

Artikel-Nr.: KG5053 **Inhalt:** 3 x 3ml
Verwendbar bis: 2011-10 **Chargen-B.:** 2993CK

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: BNP, CKMB Mass, Digoxin, D-Dimer, Homocysteine, 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 - +8°C. Stable to expiration date printed on individual vials.

OPENED: Store refrigerated (+2 - +8°C). Liquid Cardiac Controls are stable for 30 days at +2 - +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 3ml

MATERIALS REQUIRED BUT NOT PROVIDED

N/A

ASSIGNED VALUES

Each batch of Cardiac Control is submitted to a number of external laboratories and values are assigned from a consensus of results obtained by these laboratories and internal testing conducted at BGT BioGenTechnologies GmbH.

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 BGT BioGenTechnologies GmbH, Tel: 02551/4090 or email info@biogentechnologies.de.

LIQUID CARDIAC CONTROL LEVEL 3 (CRD LIQ CONTROL 3)

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Inhalt: 3 x 3ml Verw. bis: 2011-10

Bereich					
Parameter	Einheit	Zielwert	von	bis	Methoden
BNP	pmol/L	25.9	23.3	28.5	Abbott Architect
	pg/ml	89.3	80.3	98.3	
	pmol/L	15.3	11.3	19.3	Siemens Advia Centaur
	pg/ml	52.8	39.0	66.6	
CK-MB Mass	ng/ml = µg/l	91.0	66.0	116	Abbott Architect
	ng/ml = µg/l	89.5	67.4	112	Siemens Advia Centaur
	ng/ml = µg/l	93.6	84.2	103	Siemens Dimension
	ng/ml = µg/l	73.2	63.1	83.3	Roche Elecsys Modular E170 Cobas 6000
	ng/ml = µg/l	109	89.7	128	Beckman Coulter Access
	ng/ml = µg/l	131	112	150	bioMerieux Vidas
D - Dimer	ug/L	1503	1127	1879	bioMerieux Vidas
Digoxin	nmol/L	3.51	2.70	4.32	Chemiluminescence
	ng/ml	2.74	2.11	3.37	
	nmol/L	3.33	3.00	3.66	Enzyme Immunoassay
	ng/ml	2.60	2.34	2.86	
	nmol/L	3.25	2.93	3.57	Turbidimetric
	ng/ml	2.54	2.29	2.79	
Homocysteine	umol/l	32.8	29.5	36.1	Abbott AXSYM
	umol/l	34.9	27.8	42.0	Abbott Architect
hsCRP	mg/L	8.17	6.54	9.80	Nephelometric (IFCC Cal.)
	mg/L	9.86	7.61	12.1	Turbidimetric (IFCC Cal.)
	mg/L	10.4	8.32	12.5	Turbidimetric (Non IFCC Cal.)
Myoglobin	ng/ml = µg/l	418	376	460	Abbott Architect
	ng/ml = µg/l	345	292	398	Siemens Advia Centaur
	ng/ml = µg/l	368	331	405	Siemens Dimension
	ng/ml = µg/l	277	249	305	Beckman Dxl800
	ng/ml = µg/l	268	241	295	Roche Elecsys
	ng/ml = µg/l	301	243	359	bioMerieux Vidas
	ng/ml = µg/l	393	314	472	Randox Immunoturbidimetric
NT-ProBNP	pmol/L	462	370	554	Siemens Dimension 37°C
	pg/ml	3914	3135	4693	
	pmol/L	2770	2216	3324	Siemens Immulite 2500 37°C
	pg/ml	23467	18774	28160	
	pmol/L	717	574	860	Siemens Stratus 37°C
	pg/ml	6074	4863	7285	
	pmol/L	1923	1538	2308	bioMerieux Vidas 37°C
	pg/ml	16292	13030	19554	
	pmol/L	524	419	629	Roche Elecsys Modular E170 Cobas 6000 37°C
	pg/ml	4439	3550	5328	
	pmol/L	1080	864	1296	Ortho Vitros ECi 37°C
	pg/ml	9150	7320	10980	

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Parameter	Einheit	Zielwert	Bereich		Methoden
			von	bis	
Troponin I	ng/ml = µg/l	12.6	9.15	16.1	Abbott AXSYM
	ng/ml = µg/l	169	135	203	Abbott Architect
	ng/ml = µg/l	22.8	18.8	26.8	Siemens Advia Centaur
	ng/ml = µg/l	10.5	9.15	11.9	Siemens Dimension
	ng/ml = µg/l	75.3	67.8	82.8	Siemens Immulite 2500
	ng/ml = µg/l	14.7	11.6	17.8	Beckman DXi800 1st gen
	ng/ml = µg/l	13.1	11.8	14.4	Beckman Coulter Access
	ng/ml = µg/l	12.6	11.3	13.9	Siemens Stratus
Troponin T	ng/ml = µg/l	2.98	2.38	3.58	Roche Cobas TroponinT
	ng/ml = µg/l	3.34	2.46	4.22	Roche Cobas Troponin T HS