

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

CAT. NO. CQ3259 **LOT NOS.** 3768CK, 3769CK, 3770CK
SIZE: 3 x 2 ml **EXPIRY:** 2019-01

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 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 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 2 ml of redistilled water at +15 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 2 ml
	Level 2	1 x 2 ml
	Level 3	1 x 2 ml

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 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. CQ3259 Lot No. 3768CK Size: 1 x 2 ml Expiry: 2019-01

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	97	80	114	CK-NAC substrate start (DGKC) 37°C
	U/l	61	50	72	CK-NAC substrate start (DGKC) 30°C
	U/l	41	34	48	CK-NAC substrate start (DGKC) 25°C
	U/l	128	105	151	Vitros 37°C
	U/l	96	79	113	CK-NAC serum start (DGKC) 37°C
	U/l	60	49	71	CK-NAC serum start (DGKC) 30°C
	U/l	41	34	48	CK-NAC serum start (DGKC) 25°C
	U/l	97	80	114	CK-NAC (IFCC) 37°C
	U/l	61	50	72	CK-NAC (IFCC) 30°C
	U/l	41	34	48	CK-NAC (IFCC) 25°C
	U/l	97	80	114	Monothioglycerol 37°C
	U/l	61	50	72	Monothioglycerol 30°C
	U/l	41	34	48	Monothioglycerol 25°C
CK-MB Mass	ng/ml = µg/l	4.37	3.50	5.24	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	4.20	3.36	5.04	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	4.74	3.79	5.69	Beckman Coulter Access
	ng/ml = µg/l	3.40	2.72	4.08	Ortho Vitros ECI
	ng/ml = µg/l	3.74	2.99	4.49	Abbott Architect
	ng/ml = µg/l	2.65	2.12	3.18	Roche h232
Homocysteine	µmol/l	11.9	9.52	14.3	Siemens Immulite 2000/2500
	µmol/l	11.1	8.88	13.3	Abbott Architect
	µmol/l	14.3	11.4	17.2	Enzymatic
Myoglobin	ng/ml = µg/l	48.7	39.0	58.4	Roche Elecsys
	ng/ml = µg/l	37.3	29.8	44.8	Beckman Coulter Access
	ng/ml = µg/l	41.0	32.8	49.2	BioMerieux Vidas
	ng/ml = µg/l	63.5	50.8	76.2	Abbott Architect
	ng/ml = µg/l	39.0	31.2	46.8	Beckman Dxl800
	ng/ml = µg/l	72.1	57.7	86.5	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.299	0.239	0.359	Beckman Coulter Access
	ng/ml = µg/l	0.553	0.442	0.664	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.942	0.754	1.13	Ortho Vitros ECI
	ng/ml = µg/l	0.780	0.624	0.936	BioMerieux Vidas
	ng/ml = µg/l	1.33	1.06	1.60	Abbott Architect
	ng/ml = µg/l	0.782	0.626	0.938	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.224	0.179	0.269	Beckman DXi800 1st gen
	ng/ml = µg/l	0.380	0.304	0.456	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.175	0.140	0.210	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	0.287	0.230	0.344	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.551	0.441	0.661	Abbott Architect STAT hs
	ng/ml = µg/l	0.226	0.181	0.271	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	0.310	0.248	0.372	Beckman Access - A78803
	ng/ml = µg/l	0.289	0.231	0.347	Beckman Access - AccuTnl+3

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CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3259 Lot No. 3768CK Size: 1 x 2 ml Expiry: 2019-01

Range

Analyte	unit	Target	low	high	methods
Troponin T	µg/l	0.028	0.021	0.035	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. CQ3259 Lot No. 3769CK Size: 1 x 2 ml Expiry: 2019-01

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	267	219	315	CK-NAC substrate start (DGKC) 37°C
	U/l	167	137	197	CK-NAC substrate start (DGKC) 30°C
	U/l	113	93	133	CK-NAC substrate start (DGKC) 25°C
	U/l	372	305	439	Vitros 37°C
	U/l	280	230	330	CK-NAC serum start (DGKC) 37°C
	U/l	175	144	206	CK-NAC serum start (DGKC) 30°C
	U/l	119	98	140	CK-NAC serum start (DGKC) 25°C
	U/l	279	229	329	CK-NAC (IFCC) 37°C
	U/l	175	143	207	CK-NAC (IFCC) 30°C
	U/l	119	97	141	CK-NAC (IFCC) 25°C
	U/l	280	230	330	Monothioglycerol 37°C
	U/l	175	144	206	Monothioglycerol 30°C
	U/l	119	98	140	Monothioglycerol 25°C
CK-MB Activity	U/l	14.9	11.9	17.9	Vitros 37°C
	U/l	23.4	18.7	28.1	Immunoinhibition substrate start 37°C
	U/l	13.6	10.9	16.3	Immunoinhibition substrate start 30°C
	U/l	8.31	6.64	9.98	Immunoinhibition substrate start 25°C
	U/l	25.9	20.7	31.1	Immunoinhibition serum start 37°C
	U/l	15.1	12.0	18.2	Immunoinhibition serum start 30°C
	U/l	9.19	7.35	11.0	Immunoinhibition serum start 25°C
	U/l	25.9	20.7	31.1	Immunoinhibition (IFCC) 37°C
	U/l	15.1	12.0	18.2	Immunoinhibition (IFCC) 30°C
	U/l	9.19	7.35	11.0	Immunoinhibition (IFCC) 25°C
	U/l	27.0	21.6	32.3	Randox Immunoinhibition substrate start 37°C
	U/l	15.7	12.6	18.8	Randox Immunoinhibition substrate start 30°C
	U/l	9.57	7.67	11.5	Randox Immunoinhibition substrate start 25°C
	U/l	25.7	20.6	30.8	Randox Immunoinhibition serum start 37°C
	U/l	14.9	12.0	17.9	Randox Immunoinhibition serum start 30°C
	U/l	9.12	7.31	10.9	Randox Immunoinhibition serum start 25°C
CK-MB Mass	ng/ml = µg/l	16.8	13.4	20.2	Siemens Dimension
	ng/ml = µg/l	18.2	14.6	21.8	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	15.5	12.4	18.6	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	20.3	16.2	24.4	Beckman Coulter Access
	ng/ml = µg/l	13.9	11.1	16.7	Ortho Vitros Eci
	ng/ml = µg/l	24.2	19.4	29.0	BioMerieux Vidas
	ng/ml = µg/l	15.6	12.5	18.7	Abbott Architect
	ng/ml = µg/l	10.5	8.40	12.6	Roche h232
Homocysteine	µmol/l	18.9	15.1	22.7	Siemens Immulite 2000/2500
	µmol/l	18.1	14.5	21.7	Abbott Architect
	µmol/l	21.3	17.0	25.6	Enzymatic
Myoglobin	ng/ml = µg/l	134	107	161	Roche Elecsys
	ng/ml = µg/l	109	87.2	131	Beckman Coulter Access

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CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot No. 3769CK Size: 1 x 2 ml Expiry: 2019-01

Range					
Analyte	unit	Target	low	high	methods
Myoglobin	ng/ml = µg/l	120	96.0	144	BioMerieux Vidas
	ng/ml = µg/l	187	150	224	Abbott Architect
	ng/ml = µg/l	196	157	235	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	2.03	1.62	2.44	Beckman Coulter Access
	ng/ml = µg/l	3.43	2.74	4.12	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	5.55	4.44	6.66	Ortho Vitros ECI
	ng/ml = µg/l	2.38	1.90	2.86	BioMerieux Vidas
	ng/ml = µg/l	6.95	5.56	8.34	Abbott Architect
	ng/ml = µg/l	2.47	1.98	2.96	Biomerieux Vidas Ultra
	ng/ml = µg/l	1.56	1.25	1.87	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.539	0.431	0.647	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	1.70	1.36	2.04	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	1.38	1.10	1.66	Siemens Dimension Exl LOCI
	ng/ml = µg/l	3.20	2.56	3.84	Abbott Architect STAT hs
	ng/ml = µg/l	1.73	1.38	2.08	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	1.97	1.58	2.36	Beckman Access - A78803
	ng/ml = µg/l	2.00	1.60	2.40	Beckman Access - AccuTnl+3
	ng/ml = µg/l	2.84	2.27	3.41	Siemens Centaur CP
Troponin T	µg/l	0.377	0.283	0.471	Roche Cobas Troponin T HS
	µg/l	0.189	0.142	0.236	Roche h232

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CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot No. 3770CK Size: 1 x 2 ml Expiry: 2019-01

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	641	526	756	CK-NAC substrate start (DGKC) 37°C
	U/l	401	329	473	CK-NAC substrate start (DGKC) 30°C
	U/l	272	224	320	CK-NAC substrate start (DGKC) 25°C
	U/l	827	678	976	Vitros 37°C
	U/l	650	533	767	CK-NAC serum start (DGKC) 37°C
	U/l	407	334	480	CK-NAC serum start (DGKC) 30°C
	U/l	276	227	325	CK-NAC serum start (DGKC) 25°C
	U/l	639	524	754	CK-NAC (IFCC) 37°C
	U/l	400	328	472	CK-NAC (IFCC) 30°C
	U/l	272	223	321	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	107	85.6	128	Vitros 37°C
	U/l	127	102	152	Immunoinhibition substrate start 37°C
	U/l	73.8	59.3	88.3	Immunoinhibition substrate start 30°C
	U/l	45.1	36.2	54.0	Immunoinhibition substrate start 25°C
	U/l	129	103	155	Immunoinhibition serum start 37°C
	U/l	75.0	59.9	90.1	Immunoinhibition serum start 30°C
	U/l	45.8	36.6	55.0	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	130	104	156	Randox Immunoinhibition serum start 37°C
	U/l	75.6	60.4	90.7	Randox Immunoinhibition serum start 30°C
	U/l	46.2	36.9	55.4	Randox Immunoinhibition serum start 25°C
	U/l	127	102	152	Randox Immunoinhibition substrate start 37°C
	U/l	73.8	59.3	88.3	Randox Immunoinhibition substrate start 30°C
	U/l	45.1	36.2	54.0	Randox Immunoinhibition substrate start 25°C
CK-MB Mass	ng/ml = µg/l	110	88.0	132	Siemens Dimension
	ng/ml = µg/l	130	104	156	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	97.9	78.3	117	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	142	114	170	Beckman Coulter Access
	ng/ml = µg/l	89.2	71.4	107	Ortho Vitros ECI
	ng/ml = µg/l	129	103	155	BioMerieux Vidas
	ng/ml = µg/l	104	83.2	125	Abbott Architect
Homocysteine	µmol/l	36.7	29.4	44.0	Abbott Architect
	µmol/l	38.9	31.1	46.7	Enzymatic
Myoglobin	ng/ml = µg/l	194	155	233	Roche Elecsys
	ng/ml = µg/l	154	123	185	Beckman Coulter Access
	ng/ml = µg/l	168	134	202	BioMerieux Vidas
	ng/ml = µg/l	272	218	326	Abbott Architect
	ng/ml = µg/l	152	122	182	Beckman Dxl800
	ng/ml = µg/l	297	238	356	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	9.59	7.67	11.5	Beckman Coulter Access

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CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot No. 3770CK Size: 1 x 2 ml Expiry: 2019-01

Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	22.0	17.6	26.4	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	34.4	27.5	41.3	Ortho Vitros ECI
	ng/ml = µg/l	9.77	7.82	11.7	BioMerieux Vidas
	ng/ml = µg/l	34.0	27.2	40.8	Abbott Architect
	ng/ml = µg/l	10.0	8.00	12.0	Biomerieux Vidas Ultra
	ng/ml = µg/l	8.34	6.67	10.0	Beckman DXi800 1st gen
	ng/ml = µg/l	6.45	5.16	7.74	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	2.13	1.70	2.56	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	9.12	7.30	10.9	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	6.34	5.07	7.61	Siemens Dimension Exl LOCI
	ng/ml = µg/l	12.5	10.0	15.0	Abbott Architect STAT hs
	ng/ml = µg/l	8.87	7.10	10.6	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	9.75	7.80	11.7	Beckman Access - A78803
	ng/ml = µg/l	9.44	7.55	11.3	Beckman Access - AccuTnl+3
	ng/ml = µg/l	19.2	15.4	23.0	Siemens Centaur CP
Troponin T	µg/l	0.849	0.637	1.060	Roche Cobas Troponin T HS
	µg/l	0.359	0.269	0.449	Roche h232