

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

CAT. NO. CQ5053 **LOT NO.** 3837CK

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 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.

Revised 10 Aug '16 pl

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Cat. No. CQ5053 Lot No. 3837CK Size: 3 x 3 ml Expiry: 2017-05

Range					
Analyte	unit	Target	low	high	methods
CK-MB Mass	ng/ml = µg/l	103	81.0	125	Abbott Architect
	ng/ml = µg/l	104	83.2	125	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	125	100	150	Siemens Dimension
	ng/ml = µg/l	73.9	59.1	88.7	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	138	110	166	Beckman Coulter Access
	ng/ml = µg/l	129	103	155	Siemens Stratus CS
	ng/ml = µg/l	79.9	63.9	95.9	Ortho Vitros ECI
	ng/ml = µg/l	126	101	151	BioMerieux Vidas
	ng/ml = µg/l	143	114	172	Beckman Dxl800
	ng/ml = µg/l	36.2	29.0	43.4	Roche h232
	ng/ml = µg/l	152	122	182	Radiometer AQT90 Flex
	ng/ml = µg/l	119	95.2	143	Siemens Dimension Vista LOCI
	ng/ml = µg/l	110	84.7	135	Siemens Centaur CP
	ng/ml = µg/l	110	84.7	135	Siemens Centaur CP
D - Dimer	µg/l FEU	3334	2501	4168	Biomerieux Vidas Exclusion II
	µg/l FEU	15488	11616	19360	Mitsubishi Pathfast D-Dimer
	µg/l	1438	1079	1798	Roche/ Stago STA-R Evolution
	µg/l	420	315	525	Nycocard D-Dimer
	µg/l	1997	1498	2496	Roche Cobas h232 D-Dimer
	µg/l	1956	1467	2445	Roche Integra D-DI 2
	µg/l	2134	1601	2668	Alere Biosite Triage D-Dimer
	µg/l	1516	1137	1895	Abbott Architect Quantia D-Dimer
	µg/l	2792	2094	3490	Siemens Stratus CS
	µg/l	1167	875	1459	Siemens Immulite 2000 D-Dimer
	µg/l	2076	1557	2595	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	4906	3680	6133	Siemens Innovance D-Dimer
	µg/l	2119	1589	2649	Roche Cobas D-DI 2
	µg/l FEU	5100	3825	6375	HemosIL D-Dimer HS 500
	µg/l	1699	1239	2159	HemosIL D-Dimer HS
Digoxin	nmol/l	3.57	2.86	4.28	Chemiluminescence
	ng/ml	2.79	2.23	3.35	
	nmol/l	3.03	2.42	3.64	Vitros
	ng/ml	2.37	1.89	2.85	
	nmol/l	3.23	2.58	3.88	Enzyme Immunoassay
	ng/ml	2.52	2.01	3.03	
	nmol/l	3.27	2.62	3.92	Turbidimetric
	ng/ml	2.55	2.05	3.05	
hsCRP	nmol/l	3.03	2.42	3.64	KIMS
	ng/ml	2.37	1.89	2.85	
	mg/l	7.29	5.83	8.75	Nephelometric (IFCC Cal.)
	mg/l	7.90	6.32	9.48	Nephelometric (Non IFCC Cal.)
	mg/l	7.06	5.50	8.62	Turbidimetric (IFCC Cal.)
	mg/l	6.77	4.96	8.58	Turbidimetric (Non IFCC Cal.)

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Analyte	unit	Target	low	high	methods
hsCRP	mg/l	7.44	5.95	8.93	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	355	284	426	Abbott Architect
	ng/ml = µg/l	330	264	396	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	300	240	360	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	404	323	485	Siemens Dimension
	ng/ml = µg/l	260	208	312	Beckman Dxl800
	ng/ml = µg/l	262	210	314	Roche Elecsys
	ng/ml = µg/l	267	214	320	Roche Hitachi
	ng/ml = µg/l	306	245	367	Roche Integra
	ng/ml = µg/l	241	193	289	Beckman Coulter Access
	ng/ml = µg/l	215	172	258	Siemens Stratus CS
	ng/ml = µg/l	344	275	413	BioMerieux Vidas
	ng/ml = µg/l	68.9	55.1	82.7	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	586	469	703	Ortho Vitros 3600/5600/ECi
	ng/ml = µg/l	318	254	382	Siemens Dimension Vista LOCI
	ng/ml = µg/l	327	262	392	Siemens Centaur CP
	ng/ml = µg/l	246	197	295	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	352	264	440	Siemens Dimension
	pg/ml	2982	2237	3727	
	pmol/l	1871	1403	2339	Siemens Immulite 2000
	pg/ml	15851	11886	19816	
	pmol/l	493	370	616	Siemens Stratus CS
	pg/ml	4177	3135	5219	
	pmol/l	602	452	753	BioMerieux Vidas
	pg/ml	5100	3829	6371	
	pmol/l	420	315	525	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	3558	2669	4447	
	pmol/l	1650	1238	2063	Mitsubishi Chemical Pathfast
	pg/ml	13979	10488	17470	
	pmol/l	789	592	986	Ortho Vitros 3600/5600/ECi
	pg/ml	6684	5015	8353	
	pmol/l	160	120	200	Roche h232
	pg/ml	1356	1017	1695	
	pmol/l	253	190	316	Siemens Dimension Vista LOCI
	pg/ml	2143	1610	2676	
	pmol/l	179	134	224	Siemens Dimension Exl LOCI
	pg/ml	1516	1135	1897	
	pmol/l	624	468	780	Biomerieux Vidas 2
	pg/ml	5287	3965	6609	
Troponin I	ng/ml = µg/l	326	261	391	Abbott Architect
	ng/ml = µg/l	63.0	50.4	75.6	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	20.1	16.1	24.1	Siemens Dimension
	ng/ml = µg/l	39.3	31.4	47.2	Beckman DXi800 1st gen
	ng/ml = µg/l	42.9	34.3	51.5	Beckman Coulter Access
	ng/ml = µg/l	25.3	20.2	30.4	Siemens Stratus CS
	ng/ml = µg/l	231	185	277	Tosoh AIA360

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Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	225	180	270	Ortho Vitros ECI
	ng/ml = µg/l	81.4	65.1	97.7	BioMerieux Vidas
	ng/ml = µg/l	85.9	68.7	103	Biomerieux Vidas Ultra
	ng/ml = µg/l	13.9	11.1	16.7	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	52.6	41.6	63.6	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	26.1	20.9	31.3	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	26.1	20.9	31.3	Siemens Dimension Exl LOCI
	ng/ml = µg/l	45.2	36.2	54.2	Abbott Architect STAT hs
	ng/ml = µg/l	42.6	34.1	51.1	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	43.7	35.0	52.4	Beckman Access - AccuTnl+3
	ng/ml = µg/l	50.8	40.6	61.0	Siemens Centaur CP
Troponin T	µg/l	3.140	2.360	3.930	Roche Cobas TroponinT
	µg/l	3.170	2.360	3.980	Roche Cobas Troponin T HS
	µg/l	1.390	1.040	1.740	Roche h232
	µg/l	3.580	2.690	4.480	Radiometer AQT90 Flex