Status Active PolicyStat ID 16917959

Beaumont

Origination	10/29/2024
Last Approved	10/29/2024
Effective	10/29/2024
Last Revised	10/29/2024
Next Review	10/29/2026

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Area	Laboratory-Chemistry
Applicability	Taylor + Trenton + Wayne

Calibration Verification on Radiometer ABL800 series Analyzers

I. PURPOSE AND OBJECTIVE:

To provide instructions for staff performing Calibration Verification on the Radiometer ABL800 Series analyzer.

II. CLINICAL SIGNIFICANCE:

CALIBRATION VERIFICATION: The process of confirming that the current calibration settings for each analyte remain valid for a test system. The goal of calibration verification is to evaluate the manufacturer's claims for linearity. The evaluation of the linearity assay will add to the user's ability to judge whether the clinical requirements for the analysis of the analyte have been met.

Understanding of the linear relationship between a method or instrument and analyte concentration leads to a confirmation of the Analytical Measuring Range (AMR).

III. SUPPLIES:

A. VK-R7 kit (1 per analyzer)
B. VK-R7 and VK-Crea-Canton
C. Insert Range Sheet (supplied in the kits)
D. Ampoule opener

E. Ampoule adapter

F. VK Linearity Template (shared drive)

IV. EQUIPMENT:

A. ABL825 Taylor, Trenton, Wayne

B. ABL827 Canton

V. PROCEDURE:

A. Kit and paperwork preparation-VK-R7 and VK-Crea

1. Linearity kits are stored refrigerated 2-8°C.
2. Prior to use, the linearity kits must be removed from the refrigerator and warmed to room temperature overnight (or at least 5 hours). Testing must be performed within 48 hours of being removed from the refrigerator.
3. Remove the acceptable ranges list from the kit.
4. Print the LCR (Linearity, Calibration, Reportable Ranges) form from the VK Linearity Template on the shared drive to record all values. Alternatively, you can use the instrument printouts and enter values directly into the electronic LCR form.
    a. Contact the lead or manager if you do no have access to the shared drive.
5. Perform any necessary conversion calculations for the acceptable ranges to match the Radiometer printout for cCa^{2+} and cLac using the formulas below. These formulas can be found in the "Radiometer America Information Packet for Linearity and QC AMR (Analytical Measurement Range)" which is stored with the Radiometer Operator's Manual. cCa^{2+} should be converted to mg/dL and cLac should be converted to mmol/L to match the Radiometer printout.
6. Alternatively, the instrument results can be converted to match the units on the acceptable ranges using the Conversion tab in the VK Linearity Template or using the formulas below (also found in the "Radiometer America Information Packet for Linearity and QC AMR (Analytical Measurement Range) stored in the Radiometer Operator's Manual). cCa^{2+} results from the instrument should be converted to meq/L and cLac results from the instrument should be converted to mg/dL to match the acceptable ranges on the VK-R7 printout.
7. Note: cK^{+}, cNa^{+}, cCl^{-} results do not require any conversion: meq/L = mmol/L for these analytes.
8. Conversion Examples:
    a. cCa^{2+} meq/L to mg/dL
        i. cCa^{2+} (mmol/L) = cCa^{2+}(meq/L) x 0.5
        ii. cCa^{2+} (mg/dL) = cCa^{2+} (mmol/L) x 4.008
            a. **EXAMPLE**: Low Range from printout is 0.78 meq/L

i. 0.78 meq/L x 0.5 = 0.39 mmol/L → 0.39 mmol/L x 4.008 = 1.56 mg/dL

b. cCa^{2+} mg/dL to meq/L

i. cCa^{2+} (mmol/L) = cCa^{2+} (mg/dL) x 0.2495

ii. cCa^{2+}(meq/L) = cCa^{2+} (mmol/L) x 2

a. **EXAMPLE**: Result from Radiometer printout is 4.65 mg/dL

i. 4.65 mg/dl x 0.2495 = 1.16 mmol/L → 1.16 mmol/L x 2 = 2.32 meq/L

c. cLac mg/dL to mmol/L

i. cLac (mmol/L) = cLac (mg/dL) x 0.11101

a. **EXAMPLE:** Low Range from printout is 216 mg/dL

i. 216 mg/dL x 0.11101 = 23.98 mmol/L

d. cLac mmol/L to mg/dL

i. cLac (mg/dL) = cLac (mmol/L) x 9.008

a. **EXAMPLE**: Result from Radiometer printout is 1.8 mmol/L

i. 1.8 mmol/l x 9.008 = 16.21 mg/dL

9. Levels 1 and 2 of pH, pCO2 and pO2 depend on the room temperature at the time of testing. Record the temperature near the Radiometer being tested.

B. Analyzer preparation

1. Enable the CalVer button if not already enabled. (site dependent). You must have administrator privileges on the analyzer

a. Menu

b. Log on

c. Utilities

d. Set up

e. Analysis set up

f. Syringe modes

g. The screen does not show the CalVer button, but it is the box directly under the Ampoule QC box. Touch it, and it will display CalVer.

h. Check that the button is enabled-right hand side of screen

C. Testing VK-R7

1. Each kit has 4 ampoules for each level of linearity material. A minimum of 3 ampoules of each level must be tested.

2. Radiometer suggests running all levels in order for optimal performance.
    a. Shake each ampoule by holding the top and bottom between thumb and forefinger to avoid heat transfer for 15-20 seconds.
    b. Tap excess liquid from the top and let the ampoule sit for 30 seconds to allow any bubbles to dissipate.
    c. Open syringe flap, select CalVer and Start.
    d. Safely break the ampoule tip by using the ampoule opener and place ampoule in an ampoule adapter, then place at inlet probe.
    e. Enter level number, lot number or High Metabolite in Patient ID field after sampling has occurred.
3. Repeat testing on remaining ampoules of level 1,2,3 and the High Metabolite.
4. After all levels have been tested, the CalVer button must be disabled (site dependent).
    a. See step B.1 to disable the CalVer button.

D. Testing VK-Crea (Canton)
1. Run these materials as a Proficiency Test.
2. This kit contains three levels of AutoCheck 6+ quality control.
3. In addition to the AutoCheck 6+, a high creatinine check must be run to verify the high end of the creatinine range. The high creatinine material is contained in the DosiCapZip prepared cleaning solution.
4. Install a new bottle of cleaning solution.
5. The high creatinine check should be run four times so there are four values recorded.
    a. Run this solution from the QC screen, calling a manual run of the fluid.
    b. Check the range against the insert value.

E. Mark CalVer as complete (site dependent).
1. Analyzer Status
    a. Electrodes and other
    b. User activities (Select Reminders Only if not already visible)
    c. Select CalVer
    d. Log activity
    e. Done

F. Enter results on the VK Linearity Template electronic form found on the shared drive.

G. Print out reports and all graphs of measured parameters and provide all instrument printouts to lead or lab manager.

1. Correct the units on the graph header for cCa^{2+} and cLac if the acceptable ranges were adjusted.

H. If any values fall outside of the acceptable range, perform troubleshooting procedures as you would for a failed QC (see the Radiometer ABL800 Series Operator Procedure) and repeat linearity testing for the failed analyte using a new kit.
    1. If values still fall outside of the acceptable range, call Radiometer Technical Support.

VI. REVIEW AND ACCEPTANCE:

A. This task is performed by the lead medical technologist or lab manager and the medical director.

B. All values obtained from the linearity studies must be within the acceptable ranges of the package insert for each analyte.

C. Per Radiometer, "Acceptable linearity recovery is based upon measured values falling within the assayed parameter's high and low limits."

D. For AMR (Analytical Measuring Range) validation, the medical director will review the measured AMR and determine its acceptability compared to the Corewell Analytical Measuring Range for Blood Gas Analytes stated in Attachment E of the Radiometer ABL800 Series Operator Procedure. Include the following statement from the Radiometer's Operating Procedure concerning AMRs:
    1. Blood gas linearity materials for Analytical Measurement Range (AMR) verification are used according to instructions from the manufacturer. For some analytes, these materials do not cover the entire range of values reported. For example, the highest level of pCO_2 reaches approximately 60% of the upper limit of the reportable range; based on historical patient data, high pCO_2 results up to 180 mmHg correlated well with low pO_2 results. The AMRs of COHb and MetHb are extended up to 70% because ranges above the highest linearity material are clinically relevant. Medical and technical directors have approved the indicated reportable ranges to provide clinical benefit in cases of extreme acid-base disorders, methemoglobinemia and carboxyhemoglobinemia. These benefits outweigh the relatively small risk of not formally verifying the full reportable range. This approach is consistent with CAP instructions indicating: "It may be difficult to obtain specimens with values near the limits for some analytes. In such cases, reasonable procedures should be adopted based on available specimen materials. The closeness of sample concentrations or activities to the upper and lower limits of the AMR are defined at the laboratory director's discretion. The method manufacturer's instructions for verifying the AMR must be followed, when available." (Chemistry and Toxicology Checklist 09.22.2021, p. 8)

VII. REFERENCES:

1. Radiometer America Information Packet for Linearity and QC AMR (Analytical Measurement Range) Part no. 999-719
2. www.radiometeramerica.com

3. Radiometer America VK Linearity Template

Approval Signatures

Step Description	Approver	Date
Medical Director	Muhammad Arshad: Chief, Pathology	10/29/2024
Policy and Forms Steering Committee Approval (if needed)	Tanya Williams: Medical Technologist Lead	10/29/2024
	Christopher Ferguson: Dir, Lab Services	10/25/2024
	Kristen DiCicco: Mgr, Laboratory	10/24/2024
	Ashley Beesley: Mgr, Laboratory	10/23/2024
	Katherine Persinger: Mgr, Laboratory	10/21/2024
	Tanya Williams: Medical Technologist Lead	10/21/2024

Applicability

Taylor, Trenton, Wayne