

INTENDED USE

RNA Medical® Brand **CVC 123 Calibration Verification Controls** are assayed quality control materials used for confirming the calibration and linearity of blood gas, electrolyte, and metabolite instrumentation. This product may be used on stand-alone blood gas analyzers or any combination blood gas, electrolyte, and metabolite system. When used as a supplement to instrument calibration, daily QC procedures, preventative maintenance, and proper record keeping, CVC 123 will contribute to the laboratory's overall quality assurance program.

CVC 123 may be used to:

- Check analyzer linearity
- Troubleshoot analyzer problems
- Document proper calibration
- Confirm preventative maintenance
- Assist with regulatory compliance

PRODUCT DESCRIPTION

CVC 123 is a buffered aqueous solution containing electrolytes, glucose, and lactate. It has been equilibrated with specific levels of oxygen, carbon dioxide, and nitrogen. This product contains no preservatives and no biological materials.

CVC 123 is provided in convenient, ready-to-use ampuls containing 2.5 mL of solution. It is a five (5) level product with four (4) ampuls of each level in each kit. CVC 123 values cover the clinically significant range of instrument performance for pH, $p\text{CO}_2$, $p\text{O}_2$, Na^+ , K^+ , Cl^- , Ca^{++} , Mg^{++} , glucose, and lactate for documenting reportable range. For optimal performance, use of one (1) kit per analyzer is recommended.

STORAGE AND SHELF LIFE

CVC 123 has a shelf life of thirty-six (36) months from the date of manufacture when stored at 2-8 °C. It may be stored at room temperature (up to 25 °C) for nine (9) months, not exceeding the stated expiration date. This product should be protected from freezing and exposure to temperatures greater than 30 °C.

CONTROL VALUES AND ANALYTES

Lot specific values are provided with each box of controls. The typical values for CVC 123 are as follows:

| Analyte | Low Value | | High Value |
|---------------------------|-----------|---|------------|
| pH | 6.85 | - | 7.80 |
| $p\text{CO}_2$ (mmHg) | 15 | - | 87 |
| $p\text{O}_2$ (mmHg) | 22 | - | 465 |
| Na^+ (mmol/L) | 90 | - | 170 |
| K^+ (mmol/L) | 1.6 | - | 11.3 |
| Cl^- (mmol/L) | 70 | - | 135 |
| Ca^{++} (mmol/L) | 0.25 | - | 3.10 |
| Mg^{++} (mmol/L) | 0.15 | - | 2.20 |
| Glucose (mg/dL) | 0 | - | 450 |
| Lactate (mmol/L) | 0.7 | - | 17.0 |

CVC 123 SPECIFICATIONS

Packaging: 5 levels (4 ampuls per level), 2.5 mL per ampul
 Storage: 2-8 °C (up to 9 months at room temperature)
 Shelf Life: 36 months from date of manufacture
 Matrix: Buffered aqueous solution
 Analytes: pH, $p\text{CO}_2$, $p\text{O}_2$, Na^+ , K^+ , Cl^- , Ca^{++} , Mg^{++} , glucose, lactate

DIRECTIONS FOR USE

The basic steps for running CVC 123 are outlined below. Refer to the package insert for specific instructions.

1. Calibrate the instrument as directed by the manufacturer.
2. Sample each of the Level 1 ampuls until three (3) replicates are completed. Test Levels 2, 3, 4, and 5 the same way.
3. Record the results on the Data Collection and Linearity Worksheets included in the kit.
4. Calculate the mean value for each test analyte and compare it to the range on the Expected Values Chart.
5. Using the graphs provided, plot the test result against the expected result. Connect the points to visualize linearity.

Note: Steps 3, 4, and 5 may be performed on-line as a feature of PeerQCSM described below.

PEERQC STATISTICAL ANALYSIS

Available at www.RNAMedical.com, PeerQC provides web-based graphing and reporting for RNA Medical's Calibration Verification Controls. This easy-to-use service eliminates time-consuming manual data calculation and hand linearity graphing.

Specific features of PeerQC include:

- Instant data calculation and analysis
- Peer comparison data in *real-time*
- Printable graph and detailed report for each analyte
- Report download for archiving

ORDERING INFORMATION

Please specify this catalog number when ordering RNA Medical CVC 123 Calibration Verification Controls.

Catalog number: CVC 123

ADDITIONAL PRODUCTS

RNA Medical's broad line of products include blood gas controls, capillary blood collection tubes, and controls for various point-of-care tests. For further information about Calibration Verification Controls or any other RNA Medical product, please call us or visit our website at www.RNAMedical.com.

RNA Medical is a registered trademark and PeerQC is a service mark of Bionostics, Inc., Devens, MA, USA. The products described herein are covered by one or more of the following U.S. Patents and their foreign counterparts: 7,027,931; 5,558,985; 5,320,965; 5,304,491; 5,045,529; 5,013,666; 4,945,062.

INSTRUMENT REFERENCE CHART

CVC 123 Calibration Verification Controls

CVC 123

MANUFACTURER AND MODEL ANALYTES REPORTED BY INSTRUMENT IN CVC 123

BAYER®

| | |
|------------------------------|---|
| 238 | pH, pCO ₂ , pO ₂ |
| 248 | pH, pCO ₂ , pO ₂ |
| 400, 405 | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose |
| 840, 845, 850, 855, 860, 865 | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate |
| 614, 634, 644 | pH, Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ |

IL

| | |
|-----------------------------------|--|
| 1304, 1306, 1312 | pH, pCO ₂ , pO ₂ |
| BG3 | pH, pCO ₂ , pO ₂ |
| BGE | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ |
| 1610, 1620, 1630, 1640, 1650 | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ |
| Synthesis™ 10, 15, 20, 25, 30, 35 | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose |
| GEM® Premier™ | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ |
| GEM Premier3000 | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ |

ITC®

| | |
|--------------------------|--|
| IRMA® and IRMA TRUpoint® | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose |
|--------------------------|--|

MEDICA

| | |
|--------------|--|
| EasyBloodGas | pH, pCO ₂ , pO ₂ |
| EasyStat® | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ |

NOVA

| | |
|--------------------|--|
| Stat Profile® 1-9 | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate |
| Stat Profile 10 | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Glucose, Lactate |
| Stat Profile Ultra | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Mg ⁺⁺ , Glucose, Lactate |

OSMETECH®

| | |
|-----------|--|
| OPTI® CCA | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose |
| OPTI R | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Ca ⁺⁺ |

RADIOMETER

| | |
|----------------------------------|---|
| ABL® 3, 30 | pH, pCO ₂ , pO ₂ |
| ABL 300, 330 | pH, pCO ₂ , pO ₂ |
| ABL 4 | pH, pCO ₂ , pO ₂ , K ⁺ |
| ABL 5 | pH, pCO ₂ , pO ₂ |
| ABL 50, 500, 505, 510, 520 | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ |
| ABL 600, 605, 610, 615, 620, 625 | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate |
| ABL 700, 705, 710, 715, 720, 725 | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate |
| ABL 800, 805, 810, 815, 820, 825 | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate |
| ICA, KNA 1 | Na ⁺ , K ⁺ , Ca ⁺⁺ |
| EML 100, 105 | Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate |

ROCHE

| | |
|--------------------|---|
| AVL Compact Series | pH, pCO ₂ , pO ₂ |
| OMNI® 1-9 | pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Glucose, Lactate |

YSI®

| | |
|----------------|------------------|
| 2300 Stat Plus | Glucose, Lactate |
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