TRI LEVEL CARDIAC CONTROL (CRD CONTROL 1, 2, 3)

CAT NO. CQ3259 SIZE: 3 x 2ml
EXPIRY: 2014-06 LOT NOS. 3083CK
3084CK
3085CK

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 2ml 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	1 x 2ml
	Level 2	1 x 2ml
	Level 3	1 x 2ml

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 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 Support, Northern Ireland, tel: (028) 9442 2413 or email Technical.Support@randox.com

28 Oct ’10 ne

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CARDIAC CONTROL LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3259 Lot. No. 3083CK Size 1 x 2ml Expiry 2014-06

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
CK Total	U/l	66	54	78	CK-NAC substrate start (DGKC) 37°C
	U/l	41	34	48	CK-NAC substrate start (DGKC) 30°C
	U/l	28	23	33	CK-NAC substrate start (DGKC) 25°C
	U/l	84	69	99	Vitros 37°C
	U/l	66	54	78	CK-NAC serum start (DGKC) 37°C
	U/l	41	34	48	CK-NAC serum start (DGKC) 30°C
	U/l	28	23	33	CK-NAC serum start (DGKC) 25°C
	U/l	65	53	77	CK-NAC (IFCC) 37°C
	U/l	41	33	49	CK-NAC (IFCC) 30°C
	U/l	28	23	33	CK-NAC (IFCC) 25°C
	U/l	53	43	63	Dithioerythritol 37°C
	U/l	33	27	39	Dithioerythritol 30°C
	U/l	23	18	28	Dithioerythritol 25°C
	U/l	69	57	81	Monothioglycerol 37°C
	U/l	43	36	50	Monothioglycerol 30°C
	U/l	29	24	34	Monothioglycerol 25°C
CK-MB Mass	ng/ml = µg/l	3.71	2.97	4.45	Siemens Dimension
	ng/ml = µg/l	6.52	5.22	7.82	Siemens Advia Centaur
	ng/ml = µg/l	6.66	5.33	7.99	Roche Elecsys Modular E170 Cobas 6000
	ng/ml = µg/l	6.18	4.94	7.42	Abbott AXSYM
	ng/ml = µg/l	6.68	5.34	8.02	Beckman Coulter Access
	ng/ml = µg/l	5.10	4.08	6.12	Ortho Vitros ECi
	ng/ml = µg/l	8.73	6.98	10.5	bioMerieux Vidas
	ng/ml = µg/l	7.33	5.86	8.80	Tosoh
	ng/ml = µg/l	5.24	4.19	6.29	Abbott Architect
Homocysteine	umol/l	10.5	8.40	12.6	Siemens Immulite 2000/2500
	umol/l	11.6	9.28	13.9	Abbott AXSYM
Myoglobin	ng/ml = µg/l	48.7	39.0	58.4	Roche Elecsys
	ng/ml = µg/l	43.9	35.1	52.7	Siemens Dimension
	ng/ml = µg/l	32.1	25.7	38.5	Beckman Coulter Access
	ng/ml = µg/l	93.2	74.6	112	Roche Cardiac Reader
	ng/ml = µg/l	50.0	40.0	60.0	Roche Integra
	ng/ml = µg/l	34.0	27.2	40.8	bioMerieux Vidas
	ng/ml = µg/l	38.9	31.1	46.7	Tosoh
	ng/ml = µg/l	62.7	50.2	75.2	Abbott Architect
	ng/ml = µg/l	63.0	50.4	75.6	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.141	0.113	0.169	Abbott AXSYM
	ng/ml = µg/l	0.181	0.145	0.217	Siemens Dimension
	ng/ml = µg/l	0.114	0.091	0.137	Beckman Coulter Access
	ng/ml = µg/l	0.289	0.231	0.347	Siemens Immulite 2000
	ng/ml = µg/l	0.337	0.270	0.404	Siemens Advia Centaur
	ng/ml = µg/l	0.270	0.216	0.324	Ortho Vitros ECi

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CARDIAC CONTROL LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3259 Lot. No. 3083CK Size 1 x 2ml Expiry 2014-06

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
Troponin I	ng/ml = µg/l	0.271	0.217	0.325	bioMerieux Vidas
	ng/ml = µg/l	0.147	0.118	0.176	Abbott Axsym ADV
	ng/ml = µg/l	0.119	0.095	0.143	Diasorin Liaison
	ng/ml = µg/l	0.467	0.374	0.560	Abbott Architect
	ng/ml = µg/l	0.291	0.233	0.349	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.127	0.102	0.152	Beckman DXi800 1st gen
Troponin T	ng/ml = µg/l	0.049	0.039	0.059	Roche Cobas TroponinT
	ng/ml = µg/l	0.085	0.068	0.102	Roche Cobas Troponin T HS

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CARDIAC CONTROL LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot. No. 3084CK Size 1 x 2ml Expiry 2014-06

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
CK Total	U/l	250	205	295	CK-NAC substrate start (DGKC) 37°C
	U/l	157	128	186	CK-NAC substrate start (DGKC) 30°C
	U/l	106	87	125	CK-NAC substrate start (DGKC) 25°C
	U/l	302	248	356	Vitros 37°C
	U/l	246	202	290	CK-NAC serum start (DGKC) 37°C
	U/l	154	126	182	CK-NAC serum start (DGKC) 30°C
	U/l	105	86	124	CK-NAC serum start (DGKC) 25°C
	U/l	248	203	293	CK-NAC (IFCC) 37°C
	U/l	155	127	183	CK-NAC (IFCC) 30°C
	U/l	105	86	124	CK-NAC (IFCC) 25°C
	U/l	218	179	257	Dithioerythritol 37°C
	U/l	136	112	160	Dithioerythritol 30°C
	U/l	93	76	110	Dithioerythritol 25°C
	U/l	268	220	316	Monothioglycerol 37°C
	U/l	168	138	198	Monothioglycerol 30°C
	U/l	114	94	134	Monothioglycerol 25°C
CK-MB Activity	U/l	9.23	7.38	11.1	Vitros 37°C
	U/l	15.7	11.8	19.6	Immunoinhibition substrate start 37°C
	U/l	9.12	6.84	11.4	Immunoinhibition substrate start 30°C
	U/l	5.57	4.18	6.96	Immunoinhibition substrate start 25°C
	U/l	16.0	12.0	20.0	Immunoinhibition serum start 37°C
	U/l	8.78	6.59	11.0	Immunoinhibition serum start 30°C
	U/l	5.36	4.02	6.70	Immunoinhibition serum start 25°C
	U/l	16.2	13.0	19.4	Immunoinhibition (IFCC) 37°C
	U/l	9.42	7.56	11.3	Immunoinhibition (IFCC) 30°C
	U/l	5.75	4.62	6.88	Immunoinhibition (IFCC) 25°C
	U/l	14.6	11.7	17.5	Randox Immunoinhibition substrate start 37°C
	U/l	8.49	6.80	10.2	Randox Immunoinhibition substrate start 30°C
	U/l	5.18	4.15	6.21	Randox Immunoinhibition substrate start 25°C
	U/l	13.4	10.7	16.1	Randox Immunoinhibition serum start 37°C
	U/l	7.79	6.22	9.36	Randox Immunoinhibition serum start 30°C
	U/l	4.76	3.80	5.72	Randox Immunoinhibition serum start 25°C
CK-MB Mass	ng/ml = µg/l	13.7	11.0	16.4	Siemens Dimension
	ng/ml = µg/l	17.2	13.8	20.6	Siemens Advia Centaur
	ng/ml = µg/l	15.4	12.3	18.5	Roche Elecsys Modular E170 Cobas 6000
	ng/ml = µg/l	19.4	15.5	23.3	Abbott AXSYM
	ng/ml = µg/l	19.5	15.6	23.4	Beckman Coulter Access
	ng/ml = µg/l	13.7	11.0	16.4	Ortho Vitros ECi
	ng/ml = µg/l	23.9	19.1	28.7	bioMerieux Vidas
	ng/ml = µg/l	15.6	12.5	18.7	Abbott Architect
	ng/ml = µg/l	19.5	15.6	23.4	Beckman DxI800
Homocysteine	umol/l	18.7	15.0	22.4	Siemens Immulite 2000/2500

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CARDIAC CONTROL LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot. No. 3084CK Size 1 x 2ml Expiry 2014-06

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
Homocysteine	umol/l	19.9	15.9	23.9	Abbott AXSYM
Myoglobin	ng/ml = µg/l	139	111	167	Roche Elecsys
	ng/ml = µg/l	153	122	184	Siemens Dimension
	ng/ml = µg/l	101	80.8	121	Beckman Coulter Access
	ng/ml = µg/l	130	104	156	Roche Integra
	ng/ml = µg/l	140	112	168	Tosoh
	ng/ml = µg/l	196	157	235	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.759	0.607	0.911	Abbott AXSYM
	ng/ml = µg/l	0.724	0.579	0.869	Siemens Dimension
	ng/ml = µg/l	0.483	0.386	0.580	Beckman Coulter Access
	ng/ml = µg/l	1.73	1.38	2.08	Siemens Advia Centaur
	ng/ml = µg/l	1.90	1.52	2.28	Ortho Vitros ECi
	ng/ml = µg/l	0.992	0.794	1.19	bioMerieux Vidas
	ng/ml = µg/l	3.47	2.78	4.16	Tosoh
	ng/ml = µg/l	0.733	0.586	0.880	Abbott Axsym ADV
	ng/ml = µg/l	0.479	0.383	0.575	Diasorin Liaison
	ng/ml = µg/l	2.22	1.78	2.66	Abbott Architect
	ng/ml = µg/l	0.991	0.793	1.19	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.485	0.388	0.582	Beckman DXi800 1st gen
Troponin T	ng/ml = µg/l	0.168	0.134	0.202	Roche Cobas TroponinT
	ng/ml = µg/l	0.228	0.182	0.274	Roche Cobas Troponin T HS

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CARDIAC CONTROL LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot. No. 3085CK Size 1 x 2ml Expiry 2014-06

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
CK Total	U/l	597	490	704	CK-NAC substrate start (DGKC) 37°C
	U/l	374	307	441	CK-NAC substrate start (DGKC) 30°C
	U/l	254	208	300	CK-NAC substrate start (DGKC) 25°C
	U/l	732	600	864	Vitros 37°C
	U/l	588	482	694	CK-NAC serum start (DGKC) 37°C
	U/l	368	302	434	CK-NAC serum start (DGKC) 30°C
	U/l	250	205	295	CK-NAC serum start (DGKC) 25°C
	U/l	583	478	688	CK-NAC (IFCC) 37°C
	U/l	365	299	431	CK-NAC (IFCC) 30°C
	U/l	248	203	293	CK-NAC (IFCC) 25°C
	U/l	524	430	618	Dithioerythritol 37°C
	U/l	328	269	387	Dithioerythritol 30°C
	U/l	223	183	263	Dithioerythritol 25°C
	U/l	599	491	707	Monothioglycerol 37°C
	U/l	375	307	443	Monothioglycerol 30°C
	U/l	255	209	301	Monothioglycerol 25°C
CK-MB Activity	U/l	110	88.0	132	Vitros 37°C
	U/l	116	92.8	139	Immunoinhibition substrate start 37°C
	U/l	67.4	53.9	80.9	Immunoinhibition substrate start 30°C
	U/l	41.2	32.9	49.5	Immunoinhibition substrate start 25°C
	U/l	109	87.2	131	Immunoinhibition serum start 37°C
	U/l	63.4	50.7	76.1	Immunoinhibition serum start 30°C
	U/l	38.7	31.0	46.4	Immunoinhibition serum start 25°C
	U/l	123	98.4	148	Immunoinhibition (IFCC) 37°C
	U/l	71.5	57.2	85.8	Immunoinhibition (IFCC) 30°C
	U/l	43.7	34.9	52.5	Immunoinhibition (IFCC) 25°C
	U/l	116	92.8	139	Randox Immunoinhibition substrate start 37°C
	U/l	67.4	53.9	80.9	Randox Immunoinhibition substrate start 30°C
	U/l	41.2	32.9	49.5	Randox Immunoinhibition substrate start 25°C
	U/l	114	91.2	137	Randox Immunoinhibition serum start 37°C
	U/l	66.3	53.0	79.6	Randox Immunoinhibition serum start 30°C
	U/l	40.5	32.4	48.6	Randox Immunoinhibition serum start 25°C
CK-MB Mass	ng/ml = µg/l	171	137	205	Siemens Dimension
	ng/ml = µg/l	171	137	205	Siemens Advia Centaur
	ng/ml = µg/l	137	110	164	Roche Elecsys Modular E170 Cobas 6000
	ng/ml = µg/l	180	144	216	Abbott AXSYM
	ng/ml = µg/l	212	170	254	Beckman Coulter Access
	ng/ml = µg/l	201	161	241	Siemens Stratus
	ng/ml = µg/l	139	111	167	Ortho Vitros ECi
	ng/ml = µg/l	208	166	250	bioMerieux Vidas
	ng/ml = µg/l	227	182	272	Tosoh
	ng/ml = µg/l	157	126	188	Abbott Architect

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CARDIAC CONTROL LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot. No. 3085CK Size 1 x 2ml Expiry 2014-06

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	207	166	248	Beckman DxI800
Homocysteine	umol/l	38.6	30.9	46.3	Siemens Immulite 2000/2500
	umol/l	36.4	29.1	43.7	Abbott AXSYM
	umol/l	36.8	30.5	43.1	Abbott Architect
Myoglobin	ng/ml = µg/l	237	190	284	Roche Elecsys
	ng/ml = µg/l	303	242	364	Siemens Dimension
	ng/ml = µg/l	247	198	296	Siemens Stratus
	ng/ml = µg/l	180	144	216	Beckman Coulter Access
	ng/ml = µg/l	316	253	379	Abbott AXSYM
	ng/ml = µg/l	467	374	560	Roche Cardiac Reader
	ng/ml = µg/l	228	182	274	Roche Integra
	ng/ml = µg/l	292	234	350	Siemens Advia Centaur
	ng/ml = µg/l	250	200	300	Tosoh
	ng/ml = µg/l	408	326	490	Abbott Architect
	ng/ml = µg/l	183	146	220	Beckman DxI800
	ng/ml = µg/l	356	285	427	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	5.24	4.19	6.29	Abbott AXSYM
	ng/ml = µg/l	3.17	2.54	3.80	Siemens Dimension
	ng/ml = µg/l	3.60	2.88	4.32	Siemens Stratus
	ng/ml = µg/l	2.78	2.22	3.34	Beckman Coulter Access
	ng/ml = µg/l	7.62	6.10	9.14	Siemens Immulite 2000
	ng/ml = µg/l	13.6	10.9	16.3	Siemens Advia Centaur
	ng/ml = µg/l	19.3	15.4	23.2	Ortho Vitros ECi
	ng/ml = µg/l	4.64	3.71	5.57	bioMerieux Vidas
	ng/ml = µg/l	24.0	19.2	28.8	Tosoh
	ng/ml = µg/l	4.78	3.82	5.74	Abbott Axsym ADV
	ng/ml = µg/l	2.98	2.38	3.58	Diasorin Liaison
	ng/ml = µg/l	14.4	11.5	17.3	Abbott Architect
	ng/ml = µg/l	5.15	4.12	6.18	Biomerieux Vidas Ultra
	ng/ml = µg/l	3.04	2.43	3.65	Beckman DXi800 1st gen
Troponin T	ng/ml = µg/l	0.616	0.493	0.739	Roche Cobas TroponinT
	ng/ml = µg/l	0.642	0.514	0.770	Roche Cobas Troponin T HS

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