

## LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

**CAT. NO.** CQ 5052

**LOT NO.** 4247CK

**SIZE:** 3 x 3 ml

**EXPIRY:** 2019-11-28

**GTIN:** 05055273207453

### INTENDED USE

This product is intended for *in vitro* diagnostic use, in the quality control of Cardiac Markers on clinical chemistry and Immunoassay systems.

### DEVICE DESCRIPTION

The Cardiac Controls are supplied at 3 levels, 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the table below.

### SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

### STORAGE AND STABILITY

**UNOPENED:** Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

**OPENED:** Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°C, if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

### PREPARATION FOR USE

The Liquid Cardiac Controls are supplied ready to use.

### MATERIALS PROVIDED

Liquid Cardiac Control - Level 2 3 x 3 ml

### MATERIALS REQUIRED BUT NOT PROVIDED

Not applicable.

### ASSIGNED VALUES

Each batch of Cardiac Control is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories and internal testing conducted at Randox Laboratories Ltd. The expected range of the mean is provided to aid laboratory, until it has established its own mean and SD for its methods.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email [Technical.Services@randox.com](mailto:Technical.Services@randox.com).

Rev. 25 Sep '18 bm

## LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot No. 4247CK Size: 3 x 3 ml Expiry: 2019-11-28

Analyte	unit	Target	Range		methods
			low	high	
CK-MB Mass	ng/ml = µg/l	5.24	3.67	6.81	Abbott Architect
	ng/ml = µg/l	7.65	5.36	9.95	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	5.71	4.00	7.42	Siemens Dimension
	ng/ml = µg/l	5.15	3.61	6.70	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	7.63	5.34	9.92	Beckman Coulter Access
	ng/ml = µg/l	6.38	4.47	8.29	Siemens Stratus CS
	ng/ml = µg/l	8.81	6.17	11.5	BioMerieux Vidas
	ng/ml = µg/l	7.81	5.47	10.2	Beckman Dxl800
	ng/ml = µg/l	4.63	3.24	6.02	Roche h232
	ng/ml = µg/l	9.40	6.58	12.2	Radiometer AQT90 Flex
	ng/ml = µg/l	6.14	4.30	7.98	Siemens Dimension Vista LOCI
ng/ml = µg/l	6.93	4.85	9.01	Siemens Centaur CP	
D-Dimer	µg/l FEU	1428	1071	1785	Biomerieux Vidas Exclusion II
	µg/l FEU	6236	4677	7795	Mitsubishi Pathfast D-Dimer
	µg/l	616	462	770	Roche/ Stago STA-R Evolution
	µg/l	844	633	1055	Roche Cobas h232 D-Dimer
	µg/l	636	477	795	Roche Integra D-DI 2
	µg/l	955	716	1194	Alere Biosite Triage D-Dimer
	µg/l	795	596	994	Abbott Architect Quantia D-Dimer
	µg/l	1121	841	1401	Siemens Stratus CS
	µg/l	326	245	408	Siemens Immulite 2000 D-Dimer
	µg/l	884	663	1105	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	2032	1524	2540	Siemens Innovance D-Dimer
	µg/l	584	438	730	Roche Cobas D-DI 2
	µg/l FEU	2242	1682	2803	HemosIL D-Dimer HS 500
	µg/l	672	504	840	HemosIL D-Dimer
µg/l	713	535	891	HemosIL D-Dimer HS	
Digoxin	nmol/l	1.31	1.05	1.57	Chemiluminescence
	ng/ml	1.02	0.820	1.22	
	nmol/l	1.16	0.928	1.39	Enzyme Immunoassay
	ng/ml	0.906	0.725	1.09	
	nmol/l	1.28	1.02	1.54	Turbidimetric
	ng/ml	1.00	0.797	1.20	
	nmol/l	1.10	0.880	1.32	KIMS
	ng/ml	0.859	0.687	1.03	
nmol/l	1.21	0.968	1.45	Enzyme Linked Fluorescent assay	
ng/ml	0.945	0.756	1.13		
hsCRP	mg/l	1.82	1.46	2.18	Nephelometric (IFCC Cal.)
	mg/l	1.96	1.57	2.35	Turbidimetric (IFCC Cal.)
	mg/l	2.02	1.62	2.42	Turbidimetric (Non IFCC Cal.)
	mg/l	1.92	1.54	2.30	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	96.9	67.8	126	Abbott Architect

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			low	high	
Myoglobin	ng/ml = µg/l	80.3	56.2	104	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	82.7	57.9	108	Siemens Dimension
	ng/ml = µg/l	58.6	41.0	76.2	Beckman Dxl800
	ng/ml = µg/l	67.5	47.3	87.8	Roche Elecsys
	ng/ml = µg/l	73.5	51.5	95.6	Roche Hitachi
	ng/ml = µg/l	58.2	40.7	75.7	Beckman Coulter Access
	ng/ml = µg/l	43.7	30.6	56.8	Siemens Stratus CS
	ng/ml = µg/l	60.2	42.1	78.3	BioMerieux Vidas
	ng/ml = µg/l	69.2	48.4	90.0	Siemens Dimension Vista LOCI
	ng/ml = µg/l	70.8	49.6	92.0	Siemens Centaur CP
	ng/ml = µg/l	98.1	68.7	128	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	14.4	10.8	18.0	Siemens Centaur XP/XPT/Classic
	pg/ml	122	91.5	153	
	pmol/l	84.7	63.5	106	Siemens Immulite 2000
	pg/ml	718	538	898	
	pmol/l	20.7	15.5	25.9	Siemens Stratus CS
	pg/ml	175	131	219	
	pmol/l	22.5	16.9	28.1	BioMerieux Vidas
	pg/ml	191	143	239	
	pmol/l	18.2	13.7	22.8	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	154	116	192	
	pmol/l	62.4	46.8	78.0	Mitsubishi Chemical Pathfast
	pg/ml	529	396	662	
	pmol/l	32.3	24.2	40.4	Ortho Vitros 3600/5600/ECi
	pg/ml	274	205	343	
	pmol/l	13.0	9.75	16.3	Roche h232
	pg/ml	110	82.6	137	
	pmol/l	8.22	6.17	10.3	Siemens Dimension Vista LOCI
	pg/ml	69.6	52.3	86.9	
pmol/l	3.83	2.87	4.79	Siemens Dimension Exl LOCI	
pg/ml	32.4	24.3	40.5		
pmol/l	22.1	16.6	27.6	Biomerieux Vidas 2	
pg/ml	187	141	233		
Troponin I	ng/ml = µg/l	0.024	0.019	0.029	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	24.0	19.0	29.0	
	ng/ml = µg/l	0.010	0.008	0.012	Beckman Coulter Access
	ng/l = pg/ml	10.0	8.00	12.0	
	ng/ml = µg/l	0.206	0.165	0.247	Ortho Vitros ECi
	ng/l = pg/ml	206	165	247	
	ng/ml = µg/l	0.159	0.127	0.191	Biomerieux Vidas Ultra
	ng/l = pg/ml	159	127	191	
	ng/ml = µg/l	0.020	0.016	0.024	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	20.0	16.0	24.0	
ng/ml = µg/l	0.029	0.023	0.035	Abbott Architect STAT hs	
ng/l = pg/ml	29.0	23.0	35.0		
ng/ml = µg/l	0.022	0.018	0.026	Siemens Centaur CP	
ng/l = pg/ml	22.0	18.0	26.0		

# RANDOX

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Analyte	unit	Target	Range		methods
			low	high	
Troponin I	ng/ml = µg/l	0.156	0.125	0.187	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	156	125	187	