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

CAT NO. CQ3100
SIZE: 3 x 1 ml
GTIN: 05055273201840

LOT NOS. 4013CK, 4015CK, 4018CK
EXPIRY: 2020-07-28

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, CK-MB 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 1 ml 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 1 ml
	Level 2	1 x 1 ml
	Level 3	1 x 1 ml

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. 4013CK Size: 1 x 1 ml Expiry: 2020-07-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK Total	U/l	65	53	77	CK-NAC substrate start (DGKC) 37°C
	U/l	41	33	49	CK-NAC substrate start (DGKC) 30°C
	U/l	28	23	33	CK-NAC substrate start (DGKC) 25°C
	U/l	81	66	96	Vitros 37°C
	U/l	66	54	78	CK-NAC (IFCC) 37°C
	U/l	41	34	48	CK-NAC (IFCC) 30°C
	U/l	28	23	33	CK-NAC (IFCC) 25°C
	U/l	67	55	79	Monothioglycerol 37°C
	U/l	42	34	50	Monothioglycerol 30°C
	U/l	28	23	33	Monothioglycerol 25°C
	U/l	60	49	71	CK-NAC serum start (DGKC) 37°C
	U/l	38	31	44	CK-NAC serum start (DGKC) 30°C
	U/l	26	21	30	CK-NAC serum start (DGKC) 25°C
CK-MB Mass	ng/ml = µg/l	3.63	2.90	4.36	Siemens Dimension
	ng/ml = µg/l	6.21	4.97	7.45	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	4.78	3.82	5.74	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	5.81	4.65	6.97	Beckman Coulter Access
	ng/ml = µg/l	4.10	3.28	4.92	Ortho Vitros ECi
	ng/ml = µg/l	7.31	5.85	8.77	BioMerieux Vidas
	ng/ml = µg/l	4.47	3.58	5.36	Abbott Architect
	ng/ml = µg/l	6.34	5.07	7.61	Beckman DxI800
	ng/ml = µg/l	1.18	0.944	1.42	Biosite Triage Meter Plus
Homocysteine	µmol/l	11.8	9.44	14.2	Siemens Immulite 2000/2500
	µmol/l	10.4	8.32	12.5	Abbott Architect
	µmol/l	6.18	4.94	7.42	Siemens/Dade Behring Nephelometer
	µmol/l	14.1	11.3	16.9	Roche Cobas 6000/8000
	µmol/l	13.5	10.8	16.2	Enzymatic
Myoglobin	ng/ml = µg/l	43.7	35.0	52.4	Roche Elecsys
	ng/ml = µg/l	34.9	27.9	41.9	Beckman Coulter Access
	ng/ml = µg/l	36.5	29.2	43.8	BioMerieux Vidas
	ng/ml = µg/l	60.6	48.5	72.7	Abbott Architect
	ng/ml = µg/l	22.2	17.8	26.6	Biosite Triage Meter Plus
	ng/ml = µg/l	70.2	56.2	84.2	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.778	0.622	0.934	Siemens Immulite 1000
	ng/ml = µg/l	0.902	0.722	1.08	Siemens Immulite 2000
	ng/ml = µg/l	0.654	0.523	0.785	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	1.41	1.13	1.69	Ortho Vitros ECi
	ng/ml = µg/l	0.740	0.592	0.888	BioMerieux Vidas
	ng/ml = µg/l	2.18	1.74	2.62	Tosoh AIA360
	ng/ml = µg/l	0.703	0.562	0.844	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.174	0.139	0.209	Beckman DXi800 1st gen
	ng/ml = µg/l	0.157	0.126	0.188	Roche Elecsys/E170/c6000/e411

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CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3100 Lot No. 4013CK Size: 1 x 1 ml Expiry: 2020-07-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Troponin I	ng/ml = µg/l	0.268	0.214	0.322	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.212	0.170	0.254	Siemens Dimension ExI LOCI
	ng/ml = µg/l	0.412	0.330	0.494	Abbott Architect STAT hs
	ng/ml = µg/l	0.167	0.134	0.200	Beckman DxI - AccuTnI+3
	ng/ml = µg/l	0.202	0.162	0.242	Beckman Access - A78803
	ng/ml = µg/l	0.195	0.156	0.234	Beckman Access - AccuTnI+3
	ng/ml = µg/l	0.485	0.388	0.582	Siemens Centaur CP
Troponin T	µg/l	0.062	0.047	0.078	Roche Cobas Troponin T HS
	µg/l	0.054	0.041	0.068	Roche h232
	µg/l	0.062	0.047	0.078	Roche Cobas Troponin T hs STAT

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CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3100 Lot No. 4015CK Size: 1 x 1 ml Expiry: 2020-07-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK Total	U/l	217	178	256	CK-NAC substrate start (DGKC) 37°C
	U/l	136	111	161	CK-NAC substrate start (DGKC) 30°C
	U/l	92	76	108	CK-NAC substrate start (DGKC) 25°C
	U/l	286	235	337	Vitros 37°C
	U/l	217	178	256	CK-NAC (IFCC) 37°C
	U/l	136	111	161	CK-NAC (IFCC) 30°C
	U/l	92	76	108	CK-NAC (IFCC) 25°C
	U/l	230	189	271	Monothioglycerol 37°C
	U/l	144	118	170	Monothioglycerol 30°C
	U/l	98	80	116	Monothioglycerol 25°C
	U/l	200	164	236	CK-NAC serum start (DGKC) 37°C
	U/l	125	103	148	CK-NAC serum start (DGKC) 30°C
	U/l	85	70	100	CK-NAC serum start (DGKC) 25°C
CK-MB Activity	U/l	10.8	8.64	13.0	Vitros 37°C
	U/l	24.6	19.7	29.5	Immunoinhibition substrate start 37°C
	U/l	14.3	11.4	17.2	Immunoinhibition substrate start 30°C
	U/l	8.73	6.99	10.5	Immunoinhibition substrate start 25°C
	U/l	22.6	18.1	27.1	Immunoinhibition serum start 37°C
	U/l	13.1	10.5	15.7	Immunoinhibition serum start 30°C
	U/l	8.02	6.43	9.61	Immunoinhibition serum start 25°C
	U/l	23.0	18.4	27.6	Immunoinhibition (IFCC) 37°C
	U/l	13.4	10.7	16.1	Immunoinhibition (IFCC) 30°C
	U/l	8.17	6.53	9.81	Immunoinhibition (IFCC) 25°C
	U/l	23.3	18.6	28.0	Randox Immunoinhibition serum start 37°C
	U/l	13.5	10.8	16.3	Randox Immunoinhibition serum start 30°C
	U/l	8.27	6.60	9.94	Randox Immunoinhibition serum start 25°C
	U/l	24.2	19.4	29.0	Randox Immunoinhibition substrate start 37°C
	U/l	14.1	11.3	16.9	Randox Immunoinhibition substrate start 30°C
	U/l	8.59	6.89	10.3	Randox Immunoinhibition substrate start 25°C
CK-MB Mass	ng/ml = µg/l	15.7	12.6	18.8	Siemens Dimension
	ng/ml = µg/l	20.9	16.7	25.1	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	16.4	13.1	19.7	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	22.6	18.1	27.1	Beckman Coulter Access
	ng/ml = µg/l	15.5	12.4	18.6	Ortho Vitros ECi
	ng/ml = µg/l	24.7	19.8	29.6	BioMerieux Vidas
	ng/ml = µg/l	16.6	13.3	19.9	Abbott Architect
	ng/ml = µg/l	23.4	18.7	28.1	Beckman DxI800
	ng/ml = µg/l	3.88	3.10	4.66	Biosite Triage Meter Plus
Homocysteine	µmol/l	19.1	15.3	22.9	Siemens Immulite 2000/2500
	µmol/l	16.8	13.4	20.2	Abbott Architect
	µmol/l	28.0	22.4	33.6	Roche Cobas 6000/8000
	µmol/l	21.6	17.3	25.9	Enzymatic

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CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3100 Lot No. 4015CK Size: 1 x 1 ml Expiry: 2020-07-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Myoglobin	ng/ml = µg/l	124	99.0	149	Roche Elecsys
	ng/ml = µg/l	159	127	191	Siemens Dimension
	ng/ml = µg/l	102	81.6	122	Beckman Coulter Access
	ng/ml = µg/l	115	92.0	138	BioMerieux Vidas
	ng/ml = µg/l	185	148	222	Abbott Architect
	ng/ml = µg/l	106	84.8	127	Beckman DxI800
	ng/ml = µg/l	68.2	54.6	81.8	Biosite Triage Meter Plus
	ng/ml = µg/l	200	160	240	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.590	0.472	0.708	Siemens Stratus CS
	ng/ml = µg/l	2.88	2.30	3.46	Siemens Immulite 1000
	ng/ml = µg/l	3.31	2.65	3.97	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	7.21	5.77	8.65	Ortho Vitros ECi
	ng/ml = µg/l	2.57	2.06	3.08	BioMerieux Vidas
	ng/ml = µg/l	2.52	2.02	3.02	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.765	0.612	0.918	Beckman DXi800 1st gen
	ng/ml = µg/l	0.493	0.394	0.592	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	1.47	1.18	1.76	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.692	0.554	0.830	Siemens Dimension Exl LOCI
	ng/ml = µg/l	1.38	1.10	1.66	Abbott Architect STAT hs
	ng/ml = µg/l	0.748	0.598	0.898	Beckman DxI - AccuTnI+3
	ng/ml = µg/l	0.829	0.663	0.995	Beckman Access - A78803
	ng/ml = µg/l	0.791	0.633	0.949	Beckman Access - AccuTnI+3
	ng/ml = µg/l	2.66	2.13	3.19	Siemens Centaur CP
Troponin T	µg/l	0.633	0.475	0.791	Roche Cobas Troponin T HS
	µg/l	0.376	0.282	0.470	Roche h232
	µg/l	0.641	0.481	0.801	Roche Cobas Troponin T hs STAT

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CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3100 Lot No. 4018CK Size: 1 x 1 ml Expiry: 2020-07-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK Total	U/l	593	486	700	CK-NAC substrate start (DGKC) 37°C
	U/l	371	304	438	CK-NAC substrate start (DGKC) 30°C
	U/l	252	207	297	CK-NAC substrate start (DGKC) 25°C
	U/l	737	604	870	Vitros 37°C
	U/l	531	435	627	CK-NAC serum start (DGKC) 37°C
	U/l	332	272	392	CK-NAC serum start (DGKC) 30°C
	U/l	226	185	267	CK-NAC serum start (DGKC) 25°C
	U/l	587	481	693	CK-NAC (IFCC) 37°C
	U/l	367	301	433	CK-NAC (IFCC) 30°C
	U/l	249	204	294	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	118	94.4	142	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	124	99.0	149	Immunoinhibition serum start 37°C
	U/l	72.1	57.5	86.7	Immunoinhibition serum start 30°C
	U/l	44.0	35.1	52.9	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	120	96.0	144	Randox Immunoinhibition serum start 37°C
	U/l	69.7	55.8	83.7	Randox Immunoinhibition serum start 30°C
	U/l	42.6	34.1	51.1	Randox Immunoinhibition serum start 25°C
	U/l	119	95.2	143	Randox Immunoinhibition substrate start 37°C
	U/l	69.2	55.3	83.1	Randox Immunoinhibition substrate start 30°C
	U/l	42.2	33.8	50.8	Randox Immunoinhibition substrate start 25°C
CK-MB Mass	ng/ml = µg/l	139	111	167	Siemens Dimension
	ng/ml = µg/l	162	130	194	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	118	94.4	142	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	173	138	208	Beckman Coulter Access
	ng/ml = µg/l	107	85.6	128	Ortho Vitros ECi
	ng/ml = µg/l	162	130	194	BioMerieux Vidas
	ng/ml = µg/l	122	97.6	146	Abbott Architect
	ng/ml = µg/l	29.7	23.8	35.6	Biosite Triage Meter Plus
Homocysteine	µmol/l	42.1	33.7	50.5	Siemens Immulite 2000/2500
	µmol/l	35.7	28.6	42.8	Abbott Architect
	µmol/l	13.6	10.9	16.3	Siemens/Dade Behring Nephelometer
	µmol/l	55.4	44.3	66.5	Roche Cobas 6000/8000
	µmol/l	39.5	31.6	47.4	Enzymatic
Myoglobin	ng/ml = µg/l	213	170	256	Roche Elecsys
	ng/ml = µg/l	289	231	347	Siemens Dimension
	ng/ml = µg/l	181	145	217	Beckman Coulter Access

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CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3100 Lot No. 4018CK Size: 1 x 1 ml Expiry: 2020-07-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Myoglobin	ng/ml = µg/l	193	154	232	BioMerieux Vidas
	ng/ml = µg/l	329	263	395	Abbott Architect
	ng/ml = µg/l	181	145	217	Beckman DxI800
	ng/ml = µg/l	111	88.8	133	Biosite Triage Meter Plus
	ng/ml = µg/l	354	283	425	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	2.87	2.30	3.44	Siemens Stratus CS
	ng/ml = µg/l	14.1	11.3	16.9	Siemens Immulite 1000
	ng/ml = µg/l	18.1	14.5	21.7	Siemens Immulite 2000
	ng/ml = µg/l	25.3	20.2	30.4	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	37.2	29.8	44.6	Ortho Vitros ECi
	ng/ml = µg/l	11.3	9.04	13.6	BioMerieux Vidas
	ng/ml = µg/l	40.3	32.2	48.4	Tosoh AIA360
	ng/ml = µg/l	10.4	8.32	12.5	Biomerieux Vidas Ultra
	ng/ml = µg/l	5.14	4.11	6.17	Beckman DXi800 1st gen
	ng/ml = µg/l	1.75	1.40	2.10	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	8.78	7.02	10.5	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	2.88	2.30	3.46	Siemens Dimension Exl LOCI
	ng/ml = µg/l	6.07	4.86	7.28	Abbott Architect STAT hs
	ng/ml = µg/l	4.77	3.82	5.72	Beckman DxI - AccuTnI+3
	ng/ml = µg/l	5.12	4.10	6.14	Beckman Access - A78803
	ng/ml = µg/l	4.97	3.98	5.96	Beckman Access - AccuTnI+3
	ng/ml = µg/l	17.9	14.3	21.5	Siemens Centaur CP
Troponin T	µg/l	1.360	1.020	1.700	Roche Cobas Troponin T HS
	µg/l	0.801	0.601	1.000	Roche h232
	µg/l	1.350	1.010	1.690	Roche Cobas Troponin T hs STAT