

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

CAT. NO. CQ 5052

SIZE: 3 x 3 ml

LOT NO. 4315CK

EXPIRY: 2020-06-28

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 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 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.

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Cat. No. CQ5052 Lot No. 4315CK Size: 3 x 3 ml Expiry: 2020-06-28

Range					
Analyte	unit	Target	low	high	methods
CK-MB Mass	ng/ml = µg/l	5.07	3.55	6.59	Abbott Architect
	ng/ml = µg/l	9.19	6.43	11.9	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	7.19	5.03	9.35	Siemens Dimension
	ng/ml = µg/l	5.78	4.05	7.51	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	8.33	5.83	10.8	Beckman Coulter Access
	ng/ml = µg/l	7.40	5.18	9.62	Siemens Stratus CS
	ng/ml = µg/l	4.36	3.05	5.67	Ortho Vitros ECI
	ng/ml = µg/l	7.18	5.03	9.33	BioMerieux Vidas
	ng/ml = µg/l	8.60	6.02	11.2	Beckman Dxl800
	ng/ml = µg/l	5.83	4.08	7.58	Roche h232
	ng/ml = µg/l	10.2	7.14	13.3	Radiometer AQT90 Flex
	ng/ml = µg/l	7.53	5.27	9.79	Siemens Centaur CP
D-Dimer	µg/l FEU	1700	1275	2125	Biomerieux Vidas Exclusion II
	µg/l FEU	7892	5919	9865	Mitsubishi Pathfast D-Dimer
	µg/l	689	517	861	Roche/ Stago STA-R Evolution
	µg/l	1005	754	1256	Roche Cobas h232 D-Dimer
	µg/l	753	565	941	Roche Integra D-DI 2
	µg/l	879	659	1099	Alere Biosite Triage D-Dimer
	µg/l	862	647	1078	Abbott Architect Quantia D-Dimer
	µg/l	1350	1013	1688	Siemens Stratus CS
	µg/l	615	461	769	Siemens Immulite 2000 D-Dimer
	µg/l	919	689	1149	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	2348	1761	2935	Siemens Innovance D-Dimer
	µg/l	667	500	834	Roche Cobas D-DI 2
	µg/l FEU	2470	1853	3088	HemosIL D-Dimer HS 500
	µg/l	755	566	944	HemosIL D-Dimer
	µg/l	797	598	996	HemosIL D-Dimer HS
Digoxin	nmol/l	1.51	1.21	1.81	Chemiluminescence
	ng/ml	1.18	0.945	1.42	
	nmol/l	1.42	1.14	1.70	Enzyme Immunoassay
	ng/ml	1.11	0.890	1.33	
	nmol/l	1.29	1.03	1.55	Turbidimetric
	ng/ml	1.01	0.804	1.22	
	nmol/l	1.44	1.15	1.73	KIMS
	ng/ml	1.12	0.898	1.34	
hsCRP	nmol/l	1.37	1.10	1.64	Enzyme Linked Fluorescent assay
	ng/ml	1.07	0.859	1.28	
	mg/l	1.90	1.52	2.28	
	mg/l	2.08	1.66	2.50	
Myoglobin	mg/l	2.08	1.66	2.50	Nephelometric (IFCC Cal.)
	mg/l	1.89	1.51	2.27	Turbidimetric (IFCC Cal.)
	mg/l	2.08	1.66	2.50	Turbidimetric (Non IFCC Cal.)
	ng/ml = µg/l	85.4	59.8	111	Randox Immunoturbidimetric
	ng/ml = µg/l	85.4	59.8	111	Abbott Architect

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Analyte	unit	Target	low	high	methods
Myoglobin	ng/ml = µg/l	80.3	56.2	104	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	82.8	58.0	108	Siemens Dimension
	ng/ml = µg/l	61.9	43.3	80.5	Beckman Dxl800
	ng/ml = µg/l	64.8	45.4	84.2	Roche Elecsys
	ng/ml = µg/l	69.9	48.9	90.9	Roche Hitachi
	ng/ml = µg/l	59.8	41.9	77.7	Beckman Coulter Access
	ng/ml = µg/l	42.4	29.7	55.1	Siemens Stratus CS
	ng/ml = µg/l	71.0	49.7	92.3	BioMerieux Vidas
	ng/ml = µg/l	64.8	45.4	84.2	Siemens Dimension Vista LOCI
	ng/ml = µg/l	72.1	50.5	93.7	Siemens Centaur CP
	ng/ml = µg/l	96.4	67.5	125	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	13.5	10.1	16.9	Siemens Centaur XP/XPT/Classic
	pg/ml	114	85.6	142	
	pmol/l	70.6	53.0	88.3	Siemens Immulite 2000
	pg/ml	598	449	747	
	pmol/l	19.1	14.3	23.9	Siemens Stratus CS
	pg/ml	162	121	203	
	pmol/l	16.9	12.7	21.1	BioMerieux Vidas
	pg/ml	143	108	178	
	pmol/l	16.5	12.4	20.6	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	140	105	175	
	pmol/l	59.0	44.3	73.8	Mitsubishi Chemical Pathfast
	pg/ml	500	375	625	
	pmol/l	30.6	23.0	38.3	Ortho Vitros 3600/5600/ECi
	pg/ml	259	195	323	
	pmol/l	9.66	7.25	12.1	Roche h232
	pg/ml	81.8	61.4	102	
	pmol/l	6.88	5.16	8.60	Siemens Dimension Vista LOCI
	pg/ml	58.3	43.7	72.9	
	pmol/l	3.58	2.69	4.48	Siemens Dimension Exl LOCI
	pg/ml	30.3	22.8	37.8	
	pmol/l	16.5	12.4	20.6	Biomerieux Vidas 2
	pg/ml	140	105	175	
Troponin I	ng/ml = µg/l	0.048	0.038	0.058	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	48.0	38.0	58.0	
	ng/ml = µg/l	0.208	0.166	0.250	Ortho Vitros ECi
	ng/l = pg/ml	208	166	250	
	ng/ml = µg/l	0.135	0.108	0.162	Biomerieux Vidas Ultra
	ng/l = pg/ml	135	108	162	
	ng/ml = µg/l	0.019	0.015	0.023	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	19.0	15.0	23.0	
	ng/ml = µg/l	0.060	0.048	0.072	Abbott Architect STAT hs
	ng/l = pg/ml	60.0	48.0	72.0	
	ng/ml = µg/l	0.034	0.027	0.041	Beckman Dxl - AccuTnl+3
	ng/l = pg/ml	34.0	27.0	41.0	
	ng/ml = µg/l	0.042	0.034	0.050	Siemens Centaur CP
	ng/l = pg/ml	42.0	34.0	50.0	

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Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	0.146	0.117	0.175	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	146	117	175	
	ng/ml = µg/l	0.083	0.066	0.100	Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH)
	ng/l = pg/ml	83.0	66.0	100	