BGT BioGenTechnologies GmbH
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-o-trol LIQUID CARDIAC CONTROL LEVEL 2 (CRD LIQ CONTROL 2)

CE

Artikel-Nr.: KG5052 **Inhalt**: 3 x 3ml
Verwendbar bis: 2011-10 **Chargen-B.**: 2992CK

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 2 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.

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			Bereich		
Parameter	**Einheit**	**Zielwert**	**von**	**bis**	**Methoden**
BNP	pmol/L	9.39	8.45	10.3	Abbott AXSYM
	pg/ml	32.4	29.1	35.7	
	pmol/L	4.96	3.97	5.95	Abbott Architect
	pg/ml	17.1	13.7	20.5	
	pmol/L	5.25	4.20	6.30	Siemens Advia Centaur
	pg/ml	18.1	14.5	21.7	
CK-MB Mass	ng/ml = µg/l	17.2	14.3	20.1	Abbott Architect
	ng/ml = µg/l	19.0	14.7	23.3	Siemens Advia Centaur
	ng/ml = µg/l	16.1	14.1	18.1	Siemens Dimension
	ng/ml = µg/l	16.4	14.8	18.0	Roche Elecsys Modular E170 Cobas 6000
	ng/ml = µg/l	20.5	18.2	22.8	Beckman Coulter Access
	ng/ml = µg/l	28.0	23.6	32.4	bioMerieux Vidas
D - Dimer	ug/L	1427	1070	1784	bioMerieux Vidas
	ug/L	881	661	1101	IL/Beckman ACL Top/500
Digoxin	nmol/L	2.66	2.39	2.93	Chemiluminescence
	ng/ml	2.08	1.87	2.29	
	nmol/L	2.33	2.08	2.58	Enzyme Immunoassay
	ng/ml	1.82	1.62	2.02	
	nmol/L	2.48	2.11	2.85	Turbidimetric
	ng/ml	1.94	1.65	2.23	
	nmol/L	2.50	2.21	2.79	KIMS
	ng/ml	1.95	1.73	2.17	
Homocysteine	umol/l	18.5	16.7	20.3	Abbott AXSYM
	umol/l	20.0	18.0	22.0	Abbott Architect
hsCRP	mg/L	2.22	1.78	2.66	Nephelometric (IFCC Cal.)
	mg/L	2.81	2.21	3.41	Turbidimetric (IFCC Cal.)
	mg/L	2.82	2.42	3.22	Turbidimetric (Non IFCC Cal.)
Myoglobin	ng/ml = µg/l	161	145	177	Abbott Architect
	ng/ml = µg/l	139	125	153	Siemens Advia Centaur
	ng/ml = µg/l	143	129	157	Siemens Dimension
	ng/ml = µg/l	121	86.5	156	Beckman DxI800
	ng/ml = µg/l	118	103	133	Roche Elecsys
	ng/ml = µg/l	103	92.7	113	Beckman Coulter Access
	ng/ml = µg/l	129	95.7	162	bioMerieux Vidas
	ng/ml = µg/l	162	130	194	Randox Immunoturbidimetric
NT-ProBNP	pmol/L	25.0	22.4	27.6	Siemens Dimension
	pg/ml	212	190	234	
	pmol/L	238	182	294	Siemens Immulite 2500
	pg/ml	2016	1542	2490	
	pmol/L	74.6	67.1	82.1	Siemens Stratus
	pg/ml	632	568	696	
	pmol/L	160	128	192	bioMerieux Vidas
	pg/ml	1356	1084	1628	

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NT-ProBNP	pmol/L	46.3	41.7	50.9	Roche Elecsys Modular E170 Cobas 6000
	pg/ml	392	353	431	
	pmol/L	97.5	87.8	107	Ortho Vitros ECi
	pg/ml	826	744	908	
Troponin I	ng/ml = µg/l	1.65	1.22	2.08	Abbott AXSYM
	ng/ml = µg/l	18.1	15.9	20.3	Abbott Architect
	ng/ml = µg/l	1.68	1.36	2.00	Siemens Advia Centaur
	ng/ml = µg/l	0.995	0.782	1.21	Siemens Dimension
	ng/ml = µg/l	1.27	1.14	1.40	Beckman DXi800 1st gen
	ng/ml = µg/l	0.995	0.796	1.19	Beckman Coulter Access
	ng/ml = µg/l	6.15	5.54	6.76	bioMerieux Vidas
	ng/ml = µg/l	5.54	4.99	6.09	Biomerieux Vidas Ultra
Troponin T	ng/ml = µg/l	0.567	0.445	0.689	Roche Cobas TroponinT
	ng/ml = µg/l	0.654	0.523	0.785	Roche Cobas Troponin T HS

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