

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

CAT. NO. CQ 5052

LOT NO. 3991CK

SIZE: 3 x 3 ml

EXPIRY: 2018-04-28

GTIN: 05055273207453

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.

07 Oct '16 pl

LIQUID CARDIAC CONTROL LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot. No. 3991CK Size 3 x 3 ml Expiry 2018-04

Range					
Analyte	unit	Target	low	high	methods
CK-MB Mass	ng/ml = µg/l	18.5	14.8	22.2	Abbott Architect
	ng/ml = µg/l	20.2	16.2	24.2	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	17.9	14.3	21.5	Siemens Dimension
	ng/ml = µg/l	15.7	12.6	18.8	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	23.4	18.7	28.1	Beckman Coulter Access
	ng/ml = µg/l	17.2	13.8	20.6	Siemens Stratus CS
	ng/ml = µg/l	26.9	21.5	32.3	BioMerieux Vidas
	ng/ml = µg/l	24.0	19.2	28.8	Beckman Dxl800
	ng/ml = µg/l	13.5	10.8	16.2	Roche h232
	ng/ml = µg/l	29.0	23.2	34.8	Radiometer AQT90 Flex
	ng/ml = µg/l	17.5	14.0	21.0	Siemens Dimension Vista LOCI
	ng/ml = µg/l	19.1	15.3	22.9	Siemens Centaur CP
D - Dimer	µg/l FEU	1524	1143	1905	Biomerieux Vidas Exclusion II
	µg/l FEU	6350	4763	7938	Mitsubishi Pathfast D-Dimer
	µg/l	514	386	643	Roche/ Stago STA-R Evolution
	µg/l	803	602	1004	Roche Cobas h232 D-Dimer
	µg/l	510	383	638	Roche Integra D-DI 2
	µg/l	939	704	1174	Alere Biosite Triage D-Dimer
	µg/l	773	580	966	Abbott Architect Quantia D-Dimer
	µg/l	906	680	1133	Siemens Stratus CS
	µg/l	265	199	331	Siemens Immulite 2000 D-Dimer
	µg/l	871	653	1089	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1956	1467	2445	Siemens Innovance D-Dimer
	µg/l	400	300	500	Roche Cobas D-DI 2
	µg/l FEU	2148	1611	2685	HemosIL D-Dimer HS 500
	µg/l	631	473	789	HemosIL D-Dimer
	µg/l	631	473	789	HemosIL D-Dimer HS
Digoxin	nmol/l	2.12	1.70	2.54	Chemiluminescence
	ng/ml	1.66	1.33	1.99	
	nmol/l	1.88	1.50	2.26	Enzyme Immunoassay
	ng/ml	1.47	1.17	1.77	
	nmol/l	1.93	1.54	2.32	Turbidimetric
	ng/ml	1.51	1.20	1.82	
	nmol/l	1.77	1.42	2.12	KIMS
hsCRP	ng/ml	1.38	1.11	1.65	
	mg/l	3.78	3.02	4.53	Vitros (IFCC Cal.)
	mg/l	3.01	2.41	3.61	Nephelometric (IFCC Cal.)
	mg/l	2.99	2.39	3.59	Turbidimetric (IFCC Cal.)
	mg/l	3.10	2.48	3.72	Turbidimetric (Non IFCC Cal.)
Myoglobin	mg/l	2.93	2.34	3.52	Randox Immunoturbidimetric
	ng/ml = µg/l	158	126	190	Abbott Architect
	ng/ml = µg/l	113	90.4	136	Siemens/Dade Behring Nephelometer

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Range					
Analyte	unit	Target	low	high	methods
Myoglobin	ng/ml = µg/l	134	107	161	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	133	106	160	Siemens Dimension
	ng/ml = µg/l	90.6	72.5	109	Beckman Dxl800
	ng/ml = µg/l	105	84.0	126	Roche Elecsys
	ng/ml = µg/l	107	85.6	128	Roche Hitachi
	ng/ml = µg/l	124	99.0	149	Roche Integra
	ng/ml = µg/l	90.4	72.3	108	Beckman Coulter Access
	ng/ml = µg/l	70.8	56.6	85.0	Siemens Stratus CS
	ng/ml = µg/l	96.8	77.4	116	BioMerieux Vidas
	ng/ml = µg/l	116	92.8	139	Siemens Dimension Vista LOCI
	ng/ml = µg/l	136	109	163	Siemens Centaur CP
	ng/ml = µg/l	159	127	191	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	26.1	19.6	32.6	Siemens Dimension
	pg/ml	221	166	276	
	pmol/l	228	171	285	Siemens Immulite 2000
	pg/ml	1932	1449	2415	
	pmol/l	299	224	374	Siemens Immulite 1000
	pg/ml	2533	1898	3168	
	pmol/l	75.0	56.3	93.8	Siemens Stratus CS
	pg/ml	635	477	793	
	pmol/l	65.9	49.4	82.4	BioMerieux Vidas
	pg/ml	558	419	697	
	pmol/l	51.1	38.3	63.9	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	433	324	542	
	pmol/l	201	151	251	Mitsubishi Chemical Pathfast
	pg/ml	1703	1279	2127	
	pmol/l	115	86.3	144	Ortho Vitros 3600/5600/ECi
	pg/ml	974	731	1217	
	pmol/l	43.2	32.4	54.0	Roche h232
	pg/ml	366	274	458	
	pmol/l	25.2	18.9	31.5	Siemens Dimension Vista LOCI
	pg/ml	213	160	266	
	pmol/l	12.2	9.15	15.3	Siemens Dimension Exl LOCI
	pg/ml	103	77.5	129	
	pmol/l	67.4	50.6	84.3	Biomerieux Vidas 2
	pg/ml	571	429	713	
Troponin I	ng/ml = µg/l	1.02	0.816	1.22	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.438	0.350	0.526	Siemens Dimension
	ng/ml = µg/l	0.541	0.433	0.649	Beckman DXi800 1st gen
	ng/ml = µg/l	0.585	0.468	0.702	Beckman Coulter Access
	ng/ml = µg/l	0.612	0.490	0.734	Siemens Stratus CS
	ng/ml = µg/l	9.06	7.25	10.9	Tosoh AIA360
	ng/ml = µg/l	7.94	6.35	9.53	Ortho Vitros ECi
	ng/ml = µg/l	4.62	3.70	5.54	BioMerieux Vidas
	ng/ml = µg/l	4.71	3.77	5.65	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.352	0.282	0.422	Roche Elecsys/E170/c6000/e411

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Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	0.946	0.757	1.14	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	5.15	4.12	6.18	Abbott i STAT
	ng/ml = µg/l	0.534	0.427	0.641	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.529	0.423	0.635	Siemens Dimension Exl LOCI
	ng/ml = µg/l	0.891	0.713	1.07	Abbott Architect STAT hs
	ng/ml = µg/l	0.555	0.444	0.666	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	0.591	0.473	0.709	Beckman Access - AccuTnl+3
	ng/ml = µg/l	0.853	0.682	1.02	Siemens Centaur CP
Troponin T	µg/l	0.196	0.147	0.245	Roche Cobas TroponinT
	µg/l	0.207	0.155	0.259	Roche Cobas Troponin T HS
	µg/l	0.081	0.061	0.101	Roche h232
	µg/l	0.161	0.121	0.201	Radiometer AQT90 Flex