

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D2047655	<b>(X3) Date Survey Completed</b>  09/26/2022
<b>Name of Provider or Supplier</b>  Amerathon Health Llc DbA American Health	<b>Street Address, City, State</b>  10204 Lantern Road, Fishers, IN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to calibrate one of one Hematology analyzer (DXH-900, serial # BD38532), for twelve of twelve months (January through December) 2021 and four of four patient test reports (Pt#1-Pt#4) reviewed. Findings include: 1) Review of policy titled, "Beckman Coulter Unicel DxH Series Calibration Procedure, Policy Number 9-111-3M", laboratory director approval date 3-5-2020, read "C. Calibration Frequency... 2. The laboratory must calibrate and/or verify calibration at least every six months and on an 'as needed' basis to ensure accuracy of the system..." (page 3 of 7, section C). 2) Review of calibration data for Hematology testing indicated none was available for review in 2021. 3) Medical record review indicated the following four patients had Hematology testing performed in 2021: Pt# Result Date Pt#1 WBC=6.3 K/cmm 1/26/21 Pt#2 RBC=4.09 M/cmm 4/23/21 Pt#3 Hgb=9.9 g/dL 6/23/21 Pt#4 Hct=34.7 % 11/17/21 Pt#=patient number WBC=White Blood Cell K/cmm=cells per microliter RBC=Red blood Cell M /cmm=cells per microliter Hgb = Hemoglobin g/dL=grams per deciliter Hct=Hematocrit 4) In interview on 9/26/22 at 1:02 pm, SP-2 (Testing Personnel)</p>

confirmed no calibrations were performed in 2021 on the DXH-900 series analyzer used for Hematology testing. 5) Approximate annual test volume for Hematology=12,254,368.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform calibration verification/linearities on two of two analyzers (Hematology: DXH-900/Serial# BD38532 and Chemistry: Au-5800/Serial# 2018013706) for twelve of twelve months (January through December) 2021 and eight of eight patients (Pt#1-Pt#8) reviewed. Findings include: 1) Review of policy titled, "Beckman Coulter Unicel DxH Series Calibration Procedure, Policy Number 9-111-3M, laboratory director approval date 3-5-2020, read "C. Calibration Frequency... 2. The laboratory must calibrate and/or verify calibration at least every six months and on an 'as needed' basis to ensure accuracy of the system..." (page 3 of 7, section C). 2) Review of policy titled, "Chemistry Calibration, Calibration Verification and AMR Guidelines, Policy Number 8-101.3M," (AMR = Analytic Measurement Range) laboratory director approval date 12-5-2019, read "D. Calibration Verification Frequency. 1) Same as for AMR Verification frequency listed below... 3. Calibration and AMR Verification Frequency... 6. At least every six months..." (page 3 and 4, section D). 3) Review of calibration, calibration verification and AMR data for Hematology and Chemistry testing indicated none was available for review from 2021. 4) Medical Record review indicated the following patients had Hematology and Chemistry testing performed in 2021: a. Hematology: Pt# Result Date Pt#1 WBC=6.3 K/cmm 1/26/21 Pt#2 RBC=4.09 M/cmm 4/23/21 Pt#3 Hgb=9.9 g/dL 6/23/21 Pt#4 Hct=34.7 % 11/17/21 b. Chemistry: Pt# Result Date Pt#5 Sodium=134 mEq/L 1/29/21 Pt#6 Potassium=4.7 mEq/L 6/21/21 Pt#7 Calcium=8.4 mg/dL 10/20/21 Pt#8 Chloride=109 mEq/L 11/17/21 Pt#=patient number WBC=White Blood Cell K/cmm=cells per microliter RBC=Red blood Cell M/cmm=cells per microliter Hgb=Hemoglobin g/dL=grams per deciliter Hct=Hematocrit mEq/L=millimeter equivalents per liter mg/dL=milligram

per deciliter 5) Upon request for calibration verification documentation, on 9/26/22 at 1:35 pm, SP-2 confirmed no calibration verification/linearities and/or AMR verification was performed the Hematology and Chemistry analyzers in 2021. 6) Total approximate annual test volume for Hematology and Chemistry=28,539,745.