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

CAT. NO. CQ 5052 **LOT NO.** 3911CK
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, D-Dimer, Digoxin, 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 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.

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			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	19.5	15.6	23.4	Abbott Architect
	ng/ml = µg/l	20.9	16.7	25.1	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	18.9	15.1	22.7	Siemens Dimension
	ng/ml = µg/l	16.4	13.1	19.7	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	24.3	19.4	29.2	Beckman Coulter Access
	ng/ml = µg/l	19.0	15.2	22.8	Siemens Stratus CS
	ng/ml = µg/l	30.3	24.2	36.4	BioMerieux Vidas
	ng/ml = µg/l	24.5	19.6	29.4	Beckman DxI800
	ng/ml = µg/l	12.0	9.60	14.4	Biosite Triage Meter Plus
	ng/ml = µg/l	15.8	12.6	19.0	Roche h232
	ng/ml = µg/l	30.8	24.6	37.0	Radiometer AQT90 Flex
	ng/ml = µg/l	17.6	14.1	21.1	Siemens Dimension Vista LOCI
	ng/ml = µg/l	19.4	15.5	23.3	Siemens Centaur CP
D - Dimer	µg/l FEU	1304	978	1630	Biomerieux Vidas Exclusion II
	µg/l FEU	4538	3404	5673	Mitsubishi Pathfast D-Dimer
	µg/l	437	328	546	Roche/ Stago STA-R Evolution
	µg/l	740	555	925	Roche Cobas h232 D-Dimer
	µg/l	418	314	523	Roche Integra D-DI 2
	µg/l	746	560	933	Alere Biosite Triage D-Dimer
	µg/l	717	538	896	Abbott Architect Quantia D-Dimer
	µg/l	747	560	934	Roche Cardiac Reader D-Dimer
	µg/l	727	545	909	Siemens Stratus CS
	µg/l	224	168	280	Siemens Immulite 2000 D-Dimer
	µg/l	710	533	888	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1778	1334	2223	Siemens Innovance D-Dimer
	µg/l	301	226	376	Roche Cobas D-DI 2
	µg/l FEU	1894	1421	2368	HemosIL D-Dimer HS 500
	µg/l	563	422	704	HemosIL D-Dimer
	µg/l	593	445	741	HemosIL D-Dimer HS
Digoxin	nmol/l	2.23	1.78	2.68	Chemiluminescence
	ng/ml	1.74	1.39	2.09	
	nmol/l	1.88	1.50	2.26	Vitros
	ng/ml	1.47	1.17	1.77	
	nmol/l	2.03	1.62	2.44	Enzyme Immunoassay
	ng/ml	1.59	1.27	1.91	
	nmol/l	1.97	1.58	2.36	Turbidimetric
	ng/ml	1.54	1.23	1.85	
	nmol/l	1.88	1.50	2.26	KIMS
	ng/ml	1.47	1.17	1.77	
hsCRP	mg/l	2.88	2.30	3.46	Nephelometric (IFCC Cal.)
	mg/l	2.89	2.31	3.47	Turbidimetric (IFCC Cal.)
	mg/l	2.93	2.34	3.52	Turbidimetric (Non IFCC Cal.)

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
hsCRP	mg/l	2.89	2.31	3.47	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	152	122	182	Abbott Architect
	ng/ml = µg/l	115	92.0	138	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	133	106	160	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	137	110	164	Siemens Dimension
	ng/ml = µg/l	93.8	75.0	113	Beckman DxI800
	ng/ml = µg/l	105	84.0	126	Roche Elecsys
	ng/ml = µg/l	106	84.8	127	Roche Hitachi
	ng/ml = µg/l	118	94.4	142	Roche Integra
	ng/ml = µg/l	90.8	72.6	109	Beckman Coulter Access
	ng/ml = µg/l	74.6	59.7	89.5	Siemens Stratus CS
	ng/ml = µg/l	114	91.2	137	BioMerieux Vidas
	ng/ml = µg/l	144	115	173	Biosite Triage Meter Plus
	ng/ml = µg/l	50.7	40.6	60.8	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	111	88.8	133	Siemens Dimension Vista LOCI
	ng/ml = µg/l	132	106	158	Siemens Centaur CP
	ng/ml = µg/l	153	122	183	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	26.4	19.8	33.0	Siemens Dimension
	pg/ml	224	168	280	
	pmol/l	209	157	261	Siemens Immulite 2000
	pg/ml	1771	1330	2212	
	pmol/l	75.1	56.3	93.9	Siemens Stratus CS
	pg/ml	636	477	795	
	pmol/l	60.4	45.3	75.5	BioMerieux Vidas
	pg/ml	512	384	640	
	pmol/l	47.5	35.6	59.4	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	402	302	502	
	pmol/l	181	136	226	Mitsubishi Chemical Pathfast
	pg/ml	1533	1152	1914	
	pmol/l	100	75.0	125	Ortho Vitros 3600/5600/ECi
	pg/ml	847	635	1059	
	pmol/l	34.9	26.2	43.6	Roche h232
	pg/ml	296	222	370	
	pmol/l	27.6	20.7	34.5	Siemens Dimension Vista LOCI
	pg/ml	234	175	293	
	pmol/l	13.7	10.3	17.1	Siemens Dimension Exl LOCI
	pg/ml	116	87.3	145	
	pmol/l	60.7	45.5	75.9	Biomerieux Vidas 2
	pg/ml	514	385	643	
Troponin I	ng/ml = µg/l	15.5	12.4	18.6	Abbott Architect
	ng/ml = µg/l	1.27	1.02	1.52	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.499	0.399	0.599	Siemens Dimension
	ng/ml = µg/l	4.07	3.26	4.88	Siemens Immulite 2000
	ng/ml = µg/l	0.679	0.543	0.815	Beckman DXi800 1st gen
	ng/ml = µg/l	0.631	0.505	0.757	Beckman Coulter Access
	ng/ml = µg/l	0.746	0.597	0.895	Siemens Stratus CS

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Troponin I	ng/ml = µg/l	10.2	8.16	12.2	Tosoh AIA360
	ng/ml = µg/l	8.57	6.86	10.3	Ortho Vitros ECi
	ng/ml = µg/l	4.87	3.90	5.84	BioMerieux Vidas
	ng/ml = µg/l	5.24	4.19	6.29	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.449	0.359	0.539	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	1.14	0.912	1.37	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	6.26	5.01	7.51	Abbott i STAT
	ng/ml = µg/l	0.680	0.544	0.816	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.648	0.518	0.778	Siemens Dimension Exl LOCI
	ng/ml = µg/l	0.975	0.780	1.17	Abbott Architect STAT hs
	ng/ml = µg/l	0.695	0.556	0.834	Beckman DxI - AccuTnI+3
	ng/ml = µg/l	0.648	0.518	0.778	Beckman Access - AccuTnI+3
	ng/ml = µg/l	1.02	0.816	1.22	Siemens Centaur CP
Troponin T	µg/l	0.190	0.143	0.238	Roche Cobas TroponinT
	µg/l	0.193	0.145	0.241	Roche Cobas Troponin T HS
	µg/l	0.074	0.056	0.093	Roche h232
	µg/l	0.156	0.117	0.195	Radiometer AQT90 Flex