

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

CAT. NO. CQ505I **LOT NO.** 3833CK

SIZE: 3 x 3 ml **EXPIRY:** 2017-04

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.

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

Cat. No. CQ5051 Lot No. 3833CK Size: 3 x 3 ml Expiry: 2017-04

Range					
Analyte	unit	Target	low	high	methods
CK-MB Mass	ng/ml = µg/l	2.75	2.20	3.30	Abbott Architect
	ng/ml = µg/l	3.84	3.07	4.61	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	2.19	1.75	2.63	Siemens Dimension
	ng/ml = µg/l	2.95	2.36	3.54	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	3.48	2.78	4.18	Beckman Coulter Access
	ng/ml = µg/l	2.74	2.19	3.29	Siemens Stratus CS
	ng/ml = µg/l	5.71	4.57	6.85	BioMerieux Vidas
	ng/ml = µg/l	3.66	2.93	4.39	Beckman Dxl800
	ng/ml = µg/l	1.08	0.864	1.30	Biosite Triage Meter Plus
	ng/ml = µg/l	3.21	2.57	3.85	Roche h232
	ng/ml = µg/l	4.68	3.74	5.62	Radiometer AQT90 Flex
	ng/ml = µg/l	2.39	1.91	2.87	Siemens Dimension Vista LOCI
	ng/ml = µg/l	3.10	2.48	3.72	Siemens Centaur CP
	ng/ml = µg/l	3.10	2.48	3.72	Siemens Centaur CP
D - Dimer	µg/l FEU	1166	875	1458	Biomerieux Vidas Exclusion II
	µg/l FEU	3574	2681	4468	Mitsubishi Pathfast D-Dimer
	µg/l	374	281	468	Roche/ Stago STA-R Evolution
	µg/l	100	75.0	125	Nycocard D-Dimer
	µg/l	619	464	774	Roche Cobas h232 D-Dimer
	µg/l	416	312	520	Roche Integra D-DI 2
	µg/l	566	425	708	Alere Biosite Triage D-Dimer
	µg/l	649	487	811	Abbott Architect Quantia D-Dimer
	µg/l	594	446	743	Siemens Stratus CS
	µg/l	192	144	240	Siemens Immulite 2000 D-Dimer
	µg/l	672	504	840	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1614	1211	2018	Siemens Innovance D-Dimer
	µg/l	256	192	320	Roche Cobas D-DI 2
	µg/l FEU	1748	1311	2185	HemosIL D-Dimer HS 500
	µg/l	483	362	604	HemosIL D-Dimer
	µg/l	552	414	690	HemosIL D-Dimer HS
Digoxin	nmol/l	1.33	1.06	1.60	Chemiluminescence
	ng/ml	1.04	0.828	1.25	
	nmol/l	1.39	1.11	1.67	Vitros
	ng/ml	1.09	0.867	1.31	
	nmol/l	1.11	0.888	1.33	Enzyme Immunoassay
	ng/ml	0.867	0.694	1.04	
	nmol/l	1.05	0.840	1.26	Turbidimetric
	ng/ml	0.820	0.656	0.984	
hsCRP	nmol/l	1.13	0.904	1.36	KIMS
	ng/ml	0.883	0.706	1.06	
	ng/ml	0.831	0.665	0.997	
hsCRP	mg/l	0.831	0.665	0.997	Nephelometric (IFCC Cal.)
	mg/l	0.857	0.686	1.03	Nephelometric (Non IFCC Cal.)
	mg/l	0.958	0.766	1.15	Turbidimetric (IFCC Cal.)

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

Cat. No. CQ5051 Lot No. 3833CK Size: 3 x 3 ml Expiry: 2017-04

Range					
Analyte	unit	Target	low	high	methods
hsCRP	mg/l	0.996	0.797	1.20	Turbidimetric (Non IFCC Cal.)
	mg/l	0.958	0.770	1.15	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	59.3	47.4	71.2	Abbott Architect
	ng/ml = µg/l	38.9	31.1	46.7	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	50.4	40.3	60.5	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	44.3	35.4	53.2	Siemens Dimension
	ng/ml = µg/l	35.1	28.1	42.1	Beckman Dxl800
	ng/ml = µg/l	41.9	33.5	50.3	Roche Elecsys
	ng/ml = µg/l	46.8	37.4	56.2	Roche Hitachi
	ng/ml = µg/l	60.3	48.2	72.4	Roche Integra
	ng/ml = µg/l	34.6	27.7	41.5	Beckman Coulter Access
	ng/ml = µg/l	26.3	21.0	31.6	Siemens Stratus CS
	ng/ml = µg/l	42.2	33.8	50.6	BioMerieux Vidas
	ng/ml = µg/l	44.9	35.9	53.9	Biosite Triage Meter Plus
	ng/ml = µg/l	16.0	12.8	19.2	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	75.3	60.2	90.4	Ortho Vitros 3600/5600/ECi
	ng/ml = µg/l	34.0	27.2	40.8	Siemens Dimension Vista LOCI
	ng/ml = µg/l	45.5	36.4	54.6	Siemens Centaur CP
	ng/ml = µg/l	57.7	46.2	69.2	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	5.73	4.30	7.16	Siemens Dimension
	pg/ml	48.5	36.4	60.6	
	pmol/l	33.4	25.1	41.8	Siemens Immulite 2000
	pg/ml	283	213	353	
	pmol/l	13.4	10.1	16.8	Siemens Stratus CS
	pg/ml	114	85.6	142	
	pmol/l	10.2	7.65	12.8	BioMerieux Vidas
	pg/ml	86.4	64.8	108	
	pmol/l	10.2	7.65	12.8	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	86.4	64.8	108	
	pmol/l	26.5	19.9	33.1	Mitsubishi Chemical Pathfast
	pg/ml	225	169	281	
	pmol/l	17.3	13.0	21.6	Ortho Vitros 3600/5600/ECi
	pg/ml	147	110	184	
	pmol/l	5.25	3.94	6.56	Siemens Dimension Vista LOCI
	pg/ml	44.5	33.4	55.6	
	pmol/l	2.63	1.97	3.29	Siemens Dimension Exl LOCI
	pg/ml	22.3	16.7	27.9	
	pmol/l	10.4	7.80	13.0	Biomerieux Vidas 2
	pg/ml	88.1	66.1	110	
Troponin I	ng/ml = µg/l	1.81	1.45	2.17	Abbott Architect
	ng/ml = µg/l	0.102	0.082	0.122	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.600	0.480	0.720	Siemens Immulite 1000
	ng/ml = µg/l	0.060	0.048	0.072	Beckman DXi800 1st gen
	ng/ml = µg/l	0.054	0.043	0.065	Beckman Coulter Access
	ng/ml = µg/l	1.24	0.992	1.49	Tosoh AIA360
	ng/ml = µg/l	1.10	0.880	1.32	Ortho Vitros ECi

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

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Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	0.942	0.754	1.13	BioMerieux Vidas
	ng/ml = µg/l	0.950	0.760	1.14	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.091	0.073	0.109	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.044	0.035	0.053	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.049	0.039	0.059	Siemens Dimension Exl LOCI
	ng/ml = µg/l	0.103	0.082	0.124	Abbott Architect STAT hs
	ng/ml = µg/l	0.061	0.049	0.073	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	0.057	0.046	0.068	Beckman Access - AccuTnl+3
	ng/ml = µg/l	0.089	0.071	0.107	Siemens Centaur CP
Troponin T	µg/l	0.023	0.017	0.029	Roche Cobas TroponinT
	µg/l	0.025	0.019	0.031	Roche Cobas Troponin T HS
	µg/l	0.013	0.010	0.016	Radiometer AQT90 Flex