CVC 223 CO-Oximeter Calibration Verification Controls

Level 5

LOT 35242 ⌛ 2024-09-30

Expected Values Chart

Analyzers	tHb g/dL mean	tHb g/dL range	O_2Hb % mean	O_2Hb % range	COHb % mean	COHb % range	MetHb[3] % mean	MetHb[3] % range
Accriva								
AVOXimeter 1000E	22.5	20.3 - 24.7	3.6	–4.4 - 11.6				
AVOXimeter 4000	22.4	20.2 - 24.6	0.8	–7.2 - 8.8	ORL[1]		1.2	–1.7 - 4.1
IL								
482	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
682	20.7	18.7 - 22.7	1.0	–1.5 - 3.5	99.6	94.6 - 104.6	0.6	–1.4 - 2.6
Synthesis Series	19.2	17.2 - 21.2	2.2	–0.3 - 4.7	98.0	93.0 - 103.0	0.1	–1.9 - 2.1
GEM OPL	22.4	20.2 - 24.6	0.8	–7.2 - 8.8	ORL[1]		1.2	–1.7 - 4.1
GEM Premier 4000	20.5	18.5 - 22.5	2.1	–0.4 - 4.6	97.7	92.7 - 102.7	0.7	–1.3 - 2.7
GEM Premier 5000	21.2	19.2 - 23.2	1.7	–0.8 - 4.2	95.6	90.6 - 100.6	0.7	–1.3 - 2.7
Nova								
CCX	23.8	21.8 - 25.8	2.9	0.4 - 5.4	96.4	91.4 - 101.4	0.3	–1.7 - 2.3
pHOx Ultra	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
Radiometer								
ABL 700 Series	19.8	17.8 - 21.8	0.5	–2.0 - 3.0	95.9	90.9 - 100.9	3.4	1.4 - 5.4
ABL 800 Series	20.4	18.4 - 22.4	0.2	–2.3 - 2.7	95.9	90.9 - 100.9	4.1	2.1 - 6.1
ABL 80 Series	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
ABL 90 Series	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
Roche								
Cobas b 221	20.4	18.4 - 22.4	0.6	–1.9 - 3.1	97.0	92.0 - 102.0	0.8	–1.2 - 2.8
OMNI Series	20.4	18.4 - 22.4	1.5	–1.0 - 4.0	95.0	90.0 - 100.0	1.3	–0.7 - 3.3
Siemens								
400 Series	22.1	20.1 - 24.1	4.8	2.3 - 7.3	93.8	88.8 - 98.8	0.7	–1.3 - 2.7
500 Series	22.4	20.4 - 24.4	4.8	2.3 - 7.3	93.7	88.7 - 98.7	0.6	–1.4 - 2.6
1200 Series	22.3	20.3 - 24.3	4.5	2.0 - 7.0	94.6	89.6 - 99.6	0.2	–1.8 - 2.2

FOOTNOTES:

1. ORL - Outside Reportable Limits of Analyzer
2. DNA - Data Not Available at time of printing
3. MetHb range cannot determine linearity, calibration verification or reportable range.

REF — Catalog Number	Consult Instructions for Use	IVD — For In Vitro Diagnostic Use
LOT — Lot Number	Manufactured For	Store At
Use By		

INSTRUMENT MANUFACTURERS

Accriva Diagnostics, San Diego, CA
Instrumentation Laboratory, Lexington, MA
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: 322342	⌛	Set: 2024-09-30	REF	CVC 223
	Level 1: 35139		Level 1: 2024-09-30	IVD	
	Level 2: 34873		Level 2: 2024-09-30		
	Level 3: 34969		Level 3: 2024-09-30		
	Level 4: 35066		Level 4: 2024-10-31		
	Level 5: 35242		Level 5: 2024-09-30		

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.

General Instructions

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.

CVC 223 CO-Oximeter Calibration Verification Controls

Level 1

LOT 35139 2024-09-30

Expected Values Chart

Analyzers	tHb g/dL mean	tHb g/dL range	O_2Hb % mean	O_2Hb % range	COHb % mean	COHb % range	MetHb[3] % mean	MetHb[3] % range
Accriva								
AVOXimeter 1000E	5.6	5.0 - 6.2	34.1	29.5 - 38.7				
AVOXimeter 4000	5.1	4.5 - 5.7	33.2	28.6 - 37.8	70.1	63.1 - 77.1	–0.9	–3.8 - 2.0
IL								
482	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
682	5.4	4.8 - 6.0	29.6	26.6 - 32.6	72.3	68.3 - 76.3	0.1	–1.9 - 2.1
Synthesis Series	5.2	4.6 - 5.8	33.1	30.1 - 36.1	68.8	64.8 - 72.8	–0.2	–2.2 - 1.8
GEM OPL	5.1	4.5 - 5.7	33.2	28.6 - 37.8	70.1	63.1 - 77.1	–0.9	–3.8 - 2.0
GEM Premier 4000	ORL[1]		ORL[1]		ORL[1]		ORL[1]	
GEM Premier 5000	5.0	4.4 - 5.6	30.0	27.0 - 33.0	68.8	64.8 - 72.8	0.4	–1.6 - 2.4
Nova								
CCX	5.9	5.3 - 6.5	34.7	31.7 - 37.7	65.4	61.4 - 69.4	0.2	–1.8 - 2.2
pHOx Ultra	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
Radiometer								
ABL 700 Series	5.1	4.5 - 5.7	33.6	30.6 - 36.6	66.3	62.3 - 70.3	2.0	0.0 - 4.0
ABL 800 Series	4.7	4.1 - 5.3	33.3	30.3 - 36.3	66.3	62.3 - 70.3	2.7	0.7 - 4.7
ABL 80 Series	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
ABL 90 Series	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
Roche								
Cobas b 221	5.1	4.5 - 5.7	29.1	26.1 - 32.1	67.7	63.7 - 71.7	0.5	–1.5 - 2.5
OMNI Series	5.1	4.5 - 5.7	30.8	27.8 - 33.8	69.2	65.2 - 73.2	1.0	–1.0 - 3.0
Siemens								
400 Series	6.7	6.1 - 7.3	34.4	31.4 - 37.4	65.3	61.3 - 69.3	0.3	–1.7 - 2.3
500 Series	6.4	5.8 - 7.0	33.5	30.5 - 36.5	66.1	62.1 - 70.1	0.7	–1.3 - 2.7
1200 Series	5.9	5.3 - 6.5	33.3	30.3 - 36.3	66.0	62.0 - 70.0	0.6	–1.4 - 2.6

Level 2

LOT 34873 2024-09-30

Expected Values Chart

Analyzers	tHb g/dL mean	tHb g/dL range	O_2Hb % mean	O_2Hb % range	COHb % mean	COHb % range	MetHb[3] % mean	MetHb[3] % range
Accriva								
AVOXimeter 1000E	8.5	7.8 - 9.2	91.5	87.0 - 96.0				
AVOXimeter 4000	8.2	7.5 - 8.9	93.3	88.8 - 97.8	9.5	5.5 - 13.5	0.4	–2.5 - 3.3
IL								
482	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
682	7.7	7.0 - 8.4	94.1	89.1 - 99.1	6.8	2.8 - 10.8	0.4	–1.6 - 2.4
Synthesis Series	7.4	6.7 - 8.1	97.0	92.0 - 102.0	5.9	1.9 - 9.9	0.3	–1.7 - 2.3
GEM OPL	8.2	7.5 - 8.9	93.3	88.8 - 97.8	9.5	5.5 - 13.5	0.4	–2.5 - 3.3
GEM Premier 4000	8.0	7.3 - 8.7	95.2	90.2 - 100.2	4.3	0.3 - 8.3	0.6	–1.4 - 2.6
GEM Premier 5000	8.1	7.4 - 8.8	94.0	89.0 - 99.0	4.2	0.2 - 8.2	1.3	–0.7 - 3.3
Nova								
CCX	7.9	7.2 - 8.6	97.4	92.4 - 102.4	2.4	–1.6 - 6.4	0.2	–1.8 - 2.2
pHOx Ultra	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
Radiometer								
ABL 700 Series	7.9	7.2 - 8.6	95.5	90.5 - 100.5	2.7	–1.3 - 6.7	1.1	–0.9 - 3.1
ABL 800 Series	8.3	7.6 - 9.0	94.4	89.4 - 99.4	3.2	–0.8 - 7.2	1.6	–0.4 - 3.6
ABL 80 Series	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
ABL 90 Series	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
Roche								
Cobas b 221	8.1	7.4 - 8.8	94.6	89.6 - 99.6	4.5	0.5 - 8.5	0.6	–1.4 - 2.6
OMNI Series	7.4	6.7 - 8.1	95.5	90.5 - 100.5	3.8	–0.2 - 7.8	0.6	–1.4 - 2.6
Siemens								
400 Series	9.4	8.7 - 10.1	94.9	89.9 - 99.9	4.2	0.2 - 8.2	0.6	–1.4 - 2.6
500 Series	9.8	9.1 - 10.5	94.5	89.5 - 99.5	5.0	1.0 - 9.0	0.8	–1.2 - 2.8
1200 Series	9.1	8.4 - 9.8	95.3	90.3 - 100.3	5.1	1.1 - 9.1	0.3	–1.7 - 2.3

CVC 223 CO-Oximeter Calibration Verification Controls

Level 3

LOT 34969 2024-09-30

Expected Values Chart

Analyzers	tHb g/dL mean	tHb g/dL range	O_2Hb % mean	O_2Hb % range	COHb % mean	COHb % range	MetHb[3] % mean	MetHb[3] % range
Accriva								
AVOXimeter 1000E	13.1	12.0 - 14.2	80.4	76.1 - 84.7				
AVOXimeter 4000	13.1	12.0 - 14.2	81.2	76.9 - 85.5	20.7	16.2 - 25.2	0.6	–2.4 - 3.5
IL								
482	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
682	12.7	11.7 - 13.7	82.7	78.7 - 86.7	18.8	14.8 - 22.8	0.2	–1.8 - 2.2
Synthesis Series	12.9	11.9 - 13.9	84.9	80.9 - 88.9	17.7	13.7 - 21.7	0.0	–2.0 - 2.0
GEM OPL	13.1	12.0 - 14.2	81.2	76.9 - 85.5	20.7	16.2 - 25.2	0.6	–2.4 - 3.5
GEM Premier 4000	12.7	11.7 - 13.7	84.3	80.3 - 88.3	14.9	10.9 - 18.9	0.5	–1.5 - 2.5
GEM Premier 5000	12.9	11.9 - 13.9	83.6	79.6 - 87.6	15.0	11.0 - 19.0	0.4	–1.6 - 2.4
Nova								
CCX	13.7	12.7 - 14.7	86.1	82.1 - 90.1	13.0	9.0 - 17.0	0.1	–1.9 - 2.1
pHOx Ultra	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
Radiometer								
ABL 700 Series	13.2	12.2 - 14.2	85.1	81.1 - 89.1	13.2	9.2 - 17.2	1.1	–0.9 - 3.1
ABL 800 Series	13.3	12.3 - 14.3	84.5	80.5 - 88.5	13.0	9.0 - 17.0	1.1	–0.9 - 3.1
ABL 80 Series	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
ABL 90 Series	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
Roche								
Cobas b 221	12.4	11.4 - 13.4	84.3	80.3 - 88.3	15.0	11.0 - 19.0	0.4	–1.6 - 2.4
OMNI Series	12.6	11.6 - 13.6	84.6	80.6 - 88.6	14.1	10.1 - 18.1	0.9	–1.1 - 2.9
Siemens								
400 Series	14.1	13.1 - 15.1	84.5	80.5 - 88.5	15.1	11.1 - 19.1	0.0	–2.0 - 2.0
500 Series	14.3	13.3 - 15.3	84.8	80.8 - 88.8	15.1	11.1 - 19.1	0.1	–1.9 - 2.1
1200 Series	14.0	13.0 - 15.0	84.3	80.3 - 88.3	15.4	11.4 - 19.4	0.3	–1.7 - 2.3

Level 4

LOT 35066 2024-10-31

Expected Values Chart

Analyzers	tHb g/dL mean	tHb g/dL range	O_2Hb % mean	O_2Hb % range	COHb % mean	COHb % range	MetHb[3] % mean	MetHb[3] % range
Accriva								
AVOXimeter 1000E	17.2	15.9 - 18.5	53.1	48.8 - 57.4				
AVOXimeter 4000	17.0	15.7 - 18.3	54.5	50.2 - 58.8	47.5	42.2 - 52.8	0.2	–2.7 - 3.1
IL								
482	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
682	16.1	14.9 - 17.3	52.8	48.8 - 56.8	48.2	44.2 - 52.2	0.0	–2.0 - 2.0
Synthesis Series	16.0	14.8 - 17.2	58.1	54.1 - 62.1	46.4	42.4 - 50.4	–0.1	–2.1 - 1.9
GEM OPL	17.0	15.7 - 18.3	54.5	50.2 - 58.8	47.5	42.2 - 52.8	0.2	–2.7 - 3.1
GEM Premier 4000	16.4	15.2 - 17.6	54.1	50.1 - 58.1	44.0	40.0 - 48.0	0.7	–1.3 - 2.7
GEM Premier 5000	16.7	15.5 - 17.9	53.9	49.9 - 57.9	43.8	39.8 - 47.8	0.7	–1.3 - 2.7
Nova								
CCX	18.0	16.8 - 19.2	57.3	53.3 - 61.3	42.4	38.4 - 46.4	–0.1	–2.1 - 1.9
pHOx Ultra	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
Radiometer								
ABL 700 Series	16.2	15.0 - 17.4	56.8	52.8 - 60.8	42.8	38.8 - 46.8	2.3	0.3 - 4.3
ABL 800 Series	16.7	15.5 - 17.9	55.9	51.9 - 59.9	42.8	38.8 - 46.8	2.6	0.6 - 4.6
ABL 80 Series	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
ABL 90 Series	DNA[2]		DNA[2]		DNA[2]		DNA[2]	
Roche								
Cobas b 221	15.8	14.6 - 17.0	54.1	50.1 - 58.1	44.2	40.2 - 48.2	0.3	–1.7 - 2.3
OMNI Series	15.9	14.7 - 17.1	55.6	51.6 - 59.6	42.0	38.0 - 46.0	0.9	–1.1 - 2.9
Siemens								
400 Series	17.4	16.2 - 18.6	56.9	52.9 - 60.9	42.6	38.6 - 46.6	0.1	–1.9 - 2.1
500 Series	17.8	16.6 - 19.0	56.4	52.4 - 60.4	42.7	38.7 - 46.7	0.4	–1.6 - 2.4
1200 Series	17.6	16.4 - 18.8	55.6	51.6 - 59.6	43.3	39.3 - 47.3	0.5	–1.5 - 2.5