<u>CVC 223</u>

CO-OXIMETER CALIBRATION VERIFICATION CONTROLS

INTENDED USE

RNA Medical[®] Brand CVC 223 CO-Oximeter Calibration Verification Controls are assayed quality control materials used for monitoring the performance and linearity of analyzers that measure total hemoglobin and hemoglobin fractions. This control may be used on stand-alone CO-Oximeters or combination blood gas and CO-Oximetry When used as a supplement to instrument systems. procedures, calibration, daily QC preventative maintenance, and proper record keeping, CVC 223 will contribute to the laboratory's overall quality assurance program.

CVC 223 may be used to:

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

PRODUCT DESCRIPTION

CVC 223 is a purified bovine hemoglobin solution. It has been saturated with carbon monoxide or treated with precise concentrations of carbon monoxide. This product contains no preservatives and no human-based materials.

CVC 223 is provided in convenient, ready-to-use ampuls containing 1.2 mL of solution. It is a five (5) level product with four (4) ampuls of each level in each kit. CVC 223 values cover the significant range of instrument performance for total hemoglobin, oxyhemoglobin, and carboxyhemoglobin. It also contains methemoglobin. For optimal performance, use of one (1) kit per analyzer is recommended.

STORAGE AND SHELF LIFE

CVC 223 has a shelf life of eighteen (18) months from the date of manufacture when stored at 2-8 °C. This product should be protected from freezing and exposure to temperatures greater than 8 °C.

CONTROL VALUES AND ANALYTES

Lot specific values are provided with each box of controls. The typical target values for CVC 223 are as follows:

Analyte	Low Value		High Value
tHb (g/dL)	5.0	-	22.0
O ₂ Hb (%)	1.0	-	95.0
COHb (%)	5.0	-	97.0
MetHb (%)	0.0	-	1.0

CVC 223 SPECIFICATIONS

Packaging:	5 levels (4 ampuls per level), 1.2 mL per ampul
Storage:	2-8 °C

- Shelf Life: 18 months from date of manufacture
- Matrix: Bovine hemoglobin solution
- Analytes: tHb, O₂Hb, COHb, MetHb

DIRECTIONS FOR USE

The basic steps for running CVC 223 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 PeerQC 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 223 CO-Oximeter Calibration Verification Controls.

Catalog number: CVC 223

ADDITIONAL PRODUCTS

RNA Medical offers a full line of blood gas and CO-Oximetry controls, calibration verification materials, capillary blood collection tubes, and quality control materials for various point-of-care tests. For further information about CVC 223 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 registered service mark of Bionostics, Inc., Devens, MA, USA.



<u>CVC 223</u>

MANUFACTURER AND MODEL

ANALYTES REPORTED BY INSTRUMENT IN CVC 223

tHb, O ₂ Hb, COHb, MetHb	
tHb, O_2 Hb, COHb, MetHb	
tHb, O_2 Hb, COHb, MetHb	
tHb, O_2 Hb, COHb, MetHb	
tHb, O ₂ Hb, COHb, MetHb	
tHb, O ₂ Hb	
tHb, O ₂ Hb, COHb, MetHb	
tHb, O ₂ Hb, COHb, MetHb	
tHb, O ₂ Hb, COHb, MetHb	
tHb, O_2 Hb, COHb, MetHb	
tHb, O ₂ Hb, COHb, MetHb	
tHb, O ₂ Hb, COHb, MetHb	
tHb, O ₂ Hb, COHb, MetHb	
tHb, O ₂ Hb, COHb, MetHb	
tHb, O ₂ Hb, COHb, MetHb	
tHb, O ₂ Hb, COHb, MetHb	
tHb, O ₂ Hb, COHb, MetHb	
tHb, O ₂ Hb, COHb, MetHb	
tHb, O ₂ Hb, COHb, MetHb	
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	tHb, O_2 Hb, COHb, MetHb tHb, O_2 Hb, COHb, MetHb

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