BGT BioGenTechnologies GmbH
Von-Langen-Weg 10
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-o-trol
TRI LEVEL CARDIAC CONTROL
(CRD CONTROL 1, 2, 3)
KG3100 CE

Art.-Nr.:	KG3100
Ch.-B.:	2792CK
	2795CK
	2799CK
Inhalt:	3 x 1 ml
Verw. bis:	2012-04

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 at level 1; CK Total, CKMB Mass, Homocysteine, Myoglobin, Troponin I and Troponin T.
Target values and ranges are supplied for the following analytes at level 2 & 3; CK Total, CK-MB (Activity and Mass) Homocysteine, Myoglobin, 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.
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

OPENED:	Store refrigerated (+2 - +8°C). Reconstituted serum is stable for 5 days at +2 - +8°C and 4 weeks at -20°C if kept capped in original container and free from contamination. Troponin I is stable for 2 weeks at -20°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.
UNOPENED:	Store refrigerated (+2 - +8°C). Stable to expiration date printed on individual vials.

PREPARATION FOR USE
The Tri Level Cardiac Control is supplied lyophilised.
1. Carefully reconstitute each vial of lyophilised serum with exactly 1ml of redistilled water at +20 to 25°C. Close bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
2. Refer to the control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Tri Level Cardiac Control	Level 1	3 x 1ml
	Level 2	3 x 1ml
	Level 3	3 x 1ml

MATERIALS REQUIRED BUT NOT PROVIDED
Volumetric Pipette
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 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.

Revised 03 Mar '09 ne

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CARDIAC CONTROL LEVEL 1 (CRD CONTROL 1)

Art.-Nr.: KG3100 Ch.-B.: 2792CK Inhalt 3 x 1ml Verw. bis: 2012-04

			Bereich		
Parameter	**Einheit**	**Zielwert**	**von**	**bis**	**Methoden**
CK Total	U/l	84	76	93	CK-NAC substrate start (DGKC) 37°C
	U/l	53	48	58	CK-NAC substrate start (DGKC) 30°C
	U/l	36	32	40	CK-NAC substrate start (DGKC) 25°C
	U/l	110	97	123	Vitros 37°C
	U/l	79	71	87	CK-NAC serum start (DGKC) 37°C
	U/l	49	45	53	CK-NAC serum start (DGKC) 30°C
	U/l	34	30	38	CK-NAC serum start (DGKC) 25°C
	U/l	83	75	91	CK-NAC (IFCC) 37°C
	U/l	52	47	57	CK-NAC (IFCC) 30°C
	U/l	35	32	38	CK-NAC (IFCC) 25°C
	U/l	75	68	83	Dithioerythritol 37°C
	U/l	47	42	52	Dithioerythritol 30°C
	U/l	32	29	35	Dithioerythritol 25°C
	U/l	90	81	99	Monothioglycerol 37°C
	U/l	56	51	61	Monothioglycerol 30°C
	U/l	38	34	42	Monothioglycerol 25°C
CK-MB Mass	ng/ml = µg/l	3.60	2.60	4.60	Siemens Dimension
	ng/ml = µg/l	5.56	4.56	6.56	Siemens Advia Centaur
	ng/ml = µg/l	6.64	5.71	7.57	Roche Elecsys Modular E170 Cobas 6000
	ng/ml = µg/l	6.00	4.88	7.12	Abbott AXSYM
	ng/ml = µg/l	6.40	5.73	7.07	Beckman Coulter Access
	ng/ml = µg/l	4.03	3.51	4.55	Ortho Vitros ECi
	ng/ml = µg/l	7.30	5.55	9.05	bioMerieux Vidas
	ng/ml = µg/l	6.45	5.81	7.09	Tosoh
	ng/ml = µg/l	4.70	3.60	5.80	Abbott Architect
Homocysteine	umol/l	12.5	10.9	14.1	Abbott IMx
	umol/l	9.83	7.86	11.8	Siemens Immulite 2000/2500
	umol/l	8.70	6.96	10.4	Abbott AXSYM
	umol/l	5.22	4.33	6.11	Siemens Advia Centaur
Myoglobin	ng/ml = µg/l	75.9	67.0	84.8	Roche Elecsys
	ng/ml = µg/l	77.9	70.1	85.7	Siemens Dimension
	ng/ml = µg/l	52.6	47.3	57.9	Beckman Coulter Access
	ng/ml = µg/l	85.6	77.0	94.2	Abbott AXSYM
	ng/ml = µg/l	129	103	155	Roche Cardiac Reader
	ng/ml = µg/l	74.5	67.1	81.9	Roche Integra
	ng/ml = µg/l	70.9	63.8	78.0	Siemens Advia Centaur
	ng/ml = µg/l	57.0	51.3	62.7	bioMerieux Vidas
	ng/ml = µg/l	99.2	89.3	109	Diasorin Liaison
	µg/L	110	88.0	132	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.243	0.194	0.292	Abbott AXSYM
	ng/ml = µg/l	0.189	0.163	0.215	Beckman Coulter Access
	ng/ml = µg/l	0.505	0.421	0.589	Siemens Advia Centaur

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CARDIAC CONTROL LEVEL 1 (CRD CONTROL 1)

Art.-Nr.: KG3100 Ch.-B.: 2792CK Inhalt 3 x 1ml Verw. bis: 2012-04

			Bereich		
Parameter	**Einheit**	**Zielwert**	**von**	**bis**	**Methoden**
Troponin I	ng/ml = µg/l	0.921	0.829	1.01	Ortho Vitros ECi
	ng/ml = µg/l	0.632	0.454	0.810	bioMerieux Vidas
	ng/ml = µg/l	1.67	1.50	1.84	Tosoh
	ng/ml = µg/l	0.239	0.191	0.287	Abbott AXSYM **ADV**
	ng/ml = µg/l	0.210	0.178	0.242	Diasorin Liaison
	ng/ml = µg/l	0.992	0.877	1.11	Abbott Architect
	ng/ml = µg/l	0.626	0.563	0.689	Biomerieux Vidas Ultra
Troponin T	ng/ml = µg/l	0.117	0.099	0.135	Roche Elecsys
	ng/ml = µg/l	0.108	0.077	0.139	Roche Cardiac Reader

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CARDIAC CONTROL LEVEL 2 (CRD CONTROL 2)

Art.-Nr.: KG3100 Ch.-B.: 2795CK Inhalt 3 x 1ml Verw. bis: 2012-04

			Bereich		
Parameter	**Einheit**	**Zielwert**	**von**	**bis**	**Methoden**
CK Total	U/l	327	294	360	CK-NAC substrate start (DGKC) 37°C
	U/l	205	184	226	CK-NAC substrate start (DGKC) 30°C
	U/l	139	125	153	CK-NAC substrate start (DGKC) 25°C
	U/l	421	379	463	Vitros 37°C
	U/l	311	280	342	CK-NAC serum start (DGKC) 37°C
	U/l	195	175	215	CK-NAC serum start (DGKC) 30°C
	U/l	132	119	145	CK-NAC serum start (DGKC) 25°C
	U/l	319	287	351	CK-NAC (IFCC) 37°C
	U/l	200	180	220	CK-NAC (IFCC) 30°C
	U/l	136	122	150	CK-NAC (IFCC) 25°C
	U/l	302	272	332	Dithioerythritol 37°C
	U/l	189	170	208	Dithioerythritol 30°C
	U/l	128	116	140	Dithioerythritol 25°C
	U/l	340	306	374	Monothioglycerol 37°C
	U/l	213	192	234	Monothioglycerol 30°C
	U/l	145	130	160	Monothioglycerol 25°C
CK-MB Activity	U/l	10.5	8.40	12.6	Vitros 37°C
	U/l	18.8	16.0	21.6	Immunoinhibition substrate start 37°C
	U/l	10.9	9.30	12.5	Immunoinhibition substrate start 30°C
	U/l	6.67	5.68	7.66	Immunoinhibition substrate start 25°C
	U/l	17.7	15.0	20.4	Immunoinhibition serum start 37°C
	U/l	10.3	8.72	11.9	Immunoinhibition serum start 30°C
	U/l	6.28	5.33	7.23	Immunoinhibition serum start 25°C
	U/l	20.7	17.6	23.8	Immunoinhibition (IFCC) 37°C
	U/l	12.0	10.2	13.8	Immunoinhibition (IFCC) 30°C
	U/l	7.35	6.25	8.45	Immunoinhibition (IFCC) 25°C
	U/l	21.1	17.9	24.3	Randox Immunoinhibition serum start 37°C
	U/l	12.3	10.4	14.1	Randox Immunoinhibition serum start 30°C
	U/l	7.49	6.35	8.63	Randox Immunoinhibition serum start 25°C
	U/l	20.8	17.7	23.9	Randox Immunoinhibition substrate start 37°C
	U/l	12.1	10.3	13.9	Randox Immunoinhibition substrate start 30°C
	U/l	7.38	6.28	8.48	Randox Immunoinhibition substrate start 25°C
	U/l	11.0	9.35	12.7	Siemens Dimension 37°C
CK-MB Mass	ng/ml = µg/l	27.8	23.7	31.9	Siemens Immulite 1000
	ng/ml = µg/l	21.2	16.2	26.2	Siemens Dimension
	ng/ml = µg/l	22.9	18.2	27.6	Siemens Advia Centaur
	ng/ml = µg/l	22.3	19.4	25.2	Roche Elecsys Modular E170 Cobas 6000
	ng/ml = µg/l	26.5	22.2	30.8	Abbott AXSYM
	ng/ml = µg/l	30.1	27.0	33.2	Beckman Coulter Access
	ng/ml = µg/l	18.6	16.6	20.6	Ortho Vitros ECi
	ng/ml = µg/l	31.6	28.0	35.2	bioMerieux Vidas
	ng/ml = µg/l	31.3	27.9	34.7	Tosoh

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CARDIAC CONTROL LEVEL 2 (CRD CONTROL 2)

Art.-Nr.: KG3100 Ch.-B.: 2795CK Inhalt 3 x 1ml Verw. bis: 2012-04

			Bereich		
Parameter	**Einheit**	**Zielwert**	**von**	**bis**	**Methoden**
CK-MB Mass	ng/ml = µg/l	23.2	19.6	26.8	Abbott Architect
	ng/ml = µg/l	22.7	20.4	25.0	Roche Cardiac Reader
Homocysteine	umol/l	21.7	19.3	24.1	Abbott IMx
	umol/l	18.1	13.8	22.4	Siemens Immulite 2000/2500
	umol/l	41.3	33.0	49.6	HPLC
	umol/l	17.9	14.3	21.5	Abbott AXSYM
	umol/l	7.31	6.55	8.07	Siemens Advia Centaur
Myoglobin	ng/ml = µg/l	164	148	180	Roche Elecsys
	ng/ml = µg/l	206	185	227	Siemens Dimension
	ng/ml = µg/l	124	101	147	Beckman Coulter Access
	ng/ml = µg/l	212	170	254	Abbott AXSYM
	ng/ml = µg/l	262	193	331	Roche Cardiac Reader
	ng/ml = µg/l	169	152	186	Roche Integra
	ng/ml = µg/l	176	158	194	Siemens Advia Centaur
	ng/ml = µg/l	138	110	166	bioMerieux Vidas
	ng/ml = µg/l	173	152	194	Tosoh
	ng/ml = µg/l	226	203	249	Abbott Architect
	µg/L	258	206	310	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.940	0.771	1.11	Abbott AXSYM
	ng/ml = µg/l	0.538	0.388	0.688	Siemens Dimension
	ng/ml = µg/l	0.770	0.582	0.958	Siemens Stratus
	ng/ml = µg/l	0.663	0.587	0.739	Beckman Coulter Access
	ng/ml = µg/l	1.53	1.30	1.76	Siemens Immulite 1000
	ng/ml = µg/l	2.09	1.75	2.43	Siemens Advia Centaur
	ng/ml = µg/l	4.33	3.90	4.76	Ortho Vitros ECi
	ng/ml = µg/l	2.03	1.64	2.42	bioMerieux Vidas
	ng/ml = µg/l	7.77	6.78	8.76	Tosoh
	ng/ml = µg/l	1.04	0.906	1.17	Abbott AXSYM **ADV**
	ng/ml = µg/l	0.892	0.744	1.04	Diasorin Liaison
	ng/ml = µg/l	3.75	3.38	4.12	Abbott Architect
	ng/ml = µg/l	1.85	1.67	2.03	Biomerieux Vidas Ultra
Troponin T	ng/ml = µg/l	0.349	0.295	0.403	Roche Elecsys
	ng/ml = µg/l	0.215	0.172	0.258	Roche Cardiac Reader

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CARDIAC CONTROL LEVEL 3 (CRD CONTROL 3)

Art.-Nr.: KG3100 Ch.-B.: 2799CK Inhalt 3 x 1ml Verw. bis: 2012-04

			Bereich		
Parameter	**Einheit**	**Zielwert**	**von**	**bis**	**Methoden**
CK Total	U/l	834	751	917	CK-NAC substrate start (DGKC) 37°C
	U/l	522	470	574	CK-NAC substrate start (DGKC) 30°C
	U/l	354	319	389	CK-NAC substrate start (DGKC) 25°C
	U/l	1014	913	1115	Vitros 37°C
	U/l	792	693	891	CK-NAC serum start (DGKC) 37°C
	U/l	496	434	558	CK-NAC serum start (DGKC) 30°C
	U/l	337	295	379	CK-NAC serum start (DGKC) 25°C
	U/l	816	734	898	CK-NAC (IFCC) 37°C
	U/l	511	459	563	CK-NAC (IFCC) 30°C
	U/l	347	312	382	CK-NAC (IFCC) 25°C
	U/l	754	679	829	Dithioerythritol 37°C
	U/l	472	425	519	Dithioerythritol 30°C
	U/l	320	289	351	Dithioerythritol 25°C
	U/l	864	778	950	Monothioglycerol 37°C
	U/l	541	487	595	Monothioglycerol 30°C
	U/l	367	331	403	Monothioglycerol 25°C
CK-MB Activity	U/l	148	126	170	Vitros 37°C
	U/l	153	122	184	Immunoinhibition substrate start 37°C
	U/l	88.9	70.9	107	Immunoinhibition substrate start 30°C
	U/l	54.3	43.3	65.3	Immunoinhibition substrate start 25°C
	U/l	162	131	192	Immunoinhibition serum start 37°C
	U/l	94.2	76.1	112	Immunoinhibition serum start 30°C
	U/l	57.5	46.5	68.5	Immunoinhibition serum start 25°C
	U/l	167	128	207	Immunoinhibition (IFCC) 37°C
	U/l	97.1	74.4	120	Immunoinhibition (IFCC) 30°C
	U/l	59.3	45.4	73.2	Immunoinhibition (IFCC) 25°C
	U/l	160	136	184	Randox Immunoinhibition serum start 37°C
	U/l	93.0	79.0	107	Randox Immunoinhibition serum start 30°C
	U/l	56.8	48.3	65.3	Randox Immunoinhibition serum start 25°C
	U/l	163	139	187	Randox Immunoinhibition substrate start 37°C
	U/l	94.7	80.8	109	Randox Immunoinhibition substrate start 30°C
	U/l	57.9	49.3	66.4	Randox Immunoinhibition substrate start 25°C
	U/l	103	87.6	118	Siemens Dimension 37°C
CK-MB Mass	ng/ml = µg/l	217	192	242	Siemens Dimension
	ng/ml = µg/l	188	164	212	Siemens Advia Centaur
	ng/ml = µg/l	185	165	205	Roche Elecsys Modular E170 Cobas 6000
	ng/ml = µg/l	234	211	257	Abbott AXSYM
	ng/ml = µg/l	283	253	313	Beckman Coulter Access
	ng/ml = µg/l	174	157	191	Ortho Vitros ECi
	ng/ml = µg/l	256	203	309	bioMerieux Vidas
	ng/ml = µg/l	291	251	331	Tosoh
	ng/ml = µg/l	40.0	36.0	44.0	Roche Cardiac Reader

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CARDIAC CONTROL LEVEL 3 (CRD CONTROL 3)

Art.-Nr.: KG3100 Ch.-B.: 2799CK Inhalt 3 x 1ml Verw. bis: 2012-04

			Bereich		
Parameter	**Einheit**	**Zielwert**	**von**	**bis**	**Methoden**
Homocysteine	umol/l	41.6	37.4	45.8	Abbott IMx
	umol/l	39.0	29.9	48.1	Siemens Immulite 2000/2500
	umol/l	92.4	70.9	114	HPLC
	umol/l	12.3	9.84	14.8	Siemens Advia Centaur
Myoglobin	ng/ml = µg/l	266	236	296	Roche Elecsys
	ng/ml = µg/l	338	296	380	Siemens Dimension
	ng/ml = µg/l	309	278	340	Siemens Stratus
	ng/ml = µg/l	206	185	227	Beckman Coulter Access
	ng/ml = µg/l	419	377	461	Roche Cardiac Reader
	ng/ml = µg/l	285	257	313	Roche Integra
	ng/ml = µg/l	310	279	341	Siemens Advia Centaur
	ng/ml = µg/l	223	201	245	bioMerieux Vidas
	ng/ml = µg/l	296	266	326	Tosoh
	ng/ml = µg/l	209	188	230	Beckman DxI800
	µg/L	432	346	518	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	3.59	3.23	3.95	Abbott AXSYM
	ng/ml = µg/l	1.86	1.46	2.26	Siemens Dimension
	ng/ml = µg/l	2.75	2.09	3.41	Siemens Stratus
	ng/ml = µg/l	2.58	2.19	2.97	Beckman Coulter Access
	ng/ml = µg/l	6.85	6.17	7.53	Siemens Immulite 1000
	ng/ml = µg/l	9.44	7.56	11.3	Siemens Advia Centaur
	ng/ml = µg/l	20.4	17.2	23.6	Ortho Vitros ECi
	ng/ml = µg/l	6.83	6.15	7.51	bioMerieux Vidas
	ng/ml = µg/l	33.9	30.5	37.3	Tosoh
	ng/ml = µg/l	3.76	3.28	4.24	Abbott AXSYM **ADV**
	ng/ml = µg/l	4.22	3.62	4.82	Diasorin Liaison
	ng/ml = µg/l	14.7	13.2	16.2	Abbott Architect
	ng/ml = µg/l	6.65	5.98	7.32	Biomerieux Vidas Ultra
Troponin T	ng/ml = µg/l	1.10	0.940	1.26	Roche Elecsys
	ng/ml = µg/l	0.556	0.445	0.667	Roche Cardiac Reader

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