

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

CAT. NO. CQ5053

LOT NO. 4313CK

SIZE: 3 x 3 ml

EXPIRY: 2020-06-28

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.

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

Cat. No. CQ5053 Lot No. 4313CK Size: 3 x 3 ml Expiry: 2020-06-28

Analyte	unit	Target	Range		methods
			low	high	
CK-MB Mass	ng/ml = µg/l	79.6	55.7	103	Abbott Architect
	ng/ml = µg/l	119	83.3	155	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	130	91.0	169	Siemens Dimension
	ng/ml = µg/l	76.6	53.6	100	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	127	88.9	165	Beckman Coulter Access
	ng/ml = µg/l	114	79.8	148	Siemens Stratus CS
	ng/ml = µg/l	118	82.6	153	BioMerieux Vidas
	ng/ml = µg/l	130	91.0	169	Beckman Dxl800
	ng/ml = µg/l	37.3	26.1	48.5	Biosite Triage Meter Plus
	ng/ml = µg/l	39.0	27.3	50.7	Roche h232
	ng/ml = µg/l	152	106	198	Radiometer AQT90 Flex
	ng/ml = µg/l	36.5	25.6	47.5	Roche Cardiac Reader
	ng/ml = µg/l	101	70.7	131	Siemens Centaur CP
D-Dimer	µg/l FEU	2266	1700	2833	Biomerieux Vidas Exclusion II
	µg/l FEU	10882	8162	13603	Mitsubishi Pathfast D-Dimer
	µg/l	1052	789	1315	Roche/ Stago STA-R Evolution
	µg/l	1401	1051	1751	Roche Cobas h232 D-Dimer
	µg/l	1133	850	1416	Roche Integra D-DI 2
	µg/l	1313	985	1641	Alere Biosite Triage D-Dimer
	µg/l	1106	830	1383	Abbott Architect Quantia D-Dimer
	µg/l	2107	1580	2634	Siemens Stratus CS
	µg/l	929	697	1161	Siemens Immulite 2000 D-Dimer
	µg/l	1305	979	1631	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	3234	2426	4043	Siemens Innovance D-Dimer
	µg/l	1221	916	1526	Roche Cobas D-DI 2
	µg/l FEU	3104	2328	3880	HemosIL D-Dimer HS 500
	µg/l	922	692	1153	HemosIL D-Dimer
µg/l	988	741	1235	HemosIL D-Dimer HS	
Digoxin	nmol/l	3.13	2.50	3.76	Chemiluminescence
	ng/ml	2.44	1.95	2.93	
	nmol/l	3.05	2.44	3.66	Enzyme Immunoassay
	ng/ml	2.38	1.91	2.85	
	nmol/l	3.07	2.46	3.68	Turbidimetric
	ng/ml	2.40	1.92	2.88	
	nmol/l	3.10	2.48	3.72	KIMS
	ng/ml	2.42	1.94	2.90	
	nmol/l	3.10	2.48	3.72	Enzyme Linked Fluorescent assay
ng/ml	2.42	1.94	2.90		
hsCRP	mg/l	7.97	6.38	9.56	Nephelometric (IFCC Cal.)
	mg/l	7.99	6.39	9.59	Turbidimetric (IFCC Cal.)
	mg/l	7.72	6.18	9.26	Turbidimetric (Non IFCC Cal.)
	mg/l	8.08	6.46	9.70	Randox Immunoturbidimetric

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Analyte	unit	Target	Range		methods
			low	high	
Myoglobin	ng/ml = µg/l	380	266	494	Abbott Architect
	ng/ml = µg/l	376	263	489	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	387	271	503	Siemens Dimension
	ng/ml = µg/l	264	185	343	Beckman Dxl800
	ng/ml = µg/l	277	194	360	Roche Elecsys
	ng/ml = µg/l	274	192	356	Roche Hitachi
	ng/ml = µg/l	247	173	321	Beckman Coulter Access
	ng/ml = µg/l	216	151	281	Siemens Stratus CS
	ng/ml = µg/l	292	204	380	BioMerieux Vidas
	ng/ml = µg/l	344	241	447	Siemens Dimension Vista LOCI
	ng/ml = µg/l	375	263	488	Siemens Centaur CP
	ng/ml = µg/l	449	314	584	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	392	294	490	Siemens Centaur XP/XPT/Classic
	pg/ml	3321	2491	4151	
	pmol/l	2357	1768	2946	Siemens Immulite 2000
	pg/ml	19969	14978	24960	
	pmol/l	508	381	635	Siemens Stratus CS
	pg/ml	4304	3228	5380	
	pmol/l	777	583	971	BioMerieux Vidas
	pg/ml	6583	4939	8227	
	pmol/l	467	350	584	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	3956	2965	4947	
	pmol/l	1666	1250	2083	Mitsubishi Chemical Pathfast
	pg/ml	14114	10590	17638	
	pmol/l	865	649	1081	Ortho Vitros 3600/5600/ECi
	pg/ml	7328	5498	9158	
	pmol/l	256	192	320	Roche h232
	pg/ml	2169	1627	2711	
	pmol/l	241	181	301	Siemens Dimension Vista LOCI
	pg/ml	2042	1533	2551	
pmol/l	162	122	203	Siemens Dimension Exl LOCI	
pg/ml	1372	1034	1710		
pmol/l	750	563	938	Biomerieux Vidas 2	
pg/ml	6354	4770	7938		
Troponin I	ng/ml = µg/l	5.80	4.64	6.96	Abbott Architect
	ng/l = pg/ml	5800	4640	6960	
	ng/ml = µg/l	7.51	6.01	9.01	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	7510	6010	9010	
	ng/ml = µg/l	3.31	2.65	3.97	Siemens Dimension
	ng/l = pg/ml	3310	2650	3970	
	ng/ml = µg/l	3.73	2.98	4.48	Siemens Stratus CS
	ng/l = pg/ml	3730	2980	4480	
	ng/ml = µg/l	27.5	22.0	33.0	Ortho Vitros ECi
ng/l = pg/ml	27533	22000	33066		
ng/ml = µg/l	29.7	23.8	35.7	Biomerieux Vidas Ultra	
ng/l = pg/ml	29749	23800	35698		

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Analyte	unit	Target	Range		methods
			low	high	
Troponin I	ng/ml = µg/l	1.56	1.25	1.87	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	1560	1250	1870	
	ng/ml = µg/l	3.63	2.90	4.36	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	3630	2900	4360	
	ng/ml = µg/l	3.14	2.51	3.77	Siemens/Dade Dimension EXL/Vista
	ng/l = pg/ml	3140	2510	3770	
	ng/ml = µg/l	3.27	2.62	3.92	Siemens Dimension Exl LOCI
	ng/l = pg/ml	3270	2620	3920	
	ng/ml = µg/l	5.61	4.49	6.73	Abbott Architect STAT hs
	ng/l = pg/ml	5610	4490	6730	
	ng/ml = µg/l	3.32	2.66	3.98	Beckman Dxl - AccuTnl+3
	ng/l = pg/ml	3320	2660	3980	
	ng/ml = µg/l	3.23	2.58	3.88	Beckman Access - AccuTnl+3
	ng/l = pg/ml	3230	2580	3880	
	ng/ml = µg/l	5.92	4.74	7.10	Siemens Centaur CP
	ng/l = pg/ml	5920	4740	7100	
ng/ml = µg/l	30.5	24.4	36.6	bioMerieux VIDAS hs Troponin I	
ng/l = pg/ml	30466	24400	36532		