

CVC 223 CO-Oximeter Calibration Verification Controls

Level 5

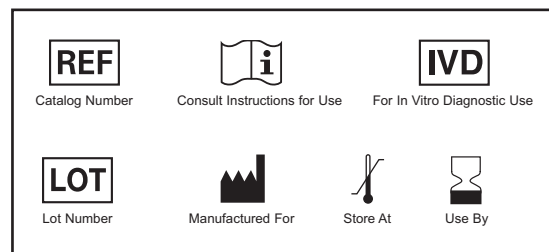
LOT 15219 2012-12

Expected Values Chart

Analyzers	tHb g/dL		O ₂ Hb %		COHb %		MetHb %	
	mean	range	mean	range	mean	range	mean	range
IL								
482	21.8	19.8 - 23.8	1.0 *	-1.5 - 3.5	98.0 *	93.0 - 103.0	0.5 *	-1.5 - 2.5
682	20.8	18.8 - 22.8	-0.1	-2.6 - 2.4	99.6	94.6 - 104.6	0.5	-1.5 - 2.5
Synthesis Series	19.3	17.3 - 21.3	2.1	-0.4 - 4.6	98.0	93.0 - 103.0	0.0	-2.0 - 2.0
GEM OPL	21.4	19.2 - 23.6	-0.9	-8.9 - 7.1	ORL ¹		0.5	-2.4 - 3.4
GEM 4000	20.4	18.4 - 22.4	0.7	-1.8 - 3.2	98.0	93.0 - 103.0	0.1	-1.9 - 2.1
ITC								
AVOXimeter 1000E	21.5	19.3 - 23.7	2.1	-5.9 - 10.1				
AVOXimeter 4000	21.3	19.1 - 23.5	-0.4	-8.4 - 7.6	ORL ¹		0.8	-2.1 - 3.7
Nova								
CCX	23.9	21.9 - 25.9	2.8	0.3 - 5.3	96.4	91.4 - 101.4	0.2	-1.8 - 2.2
Radiometer								
OSM 3	22.0	20.0 - 24.0	2.4	-0.1 - 4.9	96.0	91.0 - 101.0	0.7	-1.3 - 2.7
ABL 500 Series	22.2	20.2 - 24.2	2.0	-0.5 - 4.5	97.0	92.0 - 102.0	0.5	-1.5 - 2.5
ABL 600 Series	21.8	19.8 - 23.8	2.4	-0.1 - 4.9	97.0	92.0 - 102.0	0.5	-1.5 - 2.5
ABL 700 Series	19.9	17.9 - 21.9	0.4	-2.1 - 2.9	95.9	90.9 - 100.9	3.3	1.3 - 5.3
ABL 80 Series	DNA ²		DNA ²		DNA ²		DNA ²	
ABL 800 Series	19.9	17.9 - 21.9	0.4	-2.1 - 2.9	95.9	90.9 - 100.9	3.3	1.3 - 5.3
NPT 7	DNA ²		DNA ²		DNA ²		DNA ²	
Roche								
OMNI Series	20.5	18.5 - 22.5	1.4	-1.1 - 3.9	95.0	90.0 - 100.0	1.2	-0.8 - 3.2
Siemens (Bayer)								
400 Series	21.9	19.9 - 23.9	5.0	2.5 - 7.5	93.8	88.8 - 98.8	0.1	-1.9 - 2.1
800 Series	22.2	20.2 - 24.2	4.5	2.0 - 7.0	95.0	90.0 - 100.0	0.0	-2.0 - 2.0
1200 Series	22.4	20.4 - 24.4	5.0	2.5 - 7.5	93.8	88.8 - 98.8	0.1	-1.9 - 2.1

FOOTNOTES:

1. ORL - Outside Reportable Limits of Analyzer
2. DNA - Data Not Available at time of printing



INSTRUMENT MANUFACTURERS
 Instrumentation Laboratory, Lexington, MA
 International Technidyne Corporation, Edison, NJ
 Nova Biomedical, Waltham, MA
 Radiometer America, Westlake, OH
 Roche Diagnostics, Indianapolis, IN
 Siemens Healthcare Diagnostics, Deerfield, IL

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CVC 223

5 Levels

CVC 223 CO-Oximeter Calibration Verification Controls

LOT Set: 122321 Level 1: 15120 Level 2: 14835 Level 3: 14934 Level 4: 15029 Level 5: 15219

Set: 2012-11 Level 1: 2012-11 Level 2: 2012-11 Level 3: 2012-12 Level 4: 2012-12 Level 5: 2012-12

REF CVC 223

IVD

INTENDED USE

RNA Medical® Brand CVC 223 CO-Oximeter Calibration Verification Controls are assayed materials used for confirming the calibration and linearity of total hemoglobin and hemoglobin fractions on CO-Oximeter analyzers.

PRODUCT DESCRIPTION

CVC 223 is provided in five (5) distinct levels of total hemoglobin, oxyhemoglobin, and carboxyhemoglobin covering the physiologically significant range of instrument performance. It also contains methemoglobin. CVC 223 is packaged in sealed glass ampuls, each containing 1.2 mL of solution. Ampuls are packaged in kits containing four (4) ampuls of each level.

Active Ingredients:

CVC 223 is a purified bovine hemoglobin solution that has been saturated with carbon monoxide or treated with precise concentrations of carbon monoxide. This control contains no preservatives and no human-based materials. It is considered good laboratory practice to follow the recommended "Universal Precautions" when handling any blood product.

STORAGE

The expiration date stated on the CVC 223 packaging is for product stored at 2-8 °C. Avoid exposure to freezing and temperatures greater than 8 °C.

DIRECTIONS FOR USE

CVC 223 should be analyzed immediately after removal from refrigeration.

It is best to run CVC 223 in the same manner as patient samples, however, please refer to any specific instructions for your analyzer regarding the use of these or any other control materials.

For Roche OMNI Analyzers:

Create a new file of aqueous QC material in the QC Set-up function. Set the ranges for the CO-Oximeter parameters as follows:

Analyte	Low Limit	High Limit
tHb (g/dL)	0.0	25.0
Hb Derivatives (%)	-10.0	110.0

Run the CVC 223 samples as a QC sample in the new file, following steps one (1) through eight (8) below under "General Instructions."

For Siemens (Bayer) 800 Series Analyzers:

Follow steps one (1) through five (5) below under "General Instructions." Alternate running human blood samples with the CVC 223 samples. Complete steps six (6) through eight (8) under "General Instructions." Verify the analyzer performance with daily QC. If a shift in the daily QC values for oximetry is observed, perform the following corrective action:

- Clean the CO-Ox sample chamber per the maintenance instructions in section 3 of the Operator's Manual.
- Verify the performance with QC.
- If you still see a shift in QC, run a quantity of 10-12 normal human blood samples through the system (CO-Ox only mode is sufficient).
- Verify performance with QC.
- Contact Siemens Technical Support for assistance if the problem persists.

General Instructions for all other CO-Oximeters:

1. Calibrate your CO-Oximeter according to the manufacturer's recommendations. If the analyzer is a combination blood gas/CO-Oximetry system, a two-point calibration is suggested.
2. Beginning with level 1, gently invert the ampul to mix the solution. Tap the ampul to restore the liquid to the bottom of the ampul.
3. Open the ampul by snapping off the tip at the score. Use the Snapper

provided to protect fingers from cuts.

4. Introduce the liquid from the ampul to the analyzer. Use direct aspiration, syringe transfer, or capillary mode techniques.
5. Record the results on the Data Collection and Linearity Worksheet provided for each analyte.
6. Repeat steps 2 through 5 for the remaining ampuls of level 1 until three (3) replicates are completed. (A fourth ampul of each level is provided in the event of accidental breakage or obvious sampling error.) Test levels 2, 3, 4, and 5 the same way. Record all values on the worksheets.
7. Calculate the mean value for each test analyte and compare your mean to the range on the Expected Values Chart. If your mean is within the range, circle "Y" at the question "OK?" If your mean is outside the range, circle "N" and take corrective action.
8. To graph the linearity of your results:
 - a) Using the graph area provided, plot the Test Value (mean) against the Expected Value.
 - b) Connect the plotted points to visualize linearity.

Note: Steps 7 and 8 may be performed on-line as a feature of PeerQC described below.

EXPECTED VALUES

The values for each control analyte on the enclosed Expected Values Chart are based on multiple determinations performed on randomly selected samples from each lot. The listing for each instrument represents the expected range and mean value of this range.

The Expected Values are provided as a guide in evaluating analyzer performance. Since instrument design and operating conditions may vary, each laboratory should establish its own acceptance criteria.

STATISTICAL SUPPORT

RNA Medical PeerQC®, available at www.RNAMedical.com, features web-based graphing and reporting for its Calibration Verification Controls and is available at no charge to RNA Medical customers. The graphing steps outlined above may be performed on-line as a feature of this service. Please contact RNA Medical or visit our website for information about utilizing PeerQC for this product.

LIMITATIONS

1. Extended exposure to temperatures greater than 8 °C will affect product performance. If CVC 223 has turned brown in color, this change indicates deterioration and the formation of methemoglobin. In such a case, the control is not suitable for use and should be discarded.
2. The methemoglobin in this control can confirm product storage temperature integrity as well as the performance of the MetHb channel on CO-Oximeters. Because of its limited range of values, it will not be of significant value in determining linearity, calibration verification, and reportable range for MetHb.
3. CVC 223 is sensitive to many instrument related factors that would affect analytical results. It is a bovine blood-based material but does not contain red cells. Therefore, it may not detect certain malfunctions that would affect the testing of human blood.
4. This product is intended for use as a quality control material and can assist in evaluating the performance of laboratory instruments. It is not for use as a calibration standard and its use should not replace other aspects of a complete quality control program.

RNA Medical is a registered trademark and PeerQC is a registered service mark of Bionostics, Inc.

CVC 223 CO-Oximeter Calibration Verification Controls

Level 1

LOT 15120 2012-11

Expected Values Chart

Analyzers	tHb g/dL		O ₂ Hb %		COHb %		MetHb %	
	mean	range	mean	range	mean	range	mean	range
IL								
482	5.1	4.5 - 5.7	28.7	25.7 - 31.7	72.1	68.1 - 76.1	0.6	-1.4 - 2.6
682	4.9	4.3 - 5.5	27.7	24.7 - 30.7	73.1	69.1 - 77.1	0.5	-1.5 - 2.5
Synthesis Series	4.7	4.1 - 5.3	31.2	28.2 - 34.2	69.6	65.6 - 73.6	0.2	-1.8 - 2.2
GEM OPL	5.0	4.4 - 5.6	27.3	22.7 - 31.9	73.0	66.0 - 80.0	0.8	-2.1 - 3.7
GEM 4000	ORL ¹		ORL ¹		ORL ¹		ORL ¹	
ITC								
AVOXimeter 1000E	5.0	4.4 - 5.6	29.7	25.1 - 34.3				
AVOXimeter 4000	4.9	4.3 - 5.5	28.0	23.4 - 32.6	71.8	64.8 - 78.8	1.2	-1.7 - 4.1
Nova								
CCX	5.4	4.8 - 6.0	32.8	29.8 - 35.8	66.2	62.2 - 70.2	0.6	-1.4 - 2.6
Radiometer								
OSM 3	5.2	4.6 - 5.8	32.1	29.1 - 35.1	69.1	65.1 - 73.1	0.9	-1.1 - 2.9
ABL 500 Series	5.3	4.7 - 5.9	33.7	30.7 - 36.7	66.2	62.2 - 70.2	1.0	-1.0 - 3.0
ABL 600 Series	5.3	4.7 - 5.9	34.7	31.7 - 37.7	66.2	62.2 - 70.2	1.0	-1.0 - 3.0
ABL 700 Series	4.6	4.0 - 5.2	31.7	28.7 - 34.7	67.1	63.1 - 71.1	2.4	0.4 - 4.4
ABL 80 Series	DNA ²		DNA ²		DNA ²		DNA ²	
ABL 800 Series	4.6	4.0 - 5.2	31.7	28.7 - 34.7	67.1	63.1 - 71.1	2.4	0.4 - 4.4
NPT 7	DNA ²		DNA ²		DNA ²		DNA ²	
Roche								
OMNI Series	4.6	4.0 - 5.2	28.9	25.9 - 31.9	70.0	66.0 - 74.0	1.4	-0.6 - 3.4
Siemens (Bayer)								
400 Series	6.2	5.6 - 6.8	33.1	30.1 - 36.1	66.1	62.1 - 70.1	0.4	-1.6 - 2.4
800 Series	4.9	4.3 - 5.5	27.7	24.7 - 30.7	71.1	67.1 - 75.1	0.5	-1.5 - 2.5
1200 Series	5.9	5.3 - 6.5	33.5	30.5 - 36.5	66.1	62.1 - 70.1	0.3	-1.7 - 2.3

Level 2

LOT 14835 2012-11

Expected Values Chart

Analyzers	tHb g/dL		O ₂ Hb %		COHb %		MetHb %	
	mean	range	mean	range	mean	range	mean	range
IL								
482	8.2	7.5 - 8.9	94.9	89.9 - 99.9	7.1	3.1 - 11.1	0.6	-1.4 - 2.6
682	7.8	7.1 - 8.5	94.4	89.4 - 99.4	6.5	2.5 - 10.5	0.4	-1.6 - 2.4
Synthesis Series	7.5	6.8 - 8.2	97.3	92.3 - 102.3	5.6	1.6 - 9.6	0.3	-1.7 - 2.3
GEM OPL	8.0	7.3 - 8.7	95.9	91.4 - 100.4	5.4	1.4 - 9.4	0.4	-2.5 - 3.3
GEM 4000	7.5	6.8 - 8.2	96.5	91.5 - 101.5	4.5	0.5 - 8.5	0.2	-1.8 - 2.2
ITC								
AVOXimeter 1000E	8.0	7.3 - 8.7	93.8	89.3 - 98.3				
AVOXimeter 4000	8.0	7.3 - 8.7	95.6	91.1 - 100.1	5.4	1.4 - 9.4	0.6	-2.3 - 3.5
Nova								
CCX	8.0	7.3 - 8.7	97.7	92.7 - 102.7	2.1	-1.9 - 6.1	0.2	-1.8 - 2.2
Radiometer								
OSM 3	8.6	7.9 - 9.3	95.2	90.2 - 100.2	6.1	2.1 - 10.1	0.5	-1.5 - 2.5
ABL 500 Series	8.5	7.8 - 9.2	94.9	89.9 - 99.9	5.7	1.7 - 9.7	0.7	-1.3 - 2.7
ABL 600 Series	8.4	7.7 - 9.1	94.9	89.9 - 99.9	5.7	1.7 - 9.7	0.7	-1.3 - 2.7
ABL 700 Series	8.0	7.3 - 8.7	95.8	90.8 - 100.8	2.4	-1.6 - 6.4	1.1	-0.9 - 3.1
ABL 80 Series	DNA ²		DNA ²		DNA ²		DNA ²	
ABL 800 Series	8.0	7.3 - 8.7	95.6	90.6 - 100.6	2.4	-1.6 - 6.4	1.1	-0.9 - 3.1
NPT 7	DNA ²		DNA ²		DNA ²		DNA ²	
Roche								
OMNI Series	7.5	6.8 - 8.2	95.8	90.8 - 100.8	3.5	-0.5 - 7.5	0.6	-1.4 - 2.6
Siemens (Bayer)								
400 Series	9.3	8.6 - 10.0	95.6	90.6 - 100.6	4.2	0.2 - 8.2	0.3	-1.7 - 2.3
800 Series	7.6	6.9 - 8.3	94.2	89.2 - 99.2	5.4	1.4 - 9.4	0.3	-1.7 - 2.3
1200 Series	8.9	8.2 - 9.6	95.6	90.6 - 100.6	4.2	0.2 - 8.2	0.3	-1.7 - 2.3

CVC 223 CO-Oximeter Calibration Verification Controls

Level 3

LOT 14934 2012-12

Expected Values Chart

Analyzers	tHb g/dL		O ₂ Hb %		COHb %		MetHb %	
	mean	range	mean	range	mean	range	mean	range
IL								
482	13.7	12.7 - 14.7	79.9	75.9 - 83.9	21.6	17.6 - 25.6	0.8	-1.2 - 2.8
682	13.2	12.2 - 14.2	79.7	75.7 - 83.7	21.4	17.4 - 25.4	0.4	-1.6 - 2.4
Synthesis Series	13.4	12.4 - 14.4	81.9	77.9 - 85.9	20.3	16.3 - 24.3	0.2	-1.8 - 2.2
GEM OPL	13.7	12.6 - 14.8	80.9	76.6 - 85.2	19.8	15.3 - 24.3	0.5	-2.4 - 3.4
GEM 4000	12.8	11.8 - 13.8	81.8	77.8 - 85.8	19.6	15.6 - 23.6	0.1	-1.9 - 2.1
ITC								
AVOXimeter 1000E	13.7	12.6 - 14.8	79.2	74.9 - 83.5				
AVOXimeter 4000	13.8	12.7 - 14.9	80.5	76.2 - 84.8	19.9	15.4 - 24.4	0.6	-2.3 - 3.5
Nova								
CCX	14.2	13.2 - 15.2	83.1	79.1 - 87.1	15.6	11.6 - 19.6	0.3	-1.7 - 2.3
Radiometer								
OSM 3	14.2	13.2 - 15.2	80.8	76.8 - 84.8	20.4	16.4 - 24.4	0.8	-1.2 - 2.8
ABL 500 Series	14.7	13.7 - 15.7	79.7	75.7 - 83.7	19.7	15.7 - 23.7	0.8	-1.2 - 2.8
ABL 600 Series	14.3	13.3 - 15.3	80.9	76.9 - 84.9	19.2	15.2 - 23.2	0.6	-1.4 - 2.6
ABL 700 Series	13.7	12.7 - 14.7	82.1	78.1 - 86.1	15.8	11.8 - 19.8	1.3	-0.7 - 3.3
ABL 80 Series	DNA ²		DNA ²		DNA ²		DNA ²	
ABL 800 Series	13.7	12.7 - 14.7	82.1	78.1 - 86.1	15.6	11.6 - 19.6	1.3	-0.7 - 3.3
NPT 7	DNA ²		DNA ²		DNA ²		DNA ²	
Roche								
OMNI Series	13.1	12.1 - 14.1	81.6	77.6 - 85.6	16.7	12.7 - 20.7	1.1	-0.9 - 3.1
Siemens (Bayer)								
400 Series	14.6	13.6 - 15.6	81.8	77.8 - 85.8	17.7	13.7 - 21.7	0.2	-1.8 - 2.2
800 Series	13.4	12.4 - 14.4	79.3	75.3 - 83.3	19.8	15.8 - 23.8	0.3	-1.7 - 2.3
1200 Series	14.5	13.5 - 15.5	81.8	77.8 - 85.8	17.7	13.7 - 21.7	0.2	-1.8 - 2.2

Level 4

LOT 15029 2012-12

Expected Values Chart

Analyzers	tHb g/dL		O ₂ Hb %		COHb %		MetHb %	
	mean	range	mean	range	mean	range	mean	range
IL								
482	17.4	16.2 - 18.6	51.8	47.8 - 55.8	49.4	45.4 - 53.4	0.7	-1.3 - 2.7
682	16.6	15.4 - 17.8	51.5	47.5 - 55.5	49.2	45.2 - 53.2	0.4	-1.6 - 2.4
Synthesis Series	16.5	15.3 - 17.7	56.8	52.8 - 60.8	47.4	43.4 - 51.4	0.3	-1.7 - 2.3
GEM OPL	17.1	15.8 - 18.4	52.7	48.4 - 57.0	47.6	42.3 - 52.9	0.5	-2.4 - 3.4
GEM 4000	16.0	14.8 - 17.2	54.0	50.0 - 58.0	47.4	43.4 - 51.4	0.1	-1.9 - 2.1
ITC								
AVOXimeter 1000E	17.1	15.8 - 18.4	52.3	48.0 - 56.6				
AVOXimeter 4000	17.1	15.8 - 18.4	52.3	48.0 - 56.6	47.4	42.1 - 52.7	0.5	-2.4 - 3.4
Nova								
CCX	18.5	17.3 - 19.7	56.0	52.0 - 60.0	43.4	39.4 - 47.4	0.3	-1.7 - 2.3
Radiometer								
OSM 3	17.7	16.5 - 18.9	54.0	50.0 - 58.0	46.4	42.4 - 50.4	0.8	-1.2 - 2.8
ABL 500 Series	18.3	17.1 - 19.5	53.3	49.3 - 57.3	46.4	42.4 - 50.4	0.6	-1.4 - 2.6
ABL 600 Series	17.9	16.7 - 19.1	54.4	50.4 - 58.4	45.7	41.7 - 49.7	0.6	-1.4 - 2.6
ABL 700 Series	16.7	15.5 - 17.9	55.5	51.5 - 59.5	43.8	39.8 - 47.8	2.7	0.7 - 4.7
ABL 80 Series	DNA ²		DNA ²		DNA ²		DNA ²	
ABL 800 Series	16.7	15.5 - 17.9	55.7	51.7 - 59.7	43.8	39.8 - 47.8	2.6	0.6 - 4.6
NPT 7	DNA ²		DNA ²		DNA ²		DNA ²	
Roche								
OMNI Series	16.4	15.2 - 17.6	54.3	50.3 - 58.3	43.0	39.0 - 47.0	1.3	-0.7 - 3.3
Siemens (Bayer)								
400 Series	17.6	16.4 - 18.8	55.8	51.8 - 59.8	44.0	40.0 - 48.0	0.2	-1.8 - 2.2
800 Series	17.4	16.2 - 18.6	53.0	49.0 - 57.0	46.8	42.8 - 50.8	0.2	-1.8 - 2.2
1200 Series	17.7	16.5 - 18.9	55.8	51.8 - 59.8	44.0	40.0 - 48.0	0.2	-1.8 - 2.2