

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

CAT. NO. CQ 5052 **LOT NO.** 3836CK
SIZE: 3 x 3 ml **EXPIRY:** 2017-05

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 30 Aug '16 pl

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

Cat. No. CQ5052 Lot No. 3836CK Size: 3 x 3 ml Expiry: 2017-05

Range					
Analyte	unit	Target	low	high	methods
CK-MB Mass	ng/ml = µg/l	5.16	4.13	6.19	Abbott Architect
	ng/ml = µg/l	6.04	4.83	7.25	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	4.89	3.84	5.94	Siemens Dimension
	ng/ml = µg/l	4.60	3.68	5.52	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	6.96	5.57	8.35	Beckman Coulter Access
	ng/ml = µg/l	5.77	4.62	6.92	Siemens Stratus CS
	ng/ml = µg/l	8.29	6.63	9.95	BioMerieux Vidas
	ng/ml = µg/l	6.84	5.47	8.21	Beckman Dxl800
	ng/ml = µg/l	5.18	4.14	6.22	Roche h232
	ng/ml = µg/l	8.31	6.65	9.97	Radiometer AQT90 Flex
	ng/ml = µg/l	5.07	4.06	6.08	Siemens Dimension Vista LOCI
	ng/ml = µg/l	5.77	4.62	6.92	Siemens Centaur CP
D - Dimer	µg/l FEU	1676	1257	2095	Biomerieux Vidas Exclusion II
	µg/l FEU	8020	6015	10025	Mitsubishi Pathfast D-Dimer
	µg/l	672	504	840	Roche/ Stago STA-R Evolution
	µg/l	1032	774	1290	Roche Cobas h232 D-Dimer
	µg/l	837	628	1046	Roche Integra D-DI 2
	µg/l	1098	824	1373	Alere Biosite Triage D-Dimer
	µg/l	936	702	1170	Abbott Architect Quantia D-Dimer
	µg/l	1269	952	1586	Siemens Stratus CS
	µg/l	429	322	536	Siemens Immulite 2000 D-Dimer
	µg/l	1090	818	1363	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	2256	1692	2820	Siemens Innovance D-Dimer
	µg/l	782	587	978	Roche Cobas D-DI 2
	µg/l FEU	2450	1838	3063	HemosIL D-Dimer HS 500
	µg/l	679	509	849	HemosIL D-Dimer
	µg/l	754	566	943	HemosIL D-Dimer HS
Digoxin	nmol/l	1.77	1.42	2.12	Chemiluminescence
	ng/ml	1.38	1.11	1.65	
	nmol/l	1.46	1.17	1.75	Vitros
	ng/ml	1.14	0.914	1.37	
	nmol/l	1.54	1.23	1.85	Enzyme Immunoassay
	ng/ml	1.20	0.961	1.44	
	nmol/l	1.52	1.22	1.82	Turbidimetric
	ng/ml	1.19	0.953	1.43	
hsCRP	nmol/l	1.43	1.14	1.72	KIMS
	ng/ml	1.12	0.890	1.35	
	mg/l	1.79	1.43	2.15	Nephelometric (IFCC Cal.)
	mg/l	1.89	1.51	2.27	Nephelometric (Non IFCC Cal.)
	mg/l	1.95	1.56	2.34	Turbidimetric (IFCC Cal.)
	mg/l	1.94	1.55	2.33	Turbidimetric (Non IFCC Cal.)
	mg/l	1.95	1.56	2.34	Randox Immunoturbidimetric

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

Cat. No. CQ5052 Lot No. 3836CK Size: 3 x 3 ml Expiry: 2017-05

Range					
Analyte	unit	Target	low	high	methods
Myoglobin	ng/ml = µg/l	98.8	79.0	119	Abbott Architect
	ng/ml = µg/l	80.4	64.3	96.5	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	88.3	70.6	106	Siemens Dimension
	ng/ml = µg/l	63.2	50.6	75.8	Beckman Dxl800
	ng/ml = µg/l	72.8	58.2	87.4	Roche Elecsys
	ng/ml = µg/l	77.3	61.8	92.8	Roche Hitachi
	ng/ml = µg/l	60.8	48.6	73.0	Beckman Coulter Access
	ng/ml = µg/l	50.4	40.3	60.5	Siemens Stratus CS
	ng/ml = µg/l	79.6	63.7	95.5	BioMerieux Vidas
	ng/ml = µg/l	22.9	18.3	27.5	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	142	114	170	Ortho Vitros 3600/5600/ECi
	ng/ml = µg/l	69.5	55.6	83.4	Siemens Dimension Vista LOCI
	ng/ml = µg/l	85.2	68.2	102	Randox Immunoturbidimetric
	ng/ml = µg/l	85.2	68.2	102	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	62.0	46.5	77.5	Siemens Immulite 2000
	pg/ml	525	394	656	
	pmol/l	22.7	17.0	28.4	Siemens Stratus CS
	pg/ml	192	144	240	
	pmol/l	20.8	15.6	26.0	BioMerieux Vidas
	pg/ml	176	132	220	
	pmol/l	18.7	14.0	23.4	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	158	119	197	
	pmol/l	58.0	43.5	72.5	Mitsubishi Chemical Pathfast
	pg/ml	491	369	613	
	pmol/l	34.7	26.0	43.4	Ortho Vitros 3600/5600/ECi
	pg/ml	294	220	368	
	pmol/l	9.60	7.20	12.0	Roche h232
	pg/ml	81.3	61.0	102	
	pmol/l	3.97	2.98	4.96	Siemens Dimension Exl LOCI
	pg/ml	33.6	25.2	42.0	
	pmol/l	20.2	15.2	25.3	Biomerieux Vidas 2
	pg/ml	171	129	213	
Troponin I	ng/ml = µg/l	0.416	0.333	0.499	Abbott Architect
	ng/ml = µg/l	0.043	0.034	0.052	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.010	0.008	0.012	Siemens Dimension
	ng/ml = µg/l	0.030	0.024	0.036	Beckman DXi800 1st gen
	ng/ml = µg/l	0.030	0.024	0.036	Beckman Coulter Access
	ng/ml = µg/l	0.290	0.232	0.348	Tosoh AIA360
	ng/ml = µg/l	0.247	0.198	0.296	Ortho Vitros ECi
	ng/ml = µg/l	0.262	0.210	0.314	BioMerieux Vidas
	ng/ml = µg/l	0.255	0.204	0.306	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.102	0.082	0.122	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	0.032	0.026	0.038	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.018	0.014	0.022	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.043	0.034	0.052	Abbott Architect STAT hs
	ng/ml = µg/l	0.030	0.024	0.036	Beckman Access - AccuTnl+3
	ng/ml = µg/l	0.038	0.030	0.046	Siemens Centaur CP

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

Cat. No. CQ5052 Lot No. 3836CK Size: 3 x 3 ml Expiry: 2017-05

Range					
Analyte	unit	Target	low	high	methods
Troponin T	µg/l	0.021	0.016	0.026	Roche Cobas TroponinT
	µg/l	0.020	0.015	0.025	Roche Cobas Troponin T HS
	µg/l	0.050	0.038	0.063	Roche h232