

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

CAT NO. CQ3100

LOT NOS. 3611CK, 3613CK, 3616CK

SIZE: 3 x 1 ml

EXPIRY: 2017-12

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 the 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. 3611CK Size: 1 x 1 ml Expiry: 2017-12

Range					
Analyte	unit	target	low	high	methods
CK Total	U/l	76	62	90	CK-NAC substrate start (DGKC) 37°C
	U/l	48	39	57	CK-NAC substrate start (DGKC) 30°C
	U/l	32	26	38	CK-NAC substrate start (DGKC) 25°C
	U/l	111	91	131	Vitros 37°C
	U/l	81	66	96	CK-NAC (IFCC) 37°C
	U/l	51	41	61	CK-NAC (IFCC) 30°C
	U/l	34	28	40	CK-NAC (IFCC) 25°C
	U/l	77	63	91	CK-NAC serum start (DGKC) 37°C
	U/l	48	39	57	CK-NAC serum start (DGKC) 30°C
	U/l	33	27	39	CK-NAC serum start (DGKC) 25°C
	U/l	80	66	94	Monothioglycerol 37°C
	U/l	50	41	59	Monothioglycerol 30°C
	U/l	34	28	40	Monothioglycerol 25°C
CK-MB Mass	ng/ml = µg/l	4.69	3.75	5.63	Siemens Centaur XP/Classic
	ng/ml = µg/l	4.42	3.54	5.30	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	5.24	4.19	6.29	Beckman Coulter Access
	ng/ml = µg/l	3.82	3.06	4.58	Ortho Vitros ECI
	ng/ml = µg/l	7.16	5.67	8.65	BioMerieux Vidas
	ng/ml = µg/l	4.16	3.30	5.02	Abbott Architect
	ng/ml = µg/l	5.45	4.36	6.54	Beckman Dxl800
	ng/ml = µg/l	1.10	0.990	1.21	Biosite Triage Meter Plus
Homocysteine	µmol/l	10.8	8.64	13.0	Siemens Immulite 2000/2500
	µmol/l	11.4	9.12	13.7	Abbott AXSYM
	µmol/l	11.2	8.96	13.4	Abbott Architect
	µmol/l	14.9	11.9	17.9	Enzymatic
Myoglobin	ng/ml = µg/l	62.2	49.8	74.6	Roche Elecsys
	ng/ml = µg/l	40.7	32.6	48.8	Beckman Coulter Access
	ng/ml = µg/l	48.7	39.0	58.4	Roche Hitachi
	ng/ml = µg/l	47.0	37.6	56.4	BioMerieux Vidas
	ng/ml = µg/l	62.3	49.8	74.8	Abbott Architect
	ng/ml = µg/l	74.6	59.7	89.5	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.099	0.079	0.119	Beckman Coulter Access
	ng/ml = µg/l	0.379	0.303	0.455	Siemens Centaur XP/Classic
	ng/ml = µg/l	0.835	0.668	1.00	Ortho Vitros ECI
	ng/ml = µg/l	0.606	0.485	0.727	BioMerieux Vidas
	ng/ml = µg/l	1.54	1.23	1.85	Tosoh AIA360
	ng/ml = µg/l	1.01	0.808	1.21	Abbott Architect
	ng/ml = µg/l	0.573	0.458	0.688	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.200	0.160	0.240	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	0.169	0.135	0.203	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.092	0.074	0.110	Beckman Access - A78803
	ng/ml = µg/l	0.105	0.084	0.126	Beckman Access - AccuTnl+3

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CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3100 Lot No. 3611CK Size: 1 x 1 ml Expiry: 2017-12

Range

Analyte	unit	target	low	high	methods
Troponin T	µg/l	0.030	0.023	0.038	Roche Cardiac Reader
	µg/l	0.041	0.031	0.051	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. 3613CK Size: 1 x 1 ml Expiry: 2017-12

Range					
Analyte	unit	target	low	high	methods
CK Total	U/l	247	203	291	CK-NAC substrate start (DGKC) 37°C
	U/l	155	127	183	CK-NAC substrate start (DGKC) 30°C
	U/l	105	86	124	CK-NAC substrate start (DGKC) 25°C
	U/l	310	254	366	Vitros 37°C
	U/l	224	184	264	CK-NAC serum start (DGKC) 37°C
	U/l	140	115	165	CK-NAC serum start (DGKC) 30°C
	U/l	95	78	112	CK-NAC serum start (DGKC) 25°C
	U/l	235	193	277	CK-NAC (IFCC) 37°C
	U/l	147	121	173	CK-NAC (IFCC) 30°C
	U/l	100	82	118	CK-NAC (IFCC) 25°C
	U/l	234	192	276	Monothioglycerol 37°C
	U/l	146	120	172	Monothioglycerol 30°C
	U/l	99	82	116	Monothioglycerol 25°C
CK-MB Activity	U/l	20.2	14.1	26.3	Vitros 37°C
	U/l	20.9	16.4	25.5	Immunoinhibition substrate start 37°C
	U/l	12.1	9.53	14.7	Immunoinhibition substrate start 30°C
	U/l	7.42	5.82	9.02	Immunoinhibition substrate start 25°C
	U/l	21.9	17.5	26.3	Immunoinhibition serum start 37°C
	U/l	12.7	10.2	15.2	Immunoinhibition serum start 30°C
	U/l	7.77	6.21	9.33	Immunoinhibition serum start 25°C
	U/l	21.4	17.1	25.7	Immunoinhibition (IFCC) 37°C
	U/l	12.4	9.94	14.9	Immunoinhibition (IFCC) 30°C
	U/l	7.60	6.07	9.13	Immunoinhibition (IFCC) 25°C
	U/l	22.0	17.6	26.4	Randox Immunoinhibition serum start 37°C
	U/l	12.8	10.2	15.4	Randox Immunoinhibition serum start 30°C
	U/l	7.81	6.25	9.37	Randox Immunoinhibition serum start 25°C
	U/l	21.1	16.9	25.3	Randox Immunoinhibition substrate start 37°C
	U/l	12.3	9.82	14.8	Randox Immunoinhibition substrate start 30°C
	U/l	7.49	6.00	8.98	Randox Immunoinhibition substrate start 25°C
CK-MB Mass	ng/ml = µg/l	18.2	14.6	21.8	Siemens Dimension
	ng/ml = µg/l	20.1	15.1	25.1	Siemens Centaur XP/Classic
	ng/ml = µg/l	18.3	14.6	22.0	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	26.4	21.1	31.7	Beckman Coulter Access
	ng/ml = µg/l	17.4	13.9	20.9	Ortho Vitros Eci
	ng/ml = µg/l	30.1	24.1	36.1	BioMerieux Vidas
	ng/ml = µg/l	18.6	14.9	22.3	Abbott Architect
	ng/ml = µg/l	27.3	21.8	32.8	Beckman Dxl800
	ng/ml = µg/l	4.94	3.95	5.93	Biosite Triage Meter Plus
Homocysteine	µmol/l	19.9	14.7	25.1	Siemens Immulite 2000/2500
	µmol/l	19.1	15.3	22.9	Abbott Architect
	µmol/l	22.8	18.2	27.4	Enzymatic
Myoglobin	ng/ml = µg/l	168	134	202	Roche Elecsys

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CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3100 Lot No. 3613CK Size: 1 x 1 ml Expiry: 2017-12

Range					
Analyte	unit	target	low	high	methods
Myoglobin	ng/ml = µg/l	106	84.8	127	Beckman Coulter Access
	ng/ml = µg/l	131	105	157	BioMerieux Vidas
	ng/ml = µg/l	185	148	222	Abbott Architect
	ng/ml = µg/l	70.0	56.0	84.0	Biosite Triage Meter Plus
	ng/ml = µg/l	205	164	246	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.465	0.372	0.558	Beckman Coulter Access
	ng/ml = µg/l	2.16	1.57	2.75	Siemens Centaur XP/Classic
	ng/ml = µg/l	5.96	4.77	7.15	Ortho Vitros ECI
	ng/ml = µg/l	2.50	2.00	3.00	BioMerieux Vidas
	ng/ml = µg/l	4.73	3.78	5.68	Abbott Architect
	ng/ml = µg/l	2.47	1.98	2.96	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.450	0.360	0.540	Beckman DXi800 1st gen
	ng/ml = µg/l	0.670	0.536	0.804	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	1.05	0.840	1.26	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.470	0.376	0.564	Beckman Access - A78803
	ng/ml = µg/l	0.470	0.376	0.564	Beckman Access - AccuTnl+3
Troponin T	µg/l	0.427	0.320	0.534	Roche Cobas Troponin T HS
	µg/l	0.219	0.164	0.274	Roche h232

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CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3100 Lot No. 3616CK Size: 1 x 1 ml Expiry: 2017-12

Range					
Analyte	unit	target	low	high	methods
CK Total	U/l	641	513	769	CK-NAC substrate start (DGKC) 37°C
	U/l	401	321	481	CK-NAC substrate start (DGKC) 30°C
	U/l	272	218	326	CK-NAC substrate start (DGKC) 25°C
	U/l	821	673	969	Vitros 37°C
	U/l	625	513	738	CK-NAC (IFCC) 37°C
	U/l	391	321	461	CK-NAC (IFCC) 30°C
	U/l	266	218	314	CK-NAC (IFCC) 25°C
	U/l	615	504	726	Monothioglycerol 37°C
	U/l	385	316	454	Monothioglycerol 30°C
	U/l	261	214	308	Monothioglycerol 25°C
	U/l	624	512	736	CK-NAC serum start (DGKC) 37°C
	U/l	391	321	461	CK-NAC serum start (DGKC) 30°C
	U/l	265	218	313	CK-NAC serum start (DGKC) 25°C
CK-MB Activity	U/l	127	102	152	Vitros 37°C
	U/l	126	101	151	Immunoinhibition substrate start 37°C
	U/l	73.2	58.7	87.7	Immunoinhibition substrate start 30°C
	U/l	44.7	35.9	53.5	Immunoinhibition substrate start 25°C
	U/l	131	105	157	Immunoinhibition serum start 37°C
	U/l	76.1	61.0	91.2	Immunoinhibition serum start 30°C
	U/l	46.5	37.3	55.7	Immunoinhibition serum start 25°C
	U/l	127	102	152	Immunoinhibition (IFCC) 37°C
	U/l	73.8	59.3	88.3	Immunoinhibition (IFCC) 30°C
	U/l	45.1	36.2	54.0	Immunoinhibition (IFCC) 25°C
	U/l	125	100	150	Randox Immunoinhibition serum start 37°C
	U/l	72.7	58.1	87.3	Randox Immunoinhibition serum start 30°C
	U/l	44.4	35.5	53.3	Randox Immunoinhibition serum start 25°C
	U/l	124	99.2	149	Randox Immunoinhibition substrate start 37°C
	U/l	72.1	57.7	86.6	Randox Immunoinhibition substrate start 30°C
	U/l	44.0	35.2	52.9	Randox Immunoinhibition substrate start 25°C
CK-MB Mass	ng/ml = µg/l	159	127	191	Siemens Dimension
	ng/ml = µg/l	142	114	170	Siemens Centaur XP/Classic
	ng/ml = µg/l	130	104	156	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	197	158	236	Beckman Coulter Access
	ng/ml = µg/l	116	92.8	139	Ortho Vitros ECI
	ng/ml = µg/l	188	150	226	BioMerieux Vidas
	ng/ml = µg/l	140	112	168	Abbott Architect
	ng/ml = µg/l	205	164	246	Beckman Dxl800
	ng/ml = µg/l	42.1	33.7	50.5	Biosite Triage Meter Plus
Homocysteine	µmol/l	40.4	31.1	49.7	Abbott AXSYM
	µmol/l	37.2	29.8	44.6	Abbott Architect
	µmol/l	40.0	32.0	48.0	Enzymatic
Myoglobin	ng/ml = µg/l	286	229	343	Roche Elecsys

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CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3100 Lot No. 3616CK Size: 1 x 1 ml Expiry: 2017-12

Range					
Analyte	unit	target	low	high	methods
Myoglobin	ng/ml = µg/l	185	148	222	Beckman Coulter Access
	ng/ml = µg/l	204	163	245	Roche Hitachi
	ng/ml = µg/l	219	175	263	BioMerieux Vidas
	ng/ml = µg/l	315	252	378	Abbott Architect
	ng/ml = µg/l	94.8	74.4	115	Biosite Triage Meter Plus
	ng/ml = µg/l	370	296	444	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	2.05	1.64	2.46	Beckman Coulter Access
	ng/ml = µg/l	13.3	10.6	16.0	Siemens Centaur XP/Classic
	ng/ml = µg/l	31.8	25.4	38.2	Ortho Vitros ECI
	ng/ml = µg/l	10.5	8.40	12.6	BioMerieux Vidas
	ng/ml = µg/l	34.4	27.5	41.3	Tosoh AIA360
	ng/ml = µg/l	22.3	17.8	26.8	Abbott Architect
	ng/ml = µg/l	9.84	7.80	11.9	Biomerieux Vidas Ultra
	ng/ml = µg/l	1.97	1.58	2.36	Beckman DXi800 1st gen
	ng/ml = µg/l	2.46	1.84	3.08	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	5.26	4.21	6.31	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	2.08	1.66	2.50	Beckman Access - A78803
	ng/ml = µg/l	2.07	1.66	2.48	Beckman Access - AccuTnl+3
Troponin T	µg/l	0.553	0.415	0.691	Roche Cardiac Reader
	µg/l	1.010	0.712	1.310	Roche Cobas Troponin T HS