2 (60831102) RBC (10^6/uL) Package insert: 4.02-4.36 Laboratory (Nickname XN-2000-1-R): 3.95-4.37 HCT (%) Package insert: 31.4-35.4 Laboratory (Nickname XN-2000-1-R): 31.5-35.9 HGB (g/dL) Package insert: 11.0-11.9 Laboratory (Nickname XN-2000-1-R): 10.8-11.8 PLT (10^3/uL) Package insert: 200-276 Laboratory (Nickname XN-2000-1-R): 197-259 WBC (10^3/uL) Package insert: 6.51-7.49 Laboratory (Nickname XN-2000-1-R): 6.33-7.47 Retic (%) Package insert: 1.94-2.97 Laboratory (Nickname XN-2000-1-R): 1.95-2.83 Level 3 (60831103) RBC (10^6/uL) Package insert: 4.83-5.23 Laboratory (Nickname XN-2000-1-R): 4.74-5.24 HCT (%) Package insert: 41.1-46.3 Laboratory (Nickname XN-2000-1-R): 41.2-46.6 HGB (g/dL) Package insert: 14.8-16.1 Laboratory (Nickname XN-2000-1-R): 14.6-15.8 PLT (10^3/uL) Package insert: 471-612 Laboratory (Nickname XN-2000-1-R): 467-575 WBC (10^3/uL) Package insert: 15.79-17.81 Laboratory (Nickname XN-2000-1-R): 15.50-17.76 Retic (%) Package insert: 0.78-1.70 Laboratory (Nickname XN-2000-1-R): 0.78-1.52 3. An interview with technical consultants (TC) one and two on 08/10/2026 at 3:00 p.m. confirmed the survey findings. Word Key: # = number 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<br>CFR(s): 493.1407(e)(6)<br><br>(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the hematology quality control (QC) records for June 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 performance for QC testing on the hematology instruments used to perform complete blood count with automated differential (CBC w/Diff) and reticulocyte (Retic) patient testing in 2026. The findings include: 1. A review of the hematology QC records from the hematology instruments revealed QC ranges on the monthly QC printouts for RBC, HCT, HGB, PLT, WBC, and Retic for June 2026 (lots 6139 and 6083) 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 08/10/2026 at 3:00 p.m. confirmed the survey findings. |