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

CAT. NO. CQ3100 **LOT NOS.** 3524CK, 3526CK, 3529CK
SIZE: 3 x 1ml **EXPIRY:** 2017-05

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 levels 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°C to +8°C). Reconstituted serum is stable for 5 days at +2°C to +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°C to +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 +15°C to +25°C. Close the 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 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. 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 Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com

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CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3100 Lot No. 3524CK Size: 3 x 1ml Expiry: 2017-05

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
CK Total	U/l	73	60	86	CK-NAC substrate start (DGKC) 37°C
	U/l	46	38	54	CK-NAC substrate start (DGKC) 30°C
	U/l	31	26	36	CK-NAC substrate start (DGKC) 25°C
	U/l	104	85	123	Vitros 37°C
	U/l	75	62	89	CK-NAC serum start (DGKC) 37°C
	U/l	47	39	55	CK-NAC serum start (DGKC) 30°C
	U/l	32	26	38	CK-NAC serum start (DGKC) 25°C
	U/l	79	65	93	CK-NAC (IFCC) 37°C
	U/l	49	41	57	CK-NAC (IFCC) 30°C
	U/l	34	28	40	CK-NAC (IFCC) 25°C
	U/l	75	62	89	Monothioglycerol 37°C
	U/l	47	39	55	Monothioglycerol 30°C
	U/l	32	26	38	Monothioglycerol 25°C
	U/l	78	64	92	Dithioerythritol (DTE) IFCC correlated 37°C
	U/l	49	40	58	Dithioerythritol (DTE) IFCC correlated 30°C
	U/l	33	27	39	Dithioerythritol (DTE) IFCC correlated 25°C
CK-MB Mass	ng/ml = µg/l	4.20	3.36	5.04	Siemens Dimension
	ng/ml = µg/l	5.81	4.65	6.97	Siemens Centaur XP/Classic
	ng/ml = µg/l	5.52	4.42	6.62	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	6.51	5.21	7.81	Beckman Coulter Access
	ng/ml = µg/l	4.71	3.77	5.65	Ortho Vitros ECi
	ng/ml = µg/l	7.83	6.26	9.40	BioMerieux Vidas
	ng/ml = µg/l	5.14	4.11	6.17	Abbott Architect
	ng/ml = µg/l	6.70	5.36	8.04	Beckman DxI800
Homocysteine	µmol/l	12.2	9.76	14.6	Siemens Immulite 2000/2500
	µmol/l	11.4	9.12	13.7	Abbott AXSYM
	µmol/l	11.1	8.88	13.3	Abbott Architect
	µmol/l	14.9	11.9	17.9	Enzymatic
Myoglobin	ng/ml = µg/l	55.8	44.6	67.0	Roche Elecsys
	ng/ml = µg/l	36.7	29.4	44.0	Beckman Coulter Access
	ng/ml = µg/l	64.8	51.8	77.8	Abbott Architect
	ng/ml = µg/l	23.5	18.8	28.2	Biosite Triage Meter Plus
	ng/ml = µg/l	72.0	57.6	86.4	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.139	0.111	0.167	Beckman Coulter Access
	ng/ml = µg/l	0.298	0.238	0.358	Siemens Centaur XP/Classic
	ng/ml = µg/l	0.420	0.336	0.504	Ortho Vitros ECi
	ng/ml = µg/l	0.330	0.264	0.396	BioMerieux Vidas
	ng/ml = µg/l	0.977	0.782	1.17	Tosoh AIA360
	ng/ml = µg/l	0.612	0.490	0.734	Abbott Architect
	ng/ml = µg/l	0.348	0.278	0.418	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.166	0.133	0.199	Beckman DXi800 1st gen
	ng/ml = µg/l	0.477	0.382	0.572	Abbott i STAT

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CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3100 Lot No. 3524CK Size: 3 x 1ml Expiry: 2017-05

		Range			
Analyte	**unit**	**target**	**low**	**high**	**methods**
Troponin I	ng/ml = µg/l	0.281	0.225	0.337	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.251	0.201	0.301	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	0.140	0.112	0.168	Mitsubushi Chemical Pathfast
Troponin T	µg/l	0.047	0.035	0.059	Roche Cobas TroponinT
	µg/l	0.050	0.038	0.063	Roche Cardiac Reader
	µg/l	0.048	0.036	0.060	Roche Cobas Troponin T HS
	µg/l	0.050	0.038	0.063	Roche h232

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CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3100 Lot No. 3526CK Size: 3 x 1ml Expiry: 2017-05

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
CK Total	U/l	225	185	266	CK-NAC substrate start (DGKC) 37°C
	U/l	141	116	166	CK-NAC substrate start (DGKC) 30°C
	U/l	96	79	113	CK-NAC substrate start (DGKC) 25°C
	U/l	291	239	343	Vitros 37°C
	U/l	218	179	257	CK-NAC serum start (DGKC) 37°C
	U/l	136	112	160	CK-NAC serum start (DGKC) 30°C
	U/l	93	76	110	CK-NAC serum start (DGKC) 25°C
	U/l	224	184	264	CK-NAC (IFCC) 37°C
	U/l	140	115	165	CK-NAC (IFCC) 30°C
	U/l	95	78	112	CK-NAC (IFCC) 25°C
	U/l	220	180	260	Monothioglycerol 37°C
	U/l	138	113	163	Monothioglycerol 30°C
	U/l	94	77	111	Monothioglycerol 25°C
	U/l	238	195	281	Dithioerythritol (DTE) IFCC correlated 37°C
	U/l	149	122	176	Dithioerythritol (DTE) IFCC correlated 30°C
	U/l	101	83	119	Dithioerythritol (DTE) IFCC correlated 25°C
CK-MB Activity	U/l	21.6	17.3	25.9	Vitros 37°C
	U/l	20.9	16.7	25.1	Immunoinhibition substrate start 37°C
	U/l	12.1	9.71	14.5	Immunoinhibition substrate start 30°C
	U/l	7.42	5.93	8.91	Immunoinhibition substrate start 25°C
	U/l	22.2	17.8	26.6	Immunoinhibition serum start 37°C
	U/l	12.9	10.3	15.5	Immunoinhibition serum start 30°C
	U/l	7.88	6.32	9.44	Immunoinhibition serum start 25°C
	U/l	22.7	18.2	27.2	Immunoinhibition (IFCC) 37°C
	U/l	13.2	10.6	15.8	Immunoinhibition (IFCC) 30°C
	U/l	8.06	6.46	9.66	Immunoinhibition (IFCC) 25°C
	U/l	22.2	17.8	26.6	Randox Immunoinhibition substrate start 37°C
	U/l	12.9	10.3	15.5	Randox Immunoinhibition substrate start 30°C
	U/l	7.88	6.32	9.44	Randox Immunoinhibition substrate start 25°C
	U/l	22.2	17.8	26.6	Randox Immunoinhibition serum start 37°C
	U/l	12.9	10.3	15.5	Randox Immunoinhibition serum start 30°C
	U/l	7.88	6.32	9.44	Randox Immunoinhibition serum start 25°C
CK-MB Mass	ng/ml = µg/l	21.6	17.3	25.9	Siemens Dimension
	ng/ml = µg/l	22.7	18.2	27.2	Siemens Centaur XP/Classic
	ng/ml = µg/l	20.4	16.3	24.5	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	28.1	22.5	33.7	Beckman Coulter Access
	ng/ml = µg/l	20.0	16.0	24.0	Ortho Vitros ECi
	ng/ml = µg/l	32.9	26.3	39.5	BioMerieux Vidas
	ng/ml = µg/l	31.9	25.5	38.3	Tosoh AIA360
	ng/ml = µg/l	20.5	16.4	24.6	Abbott Architect
	ng/ml = µg/l	29.5	23.6	35.4	Beckman DxI800
Homocysteine	µmol/l	17.4	13.9	20.9	Siemens Immulite 2000/2500

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CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3100 Lot No. 3526CK Size: 3 x 1ml Expiry: 2017-05

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
Homocysteine	µmol/l	19.2	15.4	23.0	Abbott AXSYM
	µmol/l	18.6	14.9	22.3	Abbott Architect
	µmol/l	21.6	17.3	25.9	Enzymatic
Myoglobin	ng/ml = µg/l	164	131	197	Roche Elecsys
	ng/ml = µg/l	103	82.4	124	Beckman Coulter Access
	ng/ml = µg/l	121	96.8	145	Tosoh AIA360
	ng/ml = µg/l	188	150	226	Abbott Architect
	ng/ml = µg/l	111	88.8	133	Beckman DxI800
	ng/ml = µg/l	198	158	238	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.557	0.446	0.668	Siemens Dimension
	ng/ml = µg/l	0.652	0.522	0.782	Beckman Coulter Access
	ng/ml = µg/l	2.03	1.62	2.44	Siemens Centaur XP/Classic
	ng/ml = µg/l	3.34	2.67	4.01	Ortho Vitros ECi
	ng/ml = µg/l	1.35	1.08	1.62	BioMerieux Vidas
	ng/ml = µg/l	5.83	4.66	7.00	Tosoh AIA360
	ng/ml = µg/l	3.30	2.64	3.96	Abbott Architect
	ng/ml = µg/l	1.42	1.14	1.70	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.793	0.634	0.952	Beckman DXi800 1st gen
	ng/ml = µg/l	3.17	2.54	3.80	Abbott i STAT
	ng/ml = µg/l	0.969	0.775	1.16	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	1.03	0.824	1.24	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	0.848	0.678	1.02	Mitsubushi Chemical Pathfast
Troponin T	µg/l	0.393	0.295	0.491	Roche Cobas TroponinT
	µg/l	0.146	0.110	0.183	Roche Cardiac Reader
	µg/l	0.378	0.284	0.473	Roche Cobas Troponin T HS
	µg/l	0.177	0.133	0.221	Roche h232

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CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3100 Lot No. 3529CK Size: 3 x 1ml Expiry: 2017-05

			Range		
Analyte	**unit**	**target**	**low**	**high**	**methods**
CK Total	U/l	522	428	616	CK-NAC substrate start (DGKC) 37°C
	U/l	327	268	386	CK-NAC substrate start (DGKC) 30°C
	U/l	222	182	262	CK-NAC substrate start (DGKC) 25°C
	U/l	743	609	877	Vitros 37°C
	U/l	547	449	645	CK-NAC serum start (DGKC) 37°C
	U/l	342	281	403	CK-NAC serum start (DGKC) 30°C
	U/l	232	191	273	CK-NAC serum start (DGKC) 25°C
	U/l	551	452	650	CK-NAC (IFCC) 37°C
	U/l	345	283	407	CK-NAC (IFCC) 30°C
	U/l	234	192	276	CK-NAC (IFCC) 25°C
	U/l	544	446	642	Monothioglycerol 37°C
	U/l	341	279	403	Monothioglycerol 30°C
	U/l	231	190	272	Monothioglycerol 25°C
	U/l	575	472	679	Dithioerythritol (DTE) IFCC correlated 37°C
	U/l	360	295	425	Dithioerythritol (DTE) IFCC correlated 30°C
	U/l	244	201	287	Dithioerythritol (DTE) IFCC correlated 25°C
CK-MB Activity	U/l	132	106	158	Vitros 37°C
	U/l	135	108	162	Immunoinhibition substrate start 37°C
	U/l	78.5	62.8	94.2	Immunoinhibition substrate start 30°C
	U/l	47.9	38.3	57.5	Immunoinhibition substrate start 25°C
	U/l	128	102	154	Immunoinhibition serum start 37°C
	U/l	74.4	59.3	89.5	Immunoinhibition serum start 30°C
	U/l	45.4	36.2	54.6	Immunoinhibition serum start 25°C
	U/l	133	106	160	Immunoinhibition (IFCC) 37°C
	U/l	77.3	61.6	93.0	Immunoinhibition (IFCC) 30°C
	U/l	47.2	37.6	56.8	Immunoinhibition (IFCC) 25°C
	U/l	128	102	154	Randox Immunoinhibition substrate start 37°C
	U/l	74.4	59.3	89.5	Randox Immunoinhibition substrate start 30°C
	U/l	45.4	36.2	54.7	Randox Immunoinhibition substrate start 25°C
	U/l	129	103	155	Randox Immunoinhibition serum start 37°C
	U/l	75.0	59.9	90.1	Randox Immunoinhibition serum start 30°C
	U/l	45.8	36.6	55.0	Randox Immunoinhibition serum start 25°C
CK-MB Mass	ng/ml = µg/l	173	138	208	Siemens Dimension
	ng/ml = µg/l	190	152	228	Siemens Centaur XP/Classic
	ng/ml = µg/l	155	124	186	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	222	178	266	Beckman Coulter Access
	ng/ml = µg/l	136	109	163	Ortho Vitros ECi
	ng/ml = µg/l	217	174	260	BioMerieux Vidas
	ng/ml = µg/l	224	179	269	Tosoh AIA360
	ng/ml = µg/l	148	118	178	Abbott Architect
	ng/ml = µg/l	224	179	269	Beckman DxI800
Homocysteine	µmol/l	36.4	29.1	43.7	Siemens Immulite 2000/2500

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CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3100 Lot No. 3529CK Size: 3 x 1ml Expiry: 2017-05

		Range			
Analyte	**unit**	**target**	**low**	**high**	**methods**
Homocysteine	µmol/l	35.8	28.6	43.0	Abbott AXSYM
	µmol/l	35.5	28.4	42.6	Abbott Architect
	µmol/l	37.3	29.8	44.8	Enzymatic
Myoglobin	ng/ml = µg/l	281	225	337	Roche Elecsys
	ng/ml = µg/l	191	153	229	Beckman Coulter Access
	ng/ml = µg/l	216	173	259	Tosoh AIA360
	ng/ml = µg/l	322	258	386	Abbott Architect
	ng/ml = µg/l	181	145	217	Beckman DxI800
	ng/ml = µg/l	108	86.4	130	Biosite Triage Meter Plus
	ng/ml = µg/l	360	288	432	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	2.43	1.94	2.92	Siemens Dimension
	ng/ml = µg/l	3.92	3.14	4.70	Beckman Coulter Access
	ng/ml = µg/l	15.5	12.4	18.6	Siemens Centaur XP/Classic
	ng/ml = µg/l	26.7	21.4	32.0	Ortho Vitros ECi
	ng/ml = µg/l	7.08	5.66	8.50	BioMerieux Vidas
	ng/ml = µg/l	30.0	24.0	36.0	Tosoh AIA360
	ng/ml = µg/l	19.8	15.8	23.8	Abbott Architect
	ng/ml = µg/l	7.61	6.09	9.13	Biomerieux Vidas Ultra
	ng/ml = µg/l	4.76	3.81	5.71	Beckman DXi800 1st gen
	ng/ml = µg/l	4.05	3.24	4.86	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	4.59	3.67	5.51	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	6.07	4.86	7.28	Mitsubushi Chemical Pathfast
Troponin T	µg/l	1.150	0.863	1.440	Roche Cobas TroponinT
	µg/l	1.040	0.780	1.300	Roche Cobas Troponin T HS
	µg/l	0.378	0.284	0.473	Roche h232