

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

**CAT. NO.** CQ505I      **LOT NO.** 3909CK

**SIZE:** 3 x 3 ml      **EXPIRY:** 2017-10

## 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 following analytes: CK-MB Mass, Digoxin, D-Dimer, hsCRP, Myoglobin, NT-ProBNP, Troponin I and Troponin T.

## 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.

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 I      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).

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## LIQUID CARDIAC CONTROL - LEVEL 1 (CRD LIQ CONTROL 1)

Cat. No. CQ5051 Lot No. 3909CK Size: 3 x 3 ml Expiry: 2017-10

Range					
Analyte	unit	Target	low	high	methods
CK-MB Mass	ng/ml = µg/l	3.40	2.72	4.08	Abbott Architect
	ng/ml = µg/l	4.19	3.35	5.03	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	2.66	2.13	3.19	Siemens Dimension
	ng/ml = µg/l	3.32	2.66	3.98	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	3.99	3.19	4.79	Beckman Coulter Access
	ng/ml = µg/l	2.99	2.39	3.59	Siemens Stratus CS
	ng/ml = µg/l	6.29	5.03	7.55	BioMerieux Vidas
	ng/ml = µg/l	4.08	3.26	4.90	Beckman Dxl800
	ng/ml = µg/l	3.55	2.84	4.26	Roche h232
	ng/ml = µg/l	2.52	2.02	3.02	Siemens Dimension Vista LOCI
	ng/ml = µg/l	3.35	2.68	4.02	Siemens Centaur CP
D - Dimer	µg/l FEU	1116	837	1395	Biomerieux Vidas Exclusion II
	µg/l FEU	3354	2516	4193	Mitsubishi Pathfast D-Dimer
	µg/l	370	278	463	Roche/ Stago STA-R Evolution
	µg/l	637	478	796	Roche Cobas h232 D-Dimer
	µg/l	368	276	460	Roche Integra D-DI 2
	µg/l	676	507	845	Alere Biosite Triage D-Dimer
	µg/l	660	495	825	Abbott Architect Quantia D-Dimer
	µg/l	555	416	694	Roche Cardiac Reader D-Dimer
	µg/l	545	409	681	Siemens Stratus CS
	µg/l	130	97.5	163	Siemens Immulite 2000 D-Dimer
	µg/l	647	485	809	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1498	1124	1873	Siemens Innovance D-Dimer
	µg/l	241	181	301	Roche Cobas D-DI 2
	µg/l FEU	1642	1232	2053	HemosIL D-Dimer HS 500
	µg/l	473	355	591	HemosIL D-Dimer
	µg/l	510	383	638	HemosIL D-Dimer HS
Digoxin	nmol/l	1.20	0.960	1.44	Chemiluminescence
	ng/ml	0.937	0.750	1.12	
	nmol/l	1.03	0.824	1.24	Enzyme Immunoassay
	ng/ml	0.804	0.644	0.964	
	nmol/l	0.943	0.754	1.13	Turbidimetric
	ng/ml	0.736	0.589	0.883	
	nmol/l	0.915	0.732	1.10	KIMS
	ng/ml	0.715	0.572	0.858	
hsCRP	mg/l	0.793	0.634	0.952	Nephelometric (IFCC Cal.)
	mg/l	0.843	0.674	1.01	Nephelometric (Non IFCC Cal.)
	mg/l	0.902	0.722	1.08	Turbidimetric (IFCC Cal.)
	mg/l	0.890	0.720	1.06	Turbidimetric (Non IFCC Cal.)
	mg/l	0.863	0.690	1.04	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	57.9	46.3	69.5	Abbott Architect
	ng/ml = µg/l	51.6	41.3	61.9	Siemens Centaur XP/XPT/Classic

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Range					
Analyte	unit	Target	low	high	methods
Myoglobin	ng/ml = µg/l	45.8	36.6	55.0	Siemens Dimension
	ng/ml = µg/l	35.1	28.1	42.1	Beckman Dxl800
	ng/ml = µg/l	41.5	33.2	49.8	Roche Elecsys
	ng/ml = µg/l	47.5	38.0	57.0	Roche Hitachi
	ng/ml = µg/l	59.0	47.2	70.8	Roche Integra
	ng/ml = µg/l	34.8	27.8	41.8	Beckman Coulter Access
	ng/ml = µg/l	24.8	19.8	29.8	Siemens Stratus CS
	ng/ml = µg/l	38.7	31.0	46.4	BioMerieux Vidas
	ng/ml = µg/l	49.5	39.6	59.4	Biosite Triage Meter Plus
	ng/ml = µg/l	37.0	29.6	44.4	Siemens Dimension Vista LOCI
	ng/ml = µg/l	61.8	49.4	74.2	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	38.9	29.2	48.6	Siemens Immulite 2000
	pg/ml	330	247	413	
	pmol/l	13.8	10.4	17.3	Siemens Stratus CS
	pg/ml	117	88.1	146	
	pmol/l	11.4	8.55	14.3	BioMerieux Vidas
	pg/ml	96.6	72.4	121	
	pmol/l	10.9	8.18	13.6	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	92.3	69.3	115	
	pmol/l	37.6	28.2	47.0	Mitsubishi Chemical Pathfast
	pg/ml	319	239	399	
	pmol/l	21.7	16.3	27.1	Ortho Vitros 3600/5600/ECi
	pg/ml	184	138	230	
	pmol/l	7.26	5.45	9.08	Roche h232
	pg/ml	61.5	46.2	76.8	
	pmol/l	5.13	3.85	6.41	Siemens Dimension Vista LOCI
	pg/ml	43.5	32.6	54.4	
	pmol/l	2.49	1.87	3.11	Siemens Dimension Exl LOCI
	pg/ml	21.1	15.8	26.4	
	pmol/l	10.4	7.80	13.0	Biomerieux Vidas 2
	pg/ml	88.1	66.1	110	
Troponin I	ng/ml = µg/l	0.563	0.450	0.676	Abbott Architect
	ng/ml = µg/l	0.030	0.024	0.036	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.357	0.286	0.428	Tosoh AIA360
	ng/ml = µg/l	0.332	0.266	0.398	Ortho Vitros ECi
	ng/ml = µg/l	0.393	0.314	0.472	BioMerieux Vidas
	ng/ml = µg/l	0.395	0.316	0.474	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.101	0.081	0.121	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	0.029	0.023	0.035	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.016	0.013	0.019	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.043	0.034	0.052	Abbott Architect STAT hs
	ng/ml = µg/l	0.031	0.025	0.037	Siemens Centaur CP
Troponin T	µg/l	0.010	0.008	0.013	Roche Cobas Troponin T HS