

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

CAT. NO. CQ 5052 **LOT NO.** 3834CK

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 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.

Revised 10 Aug '16 pl

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

Cat. No. CQ5052 Lot No. 3834CK Size: 3 x 3 ml Expiry: 2017-04

Range					
Analyte	unit	Target	low	high	methods
CK-MB Mass	ng/ml = µg/l	17.4	13.9	20.9	Abbott Architect
	ng/ml = µg/l	17.5	14.0	21.0	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	17.1	13.7	20.5	Siemens Dimension
	ng/ml = µg/l	12.8	10.2	15.4	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	21.7	17.4	26.0	Beckman Coulter Access
	ng/ml = µg/l	17.7	14.2	21.2	Siemens Stratus CS
	ng/ml = µg/l	13.9	11.1	16.7	Ortho Vitros ECI
	ng/ml = µg/l	23.5	18.8	28.2	BioMerieux Vidas
	ng/ml = µg/l	21.9	17.5	26.3	Beckman Dxl800
	ng/ml = µg/l	13.7	11.0	16.4	Roche h232
	ng/ml = µg/l	26.9	21.5	32.3	Radiometer AQT90 Flex
	ng/ml = µg/l	16.7	13.4	20.0	Siemens Dimension Vista LOCI
	ng/ml = µg/l	17.2	13.8	20.6	Siemens Centaur CP
	ng/ml = µg/l	17.2	13.8	20.6	Siemens Centaur CP
D - Dimer	µg/l FEU	1366	1025	1708	Biomerieux Vidas Exclusion II
	µg/l FEU	5064	3798	6330	Mitsubishi Pathfast D-Dimer
	µg/l	472	354	590	Roche/ Stago STA-R Evolution
	µg/l	804	603	1005	Roche Cobas h232 D-Dimer
	µg/l	496	372	620	Roche Integra D-DI 2
	µg/l	822	617	1028	Alere Biosite Triage D-Dimer
	µg/l	717	538	896	Abbott Architect Quantia D-Dimer
	µg/l	851	638	1064	Siemens Stratus CS
	µg/l	340	255	425	Siemens Immulite 2000 D-Dimer
	µg/l	787	590	984	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1916	1437	2395	Siemens Innovance D-Dimer
	µg/l	373	280	466	Roche Cobas D-DI 2
	µg/l FEU	2134	1601	2668	HemosIL D-Dimer HS 500
	µg/l	596	447	745	HemosIL D-Dimer
	µg/l	644	483	805	HemosIL D-Dimer HS
Digoxin	nmol/l	2.44	1.95	2.93	Chemiluminescence
	ng/ml	1.91	1.52	2.30	
	nmol/l	2.16	1.73	2.59	Enzyme Immunoassay
	ng/ml	1.69	1.35	2.03	
	nmol/l	2.29	1.83	2.75	Turbidimetric
	ng/ml	1.79	1.43	2.15	
	nmol/l	2.11	1.69	2.53	KIMS
hsCRP	ng/ml	1.65	1.32	1.98	
	mg/l	2.95	2.36	3.54	Nephelometric (IFCC Cal.)
	mg/l	2.95	2.36	3.54	Nephelometric (Non IFCC Cal.)
	mg/l	3.18	2.54	3.82	Turbidimetric (IFCC Cal.)
	mg/l	3.13	2.50	3.76	Turbidimetric (Non IFCC Cal.)
Myoglobin	mg/l	3.15	2.52	3.78	Randox Immunoturbidimetric
	ng/ml = µg/l	146	117	175	Abbott Architect

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Analyte	unit	Target	low	high	methods
Myoglobin	ng/ml = µg/l	122	97.6	146	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	120	96.0	144	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	143	114	172	Siemens Dimension
	ng/ml = µg/l	100	80.0	120	Beckman Dxl800
	ng/ml = µg/l	107	85.6	128	Roche Elecsys
	ng/ml = µg/l	114	91.2	137	Roche Hitachi
	ng/ml = µg/l	133	106	160	Roche Integra
	ng/ml = µg/l	94.3	75.4	113	Beckman Coulter Access
	ng/ml = µg/l	79.9	63.9	95.9	Siemens Stratus CS
	ng/ml = µg/l	127	102	152	BioMerieux Vidas
	ng/ml = µg/l	28.0	22.4	33.6	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	215	172	258	Ortho Vitros 3600/5600/ECi
	ng/ml = µg/l	117	93.6	140	Siemens Dimension Vista LOCI
	ng/ml = µg/l	122	97.6	146	Siemens Centaur CP
	ng/ml = µg/l	109	87.2	131	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	30.3	22.7	37.9	Siemens Dimension
	pg/ml	257	192	322	
	pmol/l	166	125	208	Siemens Immulite 2000
	pg/ml	1406	1059	1753	
	pmol/l	68.9	51.7	86.1	Siemens Stratus CS
	pg/ml	584	438	730	
	pmol/l	67.1	50.3	83.9	BioMerieux Vidas
	pg/ml	568	426	710	
	pmol/l	46.4	34.8	58.0	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	393	295	491	
	pmol/l	168	126	210	Mitsubishi Chemical Pathfast
	pg/ml	1423	1067	1779	
	pmol/l	85.8	64.4	107	Ortho Vitros 3600/5600/ECi
	pg/ml	727	546	908	
	pmol/l	24.5	18.4	30.6	Roche h232
	pg/ml	208	156	260	
	pmol/l	27.8	20.9	34.8	Siemens Dimension Vista LOCI
	pg/ml	236	177	295	
	pmol/l	14.0	10.5	17.5	Siemens Dimension Exl LOCI
	pg/ml	119	89.0	149	
	pmol/l	65.9	49.4	82.4	Biomerieux Vidas 2
	pg/ml	558	419	697	
Troponin I	ng/ml = µg/l	12.6	10.1	15.1	Abbott Architect
	ng/ml = µg/l	1.73	1.38	2.08	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.835	0.668	1.00	Siemens Dimension
	ng/ml = µg/l	0.974	0.779	1.17	Beckman DXi800 1st gen
	ng/ml = µg/l	0.972	0.778	1.17	Beckman Coulter Access
	ng/ml = µg/l	1.20	0.960	1.44	Siemens Stratus CS
	ng/ml = µg/l	9.07	7.26	10.9	Tosoh AIA360
	ng/ml = µg/l	8.63	6.90	10.4	Ortho Vitros ECi
	ng/ml = µg/l	4.64	3.71	5.57	BioMerieux Vidas

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Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	4.61	3.69	5.53	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.764	0.611	0.917	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	1.48	1.18	1.78	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	1.22	0.976	1.46	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	1.23	0.984	1.48	Siemens Dimension Exl LOCI
	ng/ml = µg/l	1.28	1.02	1.54	Abbott Architect STAT hs
	ng/ml = µg/l	0.984	0.787	1.18	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	0.986	0.789	1.18	Beckman Access - AccuTnl+3
	ng/ml = µg/l	1.34	1.07	1.61	Siemens Centaur CP
Troponin T	µg/l	0.202	0.152	0.253	Roche Cobas TroponinT
	µg/l	0.224	0.168	0.280	Roche Cobas Troponin T HS
	µg/l	0.117	0.088	0.146	Roche h232
	µg/l	0.180	0.135	0.225	Radiometer AQT90 Flex