CVC 323

5 Levels

CVC 323 Electrolyte Calibration Verification Controls

LOT		Set: 2011-12	REF CVC 323
Level 1:	911701	Level 1: 2011-12	IVD
Level 2:	911801	Level 2: 2011-12	
Level 3:	911301	Level 3: 2011-12	
Level 4:	911401	Level 4: 2011-12	
Level 5:	911501	Level 5: 2011-12	

INTENDED USE

RNA Medical® Brand **CVC 323** *Calibration Verification Controls* are assayed materials used for confirming the calibration and linearity of instrumentation that measure pH; Na^+; K^+; Cl^-; Li^+ and Ca^{++}.

PRODUCT DESCRIPTION

CVC 323 is provided in five (5) distinct levels of pH, Na^+, K^+, Cl^-, Li^+ and Ca^{++}, covering the significant range of instrument performance. It is packaged in sealed glass ampuls, each containing 2.5 mL of solution. Ampuls are packaged in kits containing four (4) ampuls of each level.

Active Ingredients:
CVC 323 is a buffered aqueous solution containing pH and electrolytes. CVC 323 contains no preservatives and no human or biological materials.

STORAGE

Store unopened ampuls in closed box. The expiration date stated on the CVC 323 packaging is for product stored at 2-30°C. Avoid freezing and temperatures greater than 30°C.

DIRECTIONS FOR USE

CVC 323 should be brought to a temperature of 20-25°C (68-77°F) before use (see instructions regarding Expected Values). It is best to run calibration verification materials in the same manner as patient samples, however, please refer to the Instrument Manual or any specific instructions for your analyzer regarding the use of aqueous control materials.

Follow the procedures listed below:

1. Perform a two-point calibration on your instrument before beginning the calibration verification procedure.
2. Beginning with Level 1, hold the ampul at the top and bottom (with forefinger and thumb) and invert 15 to 20 times 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. (RNA Medical offers Snapper® Ampul Openers to protect fingers from cuts. Please contact RNA Medical for more information).
4. Immediately introduce the liquid from the ampul to the analyzer. Use direct aspiration, syringe transfer, or capillary mode techniques. ***Note**: Capillaries, if used, should not contain anticoagulants.*
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 case 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.

EXPECTED VALUES

The values for each 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 for this range for ampuls that are at 25°C when tested.

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 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. CVC 323 is sensitive to many instrument related factors that would affect analytical results. These products do not contain red blood cells and thus may not detect certain malfunctions that would affect the testing of blood.
2. This product is intended for use 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.

Level 1

LOT 911701

2011-12

Expected Values Chart	pH		Na^+ mmol/L		K^+ mmol/L		Cl^- mmol/L		Li^+ mmol/L		Ca^{++} mmol/L	
Analyzers	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*
Medica												
EasyStat	7.70	7.67 - 7.73	110	105 -115	2.2	1.7 - 2.7	72	67 - 77			0.60	0.50 - 0.70
OPTI Medical												
OPTI LION	DNA[2]		DNA[2]		DNA[2]		DNA[2]				DNA[2]	
Roche												
AVL 9180			105	100 -110	2.2	2.0 - 2.4	70	67 - 73	0.52	0.42 - 0.62	0.56	0.46 - 0.66
Siemens												
RAPIDPoint 350	DNA[2]		DNA[2]		DNA[2]		DNA[2]				DNA[2]	

Level 2

LOT 911801

2011-12

Expected Values Chart	pH		Na^+ mmol/L		K^+ mmol/L		Cl^- mmol/L		Li^+ mmol/L		Ca^{++} mmol/L	
Analyzers	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*
Medica												
EasyStat	7.50	7.47 - 7.53	124	119 - 129	2.9	2.4 - 3.4	88	83 - 93			1.24	1.14 - 1.34
OPTI Medical												
OPTI LION	DNA[2]		DNA[2]		DNA[2]		DNA[2]				DNA[2]	
Roche												
AVL 9180			120	115 - 125	3.0	2.8 - 3.2	88	85 - 91	1.85	1.70 - 2.00	1.26	1.11 - 1.41
Siemens												
RAPIDPoint 350	DNA[2]		DNA[2]		DNA[2]		DNA[2]				DNA[2]	

Level 3

LOT 911301

2011-12

Expected Values Chart	pH		Na^+ mmol/L		K^+ mmol/L		Cl^- mmol/L		Li^+ mmol/L		Ca^{++} mmol/L	
Analyzers	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*
Medica												
EasyStat	7.30	7.27 - 7.33	137	132 -142	4.4	3.9 - 4.9	111	106 -116			1.69	1.54 - 1.84
OPTI Medical												
OPTI LION	DNA[2]		DNA[2]		DNA[2]		DNA[2]				DNA[2]	
Roche												
AVL 9180			132	127 -137	4.6	4.4 - 4.8	109	106 -112	3.14	2.89 - 3.39	1.75	1.60 - 1.90
Siemens												
RAPIDPoint 350	DNA[2]		DNA[2]		DNA[2]		DNA[2]				DNA[2]	

Level 4

LOT 911401

2011-12

Expected Values Chart	pH		Na^+ mmol/L		K^+ mmol/L		Cl^- mmol/L		Li^+ mmol/L		Ca^{++} mmol/L	
Analyzers	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*
Medica												
EasyStat	7.06	7.03 - 7.09	158	153 -163	6.8	6.3 - 7.3	126	121 -131			1.92	1.77 - 2.07
OPTI Medical												
OPTI LION	DNA[2]		DNA[2]		DNA[2]		DNA[2]				DNA[2]	
Roche												
AVL 9180			156	151 -161	7.0	6.7 - 7.3	127	123 -131	4.19	3.79 - 4.59	2.04	1.89 - 2.19
Siemens												
RAPIDPoint 350	DNA[2]		DNA[2]		DNA[2]		DNA[2]				DNA[2]	

Level 5

LOT 911501

2011-12

Expected Values Chart	pH		Na^+ mmol/L		K^+ mmol/L		Cl^- mmol/L		Li^+ mmol/L		Ca^{++} mmol/L	
Analyzers	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*	*mean*	*range*
Medica												
EasyStat	6.88	6.85 - 6.91	175	170 -180	8.8	8.3 - 9.3	141	136 -146			2.78	2.38 - 3.18
OPTI Medical												
OPTI LION	DNA[2]		DNA[2]		DNA[2]		DNA[2]				DNA[2]	
Roche												
AVL 9180			174	169 -179	9.1	8.6 - 9.6	141	136 -146	ORL[1]		2.97	2.72 - 3.22
Siemens												
RAPIDPoint 350	DNA[2]		DNA[2]		DNA[2]		DNA[2]				DNA[2]	

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

RNA® MEDICAL

Calibration Verification Controls (CVC 323)

Data Collection and Linearity Worksheet

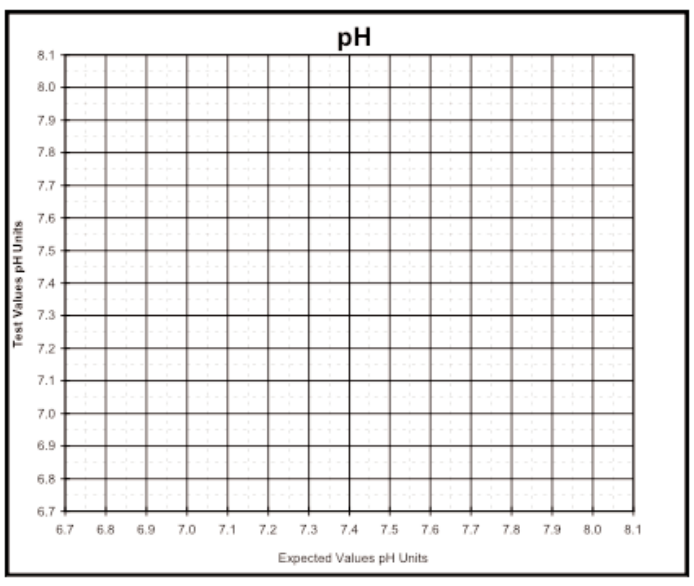
Date: _____ Operator: _____

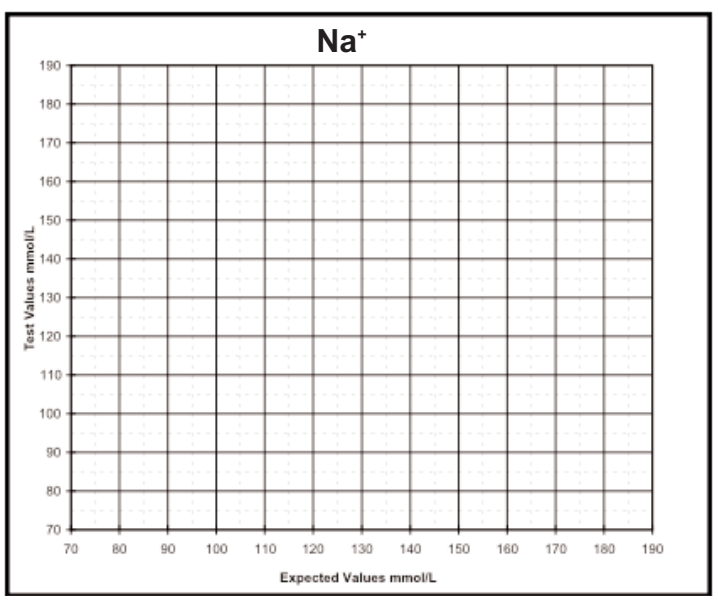
Instrument: _____ CVC 323 Lot #: _____

Instrument I.D.: _____ Expiration: _____

pH	*Level 1*	*Level 2*	*Level 3*	*Level 4*	*Level 5*
Test 1					
Test 2					
Test 3					
Test Mean					
Range					
OK?	Y or N	Y or N	Y or N	Y or N	Y or N

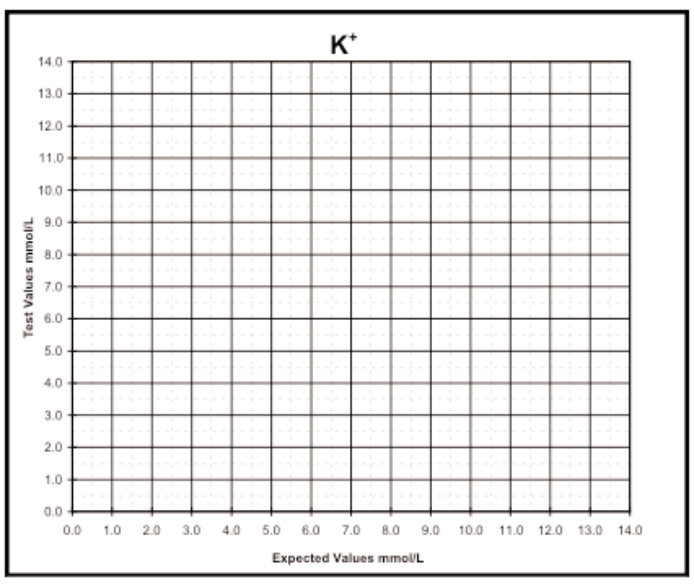
Na^+	*Level 1*	*Level 2*	*Level 3*	*Level 4*	*Level 5*
Test 1					
Test 2					
Test 3					
Test Mean					
Range					
OK?	Y or N	Y or N	Y or N	Y or N	Y or N





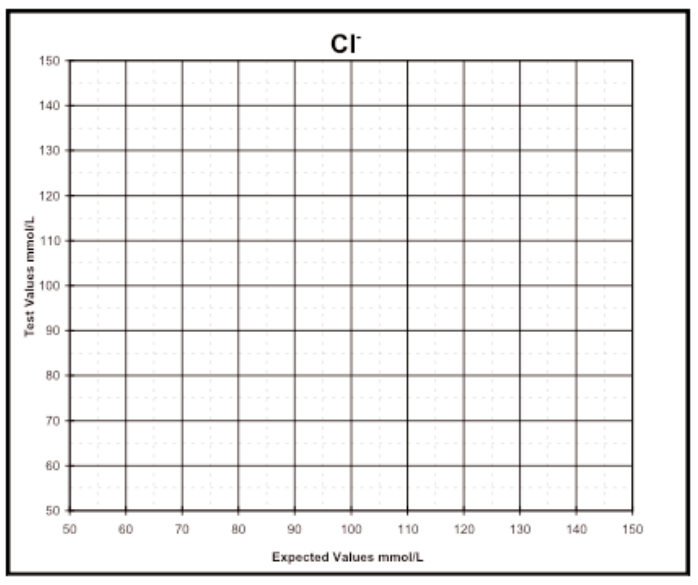
Comments: _____

K^+	*Level 1*	*Level 2*	*Level 3*	*Level 4*	*Level 5*
Test 1					
Test 2					
Test 3					
Test Mean					
Range					
OK?	Y or N	Y or N	Y or N	Y or N	Y or N



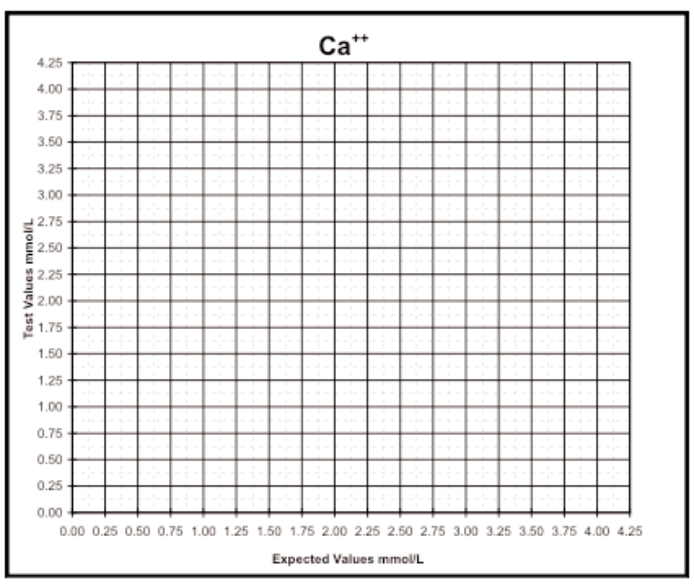
Comments: _____

Cl^-	*Level 1*	*Level 2*	*Level 3*	*Level 4*	*Level 5*
Test 1					
Test 2					
Test 3					
Test Mean					
Range					
OK?	Y or N	Y or N	Y or N	Y or N	Y or N



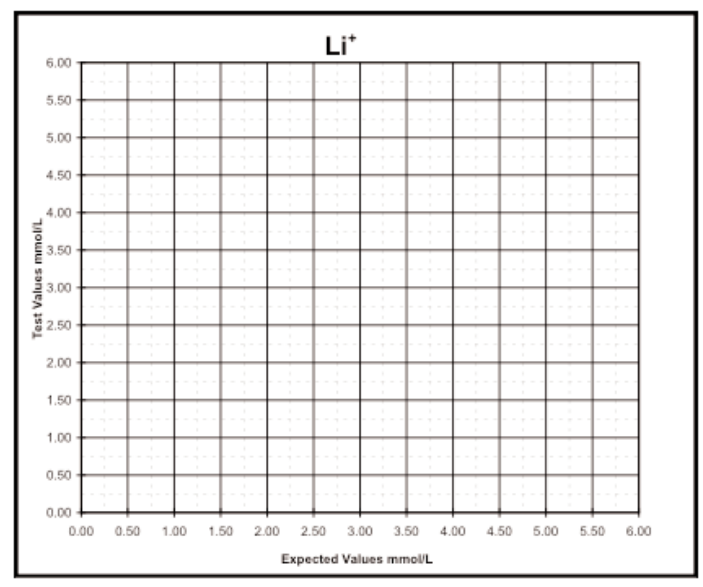
Comments: _____

Ca^{++}	*Level 1*	*Level 2*	*Level 3*	*Level 4*	*Level 5*
Test 1					
Test 2					
Test 3					
Test Mean					
Range					
OK?	Y or N	Y or N	Y or N	Y or N	Y or N



Comments: _____

Li^+	*Level 1*	*Level 2*	*Level 3*	*Level 4*	*Level 5*
Test 1					
Test 2					
Test 3					
Test Mean					
Range					
OK?	Y or N	Y or N	Y or N	Y or N	Y or N



Comments: _____

REF Catalog Number

Consult Instructions for Use

IVD For In Vitro Diagnostic Use

LOT Lot Number

Manufacturer

Store At

Use By

INSTRUMENT MANUFACTURERS

Medica Corporation, Bedford, MA
OPTI Medical, Roswell, GA
Roche Diagnostics, Indianapolis, IN
Siemens Healthcare Diagnostics, Deerfield, IL

RNA Medical, Division of Bionostics, Inc.
7 Jackson Road
Devens, MA 01434 USA
978-772-9070 • 800-533-6162
www.RNAMedical.com