

**Art.-Nr.:** KG3100  
**Ch.-B.:** 2886CK  
2889CK  
2893CK  
**Inhalt:** 3 x 1 ml  
**Verw. bis:** 2013-01

#### 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.

- 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.
- Refer to the control section of the individual analyser application.
- Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

#### MATERIALS PROVIDED

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

## CARDIAC CONTROL LEVEL 1 (CRD CONTROL 1)

Art.-Nr.: KG3100 Ch.-B.: 2886CK Inhalt 1 x 1ml Verw. bis: 2013-01

Bereich					
Parameter	Einheit	Zielwert	von	bis	Methoden
CK Total	U/l	67	59	75	CK-NAC substrate start (DGKC) 37°C
	U/l	42	37	47	CK-NAC substrate start (DGKC) 30°C
	U/l	28	25	31	CK-NAC substrate start (DGKC) 25°C
	U/l	82	70	94	Vitros 37°C
	U/l	68	61	75	CK-NAC serum start (DGKC) 37°C
	U/l	43	38	48	CK-NAC serum start (DGKC) 30°C
	U/l	29	26	32	CK-NAC serum start (DGKC) 25°C
	U/l	67	58	75	CK-NAC (IFCC) 37°C
	U/l	42	36	48	CK-NAC (IFCC) 30°C
	U/l	28	25	31	CK-NAC (IFCC) 25°C
	U/l	60	53	67	Dithioerythritol 37°C
	U/l	38	33	43	Dithioerythritol 30°C
	U/l	26	23	29	Dithioerythritol 25°C
	U/l	69	62	76	Monothioglycerol 37°C
	U/l	43	39	47	Monothioglycerol 30°C
U/l	29	26	32	Monothioglycerol 25°C	
CK-MB Mass	ng/ml = µg/l	3.32	2.66	3.98	Siemens Dimension
	ng/ml = µg/l	5.25	3.95	6.55	Siemens Advia Centaur
	ng/ml = µg/l	6.10	4.91	7.29	Roche Elecsys Modular E170 Cobas 6000
	ng/ml = µg/l	5.26	4.73	5.79	Abbott AXSYM
	ng/ml = µg/l	5.70	5.03	6.37	Beckman Coulter Access
	ng/ml = µg/l	4.35	3.92	4.78	Siemens Stratus
	ng/ml = µg/l	3.97	3.57	4.37	Ortho Vitros Eci
	ng/ml = µg/l	6.98	5.68	8.28	bioMerieux Vidas
	ng/ml = µg/l	6.55	4.98	8.12	Tosoh
	ng/ml = µg/l	4.57	3.51	5.63	Abbott Architect
	ng/ml = µg/l	3.49	3.09	3.89	Roche Cardiac Reader
ng/ml = µg/l	5.60	5.04	6.16	Beckman Dxl800	
Homocysteine	umol/l	13.1	11.8	14.4	Abbott IMx
	umol/l	10.7	8.31	13.1	Siemens Immulite 2000/2500
	umol/l	11.8	10.6	13.0	Abbott AXSYM
Myoglobin	ng/ml = µg/l	62.5	54.7	70.3	Roche Elecsys
	ng/ml = µg/l	63.1	56.8	69.4	Siemens Dimension
	ng/ml = µg/l	59.7	53.7	65.7	Siemens Stratus
	ng/ml = µg/l	44.1	39.7	48.5	Beckman Coulter Access
	ng/ml = µg/l	73.5	66.2	80.8	Abbott AXSYM
	ng/ml = µg/l	113	93.7	132	Roche Cardiac Reader
	ng/ml = µg/l	70.9	62.0	79.8	Roche Integra
	ng/ml = µg/l	56.6	49.9	63.3	Siemens Advia Centaur
	ng/ml = µg/l	45.3	40.8	49.8	bioMerieux Vidas
	ng/ml = µg/l	53.0	46.0	60.0	Tosoh
	ng/ml = µg/l	84.5	76.1	92.9	Diasorin Liaison

## CARDIAC CONTROL LEVEL 1 (CRD CONTROL 1)

Art.-Nr.: KG3100 Ch.-B.: 2886CK Inhalt 1 x 1ml Verw. bis: 2013-01

Bereich					
Parameter	Einheit	Zielwert	von	bis	Methoden
Myoglobin	ng/ml = µg/l	78.7	69.4	88.0	Abbott Architect
	ng/ml = µg/l	43.1	38.4	47.8	Beckman DxI800
	ng/ml = µg/l	88.6	70.9	106	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.293	0.224	0.362	Abbott AXSYM
	ng/ml = µg/l	0.150	0.110	0.190	Siemens Dimension
	ng/ml = µg/l	0.230	0.200	0.260	Siemens Stratus
	ng/ml = µg/l	0.210	0.176	0.244	Beckman Coulter Access
	ng/ml = µg/l	0.470	0.381	0.559	Siemens Advia Centaur
	ng/ml = µg/l	0.872	0.785	0.959	Ortho Vitros ECI
	ng/ml = µg/l	0.545	0.452	0.638	bioMerieux Vidas
	ng/ml = µg/l	1.67	1.50	1.84	Tosoh
	ng/ml = µg/l	0.298	0.237	0.359	Abbott Axsym ADV
	ng/ml = µg/l	1.08	0.969	1.19	Abbott Architect
	ng/ml = µg/l	0.548	0.493	0.603	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.247	0.197	0.297	Beckman DXi800 1st gen
Troponin T	ng/ml = µg/l	0.083	0.068	0.098	Roche Cobas TroponinT
	ng/ml = µg/l	0.100	0.090	0.110	Roche Cardiac Reader

## CARDIAC CONTROL LEVEL 2 (CRD CONTROL 2)

Art.-Nr.: KG3100 Ch.-B.: 2889CK Inhalt 1 x 1ml Verw. bis: 2013-01

Bereich					
Parameter	Einheit	Zielwert	von	bis	Methoden
CK Total	U/l	317	285	349	CK-NAC substrate start (DGKC) 37°C
	U/l	198	178	218	CK-NAC substrate start (DGKC) 30°C
	U/l	135	121	149	CK-NAC substrate start (DGKC) 25°C
	U/l	411	370	452	Vitros 37°C
	U/l	313	282	344	CK-NAC serum start (DGKC) 37°C
	U/l	196	177	215	CK-NAC serum start (DGKC) 30°C
	U/l	133	120	146	CK-NAC serum start (DGKC) 25°C
	U/l	313	282	344	CK-NAC (IFCC) 37°C
	U/l	196	177	215	CK-NAC (IFCC) 30°C
	U/l	133	120	146	CK-NAC (IFCC) 25°C
	U/l	303	272	335	Dithioerythritol 37°C
	U/l	190	170	210	Dithioerythritol 30°C
	U/l	129	116	142	Dithioerythritol 25°C
	U/l	328	295	361	Monothioglycerol 37°C
	U/l	205	185	225	Monothioglycerol 30°C
U/l	139	125	153	Monothioglycerol 25°C	
CK-MB Activity	U/l	8.50	6.40	10.6	Vitros 37°C
	U/l	18.6	15.8	21.4	Immunoinhibition substrate start 37°C
	U/l	10.8	9.18	12.4	Immunoinhibition substrate start 30°C
	U/l	6.60	5.61	7.59	Immunoinhibition substrate start 25°C
	U/l	19.2	16.3	22.1	Immunoinhibition serum start 37°C
	U/l	11.2	9.47	12.9	Immunoinhibition serum start 30°C
	U/l	6.82	5.79	7.85	Immunoinhibition serum start 25°C
	U/l	20.4	17.3	23.5	Immunoinhibition (IFCC) 37°C
	U/l	11.9	10.1	13.7	Immunoinhibition (IFCC) 30°C
	U/l	7.24	6.14	8.34	Immunoinhibition (IFCC) 25°C
	U/l	18.0	15.3	20.7	Randox Immunoinhibition serum start 37°C
	U/l	10.5	8.89	12.0	Randox Immunoinhibition serum start 30°C
	U/l	6.39	5.43	7.35	Randox Immunoinhibition serum start 25°C
	U/l	18.2	15.5	20.9	Randox Immunoinhibition substrate start 37°C
	U/l	10.6	9.01	12.1	Randox Immunoinhibition substrate start 30°C
U/l	6.46	5.50	7.42	Randox Immunoinhibition substrate start 25°C	
CK-MB Mass	ng/ml = µg/l	21.7	17.5	25.9	Siemens Dimension
	ng/ml = µg/l	25.0	22.0	28.0	Siemens Advia Centaur
	ng/ml = µg/l	23.3	21.0	25.6	Roche Elecsys Modular E170 Cobas 6000
	ng/ml = µg/l	27.8	21.0	34.6	Abbott AXSYM
	ng/ml = µg/l	32.5	29.3	35.7	Beckman Coulter Access
	ng/ml = µg/l	20.8	18.7	22.9	Ortho Vitros ECi
	ng/ml = µg/l	33.7	30.2	37.2	bioMerieux Vidas
	ng/ml = µg/l	31.4	28.3	34.5	Tosoh
	ng/ml = µg/l	25.1	21.5	28.7	Abbott Architect
Homocysteine	umol/l	20.5	17.1	23.9	Abbott IMx

## CARDIAC CONTROL LEVEL 2 (CRD CONTROL 2)

Art.-Nr.: KG3100 Ch.-B.: 2889CK Inhalt 1 x 1ml Verw. bis: 2013-01

Bereich					
Parameter	Einheit	Zielwert	von	bis	Methoden
Homocysteine	umol/l	17.8	14.2	21.4	Siemens Immulite 2000/2500
	umol/l	19.5	17.6	21.4	Abbott AXSYM
Myoglobin	ng/ml = µg/l	142	128	156	Roche Elecsys
	ng/ml = µg/l	171	154	188	Siemens Dimension
	ng/ml = µg/l	106	93.5	119	Beckman Coulter Access
	ng/ml = µg/l	278	250	306	Roche Cardiac Reader
	ng/ml = µg/l	143	126	160	Roche Integra
	ng/ml = µg/l	154	139	169	Siemens Advia Centaur
	ng/ml = µg/l	112	101	123	bioMerieux Vidas
	ng/ml = µg/l	203	183	223	Abbott Architect
	ng/ml = µg/l	205	164	246	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	1.26	1.07	1.45	Abbott AXSYM
	ng/ml = µg/l	0.576	0.450	0.702	Siemens Dimension
	ng/ml = µg/l	0.781	0.648	0.914	Beckman Coulter Access
	ng/ml = µg/l	3.09	2.47	3.71	Siemens Immulite 2000
	ng/ml = µg/l	2.00	1.80	2.20	Siemens Advia Centaur
	ng/ml = µg/l	3.91	3.46	4.36	Ortho Vitros ECI
	ng/ml = µg/l	1.76	1.40	2.12	bioMerieux Vidas
	ng/ml = µg/l	6.72	6.05	7.39	Tosoh
	ng/ml = µg/l	1.19	1.00	1.38	Abbott Axsym ADV
	ng/ml = µg/l	4.29	3.65	4.93	Abbott Architect
	ng/ml = µg/l	1.71	1.54	1.88	Biomerieux Vidas Ultra
Troponin T	ng/ml = µg/l	0.258	0.226	0.290	Roche Cobas TroponinT
	ng/ml = µg/l	0.123	0.098	0.148	Roche Cardiac Reader

## CARDIAC CONTROL LEVEL 3 (CRD CONTROL 3)

Art.-Nr.: KG3100 Ch.-B.: 2893CK Inhalt 1 x 1ml Verw. bis: 2013-01

Bereich					
Parameter	Einheit	Zielwert	von	bis	Methoden
CK Total	U/l	764	662	867	CK-NAC substrate start (DGKC) 37°C
	U/l	478	414	542	CK-NAC substrate start (DGKC) 30°C
	U/l	325	281	369	CK-NAC substrate start (DGKC) 25°C
	U/l	960	864	1056	Vitros 37°C
	U/l	790	711	869	CK-NAC serum start (DGKC) 37°C
	U/l	495	445	545	CK-NAC serum start (DGKC) 30°C
	U/l	336	302	370	CK-NAC serum start (DGKC) 25°C
	U/l	770	693	847	CK-NAC (IFCC) 37°C
	U/l	482	434	530	CK-NAC (IFCC) 30°C
	U/l	327	295	359	CK-NAC (IFCC) 25°C
	U/l	735	662	808	Dithioerythritol 37°C
	U/l	460	414	506	Dithioerythritol 30°C
	U/l	312	281	343	Dithioerythritol 25°C
	U/l	768	691	845	Monothioglycerol 37°C
	U/l	481	433	529	Monothioglycerol 30°C
U/l	326	294	358	Monothioglycerol 25°C	
CK-MB Activity	U/l	155	127	182	Vitros 37°C
	U/l	141	113	169	Immunoinhibition substrate start 37°C
	U/l	81.9	65.7	98.1	Immunoinhibition substrate start 30°C
	U/l	50.1	40.1	60.1	Immunoinhibition substrate start 25°C
	U/l	161	121	200	Immunoinhibition serum start 37°C
	U/l	93.6	70.3	117	Immunoinhibition serum start 30°C
	U/l	57.2	43.0	71.4	Immunoinhibition serum start 25°C
	U/l	162	124	200	Immunoinhibition (IFCC) 37°C
	U/l	94.2	72.1	116	Immunoinhibition (IFCC) 30°C
	U/l	57.5	44.0	71.0	Immunoinhibition (IFCC) 25°C
	U/l	156	133	179	Randox Immunoinhibition serum start 37°C
	U/l	90.7	77.3	104	Randox Immunoinhibition serum start 30°C
	U/l	55.4	47.2	63.5	Randox Immunoinhibition serum start 25°C
	U/l	156	133	179	Randox Immunoinhibition substrate start 37°C
	U/l	90.7	77.3	104	Randox Immunoinhibition substrate start 30°C
U/l	55.4	47.2	63.5	Randox Immunoinhibition substrate start 25°C	
CK-MB Mass	ng/ml = µg/l	251	197	305	Siemens Dimension
	ng/ml = µg/l	256	208	304	Siemens Advia Centaur
	ng/ml = µg/l	206	185	227	Roche Elecsys Modular E170 Cobas 6000
	ng/ml = µg/l	277	233	321	Abbott AXSYM
	ng/ml = µg/l	291	252	330	Beckman Coulter Access
	ng/ml = µg/l	193	173	213	Ortho Vitros ECi
	ng/ml = µg/l	268	235	301	bioMerieux Vidas
	ng/ml = µg/l	248	198	298	Abbott Architect
	ng/ml = µg/l	289	260	318	Beckman DxI800
Homocysteine	umol/l	39.1	35.2	43.0	Abbott IMx

## CARDIAC CONTROL LEVEL 3 (CRD CONTROL 3)

Art.-Nr.: KG3100 Ch.-B.: 2893CK Inhalt 1 x 1ml Verw. bis: 2013-01

Bereich					
Parameter	Einheit	Zielwert	von	bis	Methoden
Homocysteine	umol/l	36.8	25.9	47.7	Siemens Immulite 2000/2500
	umol/l	35.9	31.7	40.1	Abbott AXSYM
	umol/l	10.8	9.19	12.4	Siemens Advia Centaur
Myoglobin	ng/ml = µg/l	247	222	272	Roche Elecsys
	ng/ml = µg/l	320	266	374	Siemens Dimension
	ng/ml = µg/l	186	164	208	Beckman Coulter Access
	ng/ml = µg/l	450	373	527	Roche Cardiac Reader
	ng/ml = µg/l	253	228	278	Roche Integra
	ng/ml = µg/l	307	271	343	Siemens Advia Centaur
	ng/ml = µg/l	203	175	231	bioMerieux Vidas
	ng/ml = µg/l	277	229	325	Tosoh
	ng/ml = µg/l	384	344	424	Abbott Architect
Troponin I	ng/ml = µg/l	376	301	451	Randox Immunoturbidimetric
	ng/ml = µg/l	5.50	4.95	6.05	Abbott AXSYM
	ng/ml = µg/l	2.61	2.05	3.17	Siemens Dimension
	ng/ml = µg/l	3.50	2.78	4.22	Beckman Coulter Access
	ng/ml = µg/l	11.1	9.91	12.3	Siemens Advia Centaur
	ng/ml = µg/l	20.9	18.5	23.3	Ortho Vitros ECI
	ng/ml = µg/l	6.34	5.14	7.54	bioMerieux Vidas
	ng/ml = µg/l	27.8	22.2	33.4	Tosoh
	ng/ml = µg/l	5.22	4.39	6.05	Abbott Axsym ADV
	ng/ml = µg/l	18.7	16.3	21.1	Abbott Architect
Troponin T	ng/ml = µg/l	9.07	7.81	10.3	Siemens Immulite 2500
	ng/ml = µg/l	6.55	5.90	7.20	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.879	0.747	1.01	Roche Cobas TroponinT
	ng/ml = µg/l	0.407	0.326	0.488	Roche Cardiac Reader