LIQUID CARDIAC CONTROL - LEVEL 3
(CRD LIQ CONTROL 3)

CAT. NO. CQ5053 **LOT NO.** 4245CK
SIZE: 3 x 3 ml **EXPIRY:** 2019-11-28

GTIN: 05055273207460

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 3 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.

(S): 25 May 18 pl

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Cat. No. CQ5053 Lot No. 4245CK Size: 3 x 3 ml Expiry: 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	85.1	59.6	111	Abbott Architect
	ng/ml = µg/l	112	78.4	146	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	120	84.0	156	Siemens Dimension
	ng/ml = µg/l	73.4	51.4	95.4	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	124	86.8	161	Beckman Coulter Access
	ng/ml = µg/l	108	75.6	140	Siemens Stratus CS
	ng/ml = µg/l	122	85.4	159	BioMerieux Vidas
	ng/ml = µg/l	124	86.8	161	Beckman DxI800
	ng/ml = µg/l	49.6	34.7	64.5	Biosite Triage Meter Plus
	ng/ml = µg/l	34.8	24.4	45.2	Roche h232
	ng/ml = µg/l	147	103	191	Radiometer AQT90 Flex
	ng/ml = µg/l	112	78.4	146	Siemens Dimension Vista LOCI
	ng/ml = µg/l	97.5	68.3	127	Siemens Centaur CP
D-Dimer	µg/l FEU	2444	1833	3055	Biomerieux Vidas Exclusion II
	µg/l FEU	10946	8210	13682	Mitsubishi Pathfast D-Dimer
	µg/l	1043	782	1304	Roche/ Stago STA-R Evolution
	µg/l	1539	1154	1924	Roche Cobas h232 D-Dimer
	µg/l	1204	903	1505	Roche Integra D-DI 2
	µg/l	1777	1333	2221	Alere Biosite Triage D-Dimer
	µg/l	1194	896	1493	Abbott Architect Quantia D-Dimer
	µg/l	2119	1589	2649	Siemens Stratus CS
	µg/l	944	708	1180	Siemens Immulite 2000 D-Dimer
	µg/l	1426	1070	1783	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	3836	2877	4795	Siemens Innovance D-Dimer
	µg/l	1302	977	1628	Roche Cobas D-DI 2
	µg/l FEU	3610	2708	4513	HemosIL D-Dimer 500
	µg/l FEU	3890	2918	4863	HemosIL D-Dimer HS 500
	µg/l	1159	869	1449	HemosIL D-Dimer HS
Digoxin	nmol/l	3.48	2.78	4.18	Chemiluminescence
	ng/ml	2.72	2.17	3.27	
	nmol/l	3.41	2.73	4.09	Enzyme Immunoassay
	ng/ml	2.66	2.13	3.19	
	nmol/l	3.61	2.89	4.33	Turbidimetric
	ng/ml	2.82	2.26	3.38	
	nmol/l	3.41	2.73	4.09	KIMS
	ng/ml	2.66	2.13	3.19	
	nmol/l	3.62	2.90	4.34	Enzyme Linked Flourescent assay
	ng/ml	2.83	2.26	3.40	
hsCRP	mg/l	7.45	5.96	8.94	Nephelometric (IFCC Cal.)
	mg/l	7.49	5.99	8.99	Nephelometric (Non IFCC Cal.)
	mg/l	7.48	5.98	8.98	Turbidimetric (IFCC Cal.)
	mg/l	7.61	6.09	9.13	Turbidimetric (Non IFCC Cal.)

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
hsCRP	mg/l	8.37	6.70	10.0	Chemiluminescence (IFCC Cal.)
	mg/l	6.98	5.58	8.38	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	388	272	504	Abbott Architect
	ng/ml = µg/l	323	226	420	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	346	242	450	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	377	264	490	Siemens Dimension
	ng/ml = µg/l	240	168	312	Beckman DxI800
	ng/ml = µg/l	274	192	356	Roche Elecsys
	ng/ml = µg/l	270	189	351	Roche Hitachi
	ng/ml = µg/l	232	162	302	Beckman Coulter Access
	ng/ml = µg/l	215	151	280	Siemens Stratus CS
	ng/ml = µg/l	251	176	326	BioMerieux Vidas
	ng/ml = µg/l	331	232	430	Biosite Triage Meter Plus
	ng/ml = µg/l	324	227	421	Siemens Dimension Vista LOCI
	ng/ml = µg/l	357	250	464	Siemens Centaur CP
	ng/ml = µg/l	421	295	547	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	521	391	651	Siemens Centaur XP/XPT/Classic
	pg/ml	4414	3313	5515	
	pmol/l	2464	1848	3080	Siemens Immulite 2000
	pg/ml	20875	15656	26094	
	pmol/l	643	482	804	Siemens Stratus CS
	pg/ml	5447	4084	6810	
	pmol/l	836	627	1045	BioMerieux Vidas
	pg/ml	7083	5312	8854	
	pmol/l	518	389	648	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	4388	3296	5480	
	pmol/l	1930	1448	2413	Mitsubishi Chemical Pathfast
	pg/ml	16351	12267	20435	
	pmol/l	889	667	1111	Ortho Vitros 3600/5600/ECi
	pg/ml	7532	5651	9413	
	pmol/l	322	242	403	Roche h232
	pg/ml	2728	2050	3406	
	pmol/l	321	241	401	Siemens Dimension Vista LOCI
	pg/ml	2720	2042	3398	
	pmol/l	217	163	271	Siemens Dimension ExI LOCI
	pg/ml	1838	1381	2295	
	pmol/l	852	639	1065	Biomerieux Vidas 2
	pg/ml	7218	5414	9022	
Troponin I	ng/ml = µg/l	6.79	5.43	8.15	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	6790	5430	8150	
	ng/ml = µg/l	1.41	1.13	1.69	Siemens Dimension
	ng/l = pg/ml	1410	1130	1690	
	ng/ml = µg/l	1.93	1.54	2.32	Beckman DXi800 1st gen
	ng/l = pg/ml	1930	1540	2320	
	ng/ml = µg/l	1.77	1.42	2.12	Beckman Coulter Access
	ng/l = pg/ml	1770	1420	2120	

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Analyte	**unit**	**Target**	**low**	**high**	**methods**
Troponin I	ng/ml = µg/l	1.77	1.42	2.12	Siemens Stratus CS
	ng/l = pg/ml	1770	1420	2120	
	ng/ml = µg/l	31.3	25.0	37.6	Ortho Vitros ECi
	ng/l = pg/ml	31300	25000	37600	
	ng/ml = µg/l	15.7	12.6	18.8	Biomerieux Vidas Ultra
	ng/l = pg/ml	15700	12600	18800	
	ng/ml = µg/l	0.773	0.618	0.928	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	773	618	928	
	ng/ml = µg/l	6.30	5.04	7.56	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	6300	5040	7560	
	ng/ml = µg/l	1.66	1.33	1.99	Siemens/Dade Dimension EXL/Vista
	ng/l = pg/ml	1660	1330	1990	
	ng/ml = µg/l	1.69	1.35	2.03	Siemens Dimension Exl LOCI
	ng/l = pg/ml	1690	1350	2030	
	ng/ml = µg/l	2.73	2.18	3.28	Abbott Architect STAT hs
	ng/l = pg/ml	2730	2180	3280	
	ng/ml = µg/l	1.82	1.46	2.18	Beckman DxI - AccuTnI+3
	ng/l = pg/ml	1820	1460	2180	
	ng/ml = µg/l	1.81	1.45	2.17	Beckman Access - AccuTnI+3
	ng/l = pg/ml	1810	1450	2170	
	ng/ml = µg/l	5.86	4.69	7.03	Siemens Centaur CP
	ng/l = pg/ml	5860	4690	7030	