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

CAT. NO.	CQ5051	**LOT NO.**	3913CK
SIZE:	3 x 3 ml	**EXPIRY:**	2017-10
GTIN:	05055273207446		

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 1 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	5.01	4.01	6.01	Abbott Architect
	ng/ml = µg/l	6.05	4.84	7.26	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	3.94	3.15	4.73	Siemens Dimension
	ng/ml = µg/l	4.80	3.84	5.76	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	6.21	4.97	7.45	Beckman Coulter Access
	ng/ml = µg/l	4.47	3.58	5.36	Siemens Stratus CS
	ng/ml = µg/l	8.82	7.06	10.6	BioMerieux Vidas
	ng/ml = µg/l	6.33	5.06	7.60	Beckman DxI800
	ng/ml = µg/l	5.09	4.07	6.11	Roche h232
	ng/ml = µg/l	7.70	6.16	9.24	Radiometer AQT90 Flex
	ng/ml = µg/l	3.96	3.17	4.75	Siemens Dimension Vista LOCI
	ng/ml = µg/l	5.45	4.36	6.54	Siemens Centaur CP
D - Dimer	µg/l FEU	1154	866	1443	Biomerieux Vidas Exclusion II
	µg/l FEU	3706	2780	4633	Mitsubishi Pathfast D-Dimer
	µg/l	378	284	473	Roche/ Stago STA-R Evolution
	µg/l	614	461	768	Roche Cobas h232 D-Dimer
	µg/l	372	279	465	Roche Integra D-DI 2
	µg/l	651	488	814	Alere Biosite Triage D-Dimer
	µg/l	623	467	779	Abbott Architect Quantia D-Dimer
	µg/l	588	441	735	Siemens Stratus CS
	µg/l	155	116	194	Siemens Immulite 2000 D-Dimer
	µg/l	642	482	803	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1564	1173	1955	Siemens Innovance D-Dimer
	µg/l	226	170	283	Roche Cobas D-DI 2
	µg/l FEU	1718	1289	2148	HemosIL D-Dimer HS 500
	µg/l	493	370	616	HemosIL D-Dimer
	µg/l	536	402	670	HemosIL D-Dimer HS
Digoxin	nmol/l	1.39	1.11	1.67	Chemiluminescence
	ng/ml	1.09	0.867	1.31	
	nmol/l	1.19	0.952	1.43	Vitros
	ng/ml	0.929	0.744	1.11	
	nmol/l	1.19	0.952	1.43	Enzyme Immunoassay
	ng/ml	0.929	0.744	1.11	
	nmol/l	1.08	0.864	1.30	Turbidimetric
	ng/ml	0.843	0.675	1.01	
	nmol/l	0.996	0.797	1.20	KIMS
	ng/ml	0.778	0.622	0.934	
hsCRP	mg/l	1.26	1.01	1.51	Nephelometric (IFCC Cal.)
	mg/l	1.20	0.960	1.44	Nephelometric (Non IFCC Cal.)
	mg/l	1.35	1.08	1.62	Turbidimetric (IFCC Cal.)
	mg/l	1.31	1.05	1.57	Turbidimetric (Non IFCC Cal.)
	mg/l	1.35	1.08	1.62	Randox Immunoturbidimetric

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Cat. No. CQ5051 Lot No. 3913CK Size: 3 x 3 ml Expiry: 2017-10

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Myoglobin	ng/ml = µg/l	73.0	58.4	87.6	Abbott Architect
	ng/ml = µg/l	48.7	39.0	58.4	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	61.7	49.4	74.0	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	59.8	47.8	71.8	Siemens Dimension
	ng/ml = µg/l	45.6	36.5	54.7	Beckman DxI800
	ng/ml = µg/l	52.0	41.6	62.4	Roche Elecsys
	ng/ml = µg/l	56.3	45.0	67.6	Roche Hitachi
	ng/ml = µg/l	67.4	53.9	80.9	Roche Integra
	ng/ml = µg/l	42.6	34.1	51.1	Beckman Coulter Access
	ng/ml = µg/l	31.5	25.2	37.8	Siemens Stratus CS
	ng/ml = µg/l	53.7	43.0	64.4	BioMerieux Vidas
	ng/ml = µg/l	54.5	43.6	65.4	Biosite Triage Meter Plus
	ng/ml = µg/l	99.0	79.2	119	Ortho Vitros 3600/5600/ECi
	ng/ml = µg/l	46.3	37.0	55.6	Siemens Dimension Vista LOCI
	ng/ml = µg/l	76.1	60.9	91.3	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	7.87	5.90	9.84	Siemens Dimension
	pg/ml	66.7	50.0	83.4	
	pmol/l	48.2	36.2	60.3	Siemens Immulite 2000
	pg/ml	408	307	509	
	pmol/l	17.9	13.4	22.4	Siemens Stratus CS
	pg/ml	152	114	190	
	pmol/l	12.6	9.45	15.8	BioMerieux Vidas
	pg/ml	107	80.1	134	
	pmol/l	12.9	9.68	16.1	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	109	82.0	136	
	pmol/l	40.2	30.2	50.3	Mitsubishi Chemical Pathfast
	pg/ml	341	256	426	
	pmol/l	26.4	19.8	33.0	Ortho Vitros 3600/5600/ECi
	pg/ml	224	168	280	
	pmol/l	8.61	6.46	10.8	Roche h232
	pg/ml	72.9	54.7	91.1	
	pmol/l	6.87	5.15	8.59	Siemens Dimension Vista LOCI
	pg/ml	58.2	43.6	72.8	
	pmol/l	3.30	2.48	4.13	Siemens Dimension ExI LOCI
	pg/ml	28.0	21.0	35.0	
	pmol/l	12.6	9.45	15.8	Biomerieux Vidas 2
	pg/ml	107	80.1	134	
Troponin I	ng/ml = µg/l	0.013	0.010	0.016	Ortho Vitros ECi
	ng/ml = µg/l	0.002	0.000	0.004	Abbott Architect STAT hs
Troponin T	µg/l	0.011	0.008	0.014	Roche Cobas TroponinT
	µg/l	0.011	0.008	0.014	Roche Cobas Troponin T HS
	µg/l	0.047	0.035	0.059	Roche h232

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