

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

CAT. NO. CQ3259 **LOT NOS.** 3452CK, 3453CK, 3454CK
SIZE: 3 x 2 ml **EXPIRY:** 2016-12

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 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 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°C 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 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. 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: +44 (0) 28 9442 2413 or email Technical.Support@randox.com

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CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3259 Lot No. 3452CK Size: 1 x 2 ml Expiry: 2016-12

Range					
Analyte	unit	target	low	high	methods
CK Total	U/l	71	58	84	CK-NAC substrate start (DGKC) 37°C
	U/l	44	36	52	CK-NAC substrate start (DGKC) 30°C
	U/l	30	25	35	CK-NAC substrate start (DGKC) 25°C
	U/l	105	86	124	Vitros 37°C
	U/l	72	59	85	CK-NAC serum start (DGKC) 37°C
	U/l	45	37	53	CK-NAC serum start (DGKC) 30°C
	U/l	31	25	37	CK-NAC serum start (DGKC) 25°C
	U/l	75	62	89	CK-NAC (IFCC) 37°C
	U/l	47	39	55	CK-NAC (IFCC) 30°C
	U/l	32	26	38	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	74	61	87	Dithioerythritol (DTE) IFCC correlated 37°C
	U/l	46	38	54	Dithioerythritol (DTE) IFCC correlated 30°C
	U/l	31	26	36	Dithioerythritol (DTE) IFCC correlated 25°C
CK-MB Mass	ng/ml = µg/l	4.50	3.28	5.72	Siemens Dimension
	ng/ml = µg/l	6.90	5.43	8.37	Siemens Advia Centaur
	ng/ml = µg/l	6.38	5.00	7.76	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	8.16	6.53	9.79	Beckman Coulter Access
	ng/ml = µg/l	5.90	4.72	7.08	Ortho Vitros ECI
	ng/ml = µg/l	10.1	8.08	12.1	BioMerieux Vidas
	ng/ml = µg/l	8.30	6.64	9.96	Tosoh AIA360
	ng/ml = µg/l	5.81	4.65	6.97	Abbott Architect
	ng/ml = µg/l	7.45	5.96	8.94	Beckman Dxl800
	ng/ml = µg/l	2.00	1.60	2.40	Biosite Triage Meter Plus
Homocysteine	µmol/l	11.2	8.96	13.4	Siemens Immulite 2000/2500
	µmol/l	11.2	8.48	13.9	Abbott AXSYM
	µmol/l	10.9	8.56	13.2	Abbott Architect
Myoglobin	ng/ml = µg/l	56.0	44.8	67.2	Roche Elecsys
	ng/ml = µg/l	37.1	29.7	44.5	Beckman Coulter Access
	ng/ml = µg/l	40.5	32.4	48.6	BioMerieux Vidas
	ng/ml = µg/l	36.7	29.4	44.0	Tosoh AIA360
	ng/ml = µg/l	60.3	48.2	72.4	Abbott Architect
	ng/ml = µg/l	35.1	28.1	42.1	Beckman Dxl800
	ng/ml = µg/l	26.8	21.4	32.2	Biosite Triage Meter Plus
	ng/ml = µg/l	68.0	54.4	81.6	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.156	0.117	0.195	Beckman Coulter Access
	ng/ml = µg/l	0.468	0.374	0.562	Siemens Advia Centaur
	ng/ml = µg/l	1.23	0.984	1.48	Ortho Vitros ECI
	ng/ml = µg/l	0.670	0.536	0.804	BioMerieux Vidas
	ng/ml = µg/l	2.07	1.47	2.67	Tosoh AIA360

CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3259 Lot No. 3452CK Size: 1 x 2 ml Expiry: 2016-12

Range					
Analyte	unit	target	low	high	methods
Troponin I	ng/ml = µg/l	1.29	1.03	1.55	Abbott Architect
	ng/ml = µg/l	0.710	0.568	0.852	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.250	0.200	0.300	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.289	0.221	0.357	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	0.286	0.226	0.346	Mitsubishi Chemical Pathfast
Troponin T	µg/l	0.054	0.043	0.065	Roche Modular E170/Roche Cobas c501 Troponin T HS
	µg/l	0.057	0.046	0.068	Roche Elecsys/Roche Cobas e411 Troponin T HS
	µg/l	0.053	0.042	0.064	Roche Cobas TroponinT

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot No. 3453CK Size: 1 x 2 ml Expiry: 2016-12

Range					
Analyte	unit	target	low	high	methods
CK Total	U/l	222	182	262	CK-NAC substrate start (DGKC) 37°C
	U/l	139	114	164	CK-NAC substrate start (DGKC) 30°C
	U/l	94	77	111	CK-NAC substrate start (DGKC) 25°C
	U/l	329	270	388	Vitros 37°C
	U/l	234	192	276	CK-NAC serum start (DGKC) 37°C
	U/l	146	120	172	CK-NAC serum start (DGKC) 30°C
	U/l	99	82	116	CK-NAC serum start (DGKC) 25°C
	U/l	239	196	282	CK-NAC (IFCC) 37°C
	U/l	150	123	177	CK-NAC (IFCC) 30°C
	U/l	102	83	121	CK-NAC (IFCC) 25°C
	U/l	242	198	286	Monothioglycerol 37°C
	U/l	151	124	178	Monothioglycerol 30°C
	U/l	103	84	122	Monothioglycerol 25°C
	U/l	241	198	284	Dithioerythritol (DTE) IFCC correlated 37°C
	U/l	151	124	178	Dithioerythritol (DTE) IFCC correlated 30°C
	U/l	102	84	120	Dithioerythritol (DTE) IFCC correlated 25°C
CK-MB Activity	U/l	17.3	12.6	22.1	Vitros 37°C
	U/l	19.9	15.9	23.9	Immunoinhibition substrate start 37°C
	U/l	11.6	9.24	14.0	Immunoinhibition substrate start 30°C
	U/l	7.06	5.64	8.48	Immunoinhibition substrate start 25°C
	U/l	21.1	15.9	26.4	Immunoinhibition serum start 37°C
	U/l	12.3	9.24	15.4	Immunoinhibition serum start 30°C
	U/l	7.49	5.64	9.34	Immunoinhibition serum start 25°C
	U/l	19.8	15.8	23.8	Randox Immunoinhibition serum start 37°C
	U/l	11.5	9.18	13.8	Randox Immunoinhibition serum start 30°C
	U/l	7.03	5.61	8.45	Randox Immunoinhibition serum start 25°C
	U/l	19.6	15.7	23.5	Randox Immunoinhibition substrate start 37°C
	U/l	11.4	9.12	13.7	Randox Immunoinhibition substrate start 30°C
	U/l	6.96	5.57	8.34	Randox Immunoinhibition substrate start 25°C
	U/l	20.6	16.0	25.2	Immunoinhibition (IFCC) 37°C
	U/l	12.0	9.30	14.7	Immunoinhibition (IFCC) 30°C
	U/l	7.31	5.68	8.94	Immunoinhibition (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	20.8	16.6	25.0	Siemens Dimension
	ng/ml = µg/l	21.2	17.0	25.4	Siemens Advia Centaur
	ng/ml = µg/l	19.0	15.2	22.8	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	27.9	22.3	33.5	Beckman Coulter Access
	ng/ml = µg/l	18.2	14.6	21.8	Ortho Vitros ECI
	ng/ml = µg/l	33.4	26.7	40.1	BioMerieux Vidas
	ng/ml = µg/l	29.7	23.8	35.6	Tosoh AIA360
	ng/ml = µg/l	18.9	15.1	22.7	Abbott Architect
	ng/ml = µg/l	27.2	21.8	32.6	Beckman DxI800
	ng/ml = µg/l	6.95	5.56	8.34	Biosite Triage Meter Plus

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot No. 3453CK Size: 1 x 2 ml Expiry: 2016-12

Range					
Analyte	unit	target	low	high	methods
Homocysteine	μmol/l	20.3	16.2	24.4	Siemens Immulite 2000/2500
	μmol/l	18.7	15.0	22.4	Abbott AXSYM
	μmol/l	19.0	15.2	22.8	Abbott Architect
Myoglobin	ng/ml = μg/l	168	134	202	Roche Elecsys
	ng/ml = μg/l	112	89.6	134	Beckman Coulter Access
	ng/ml = μg/l	133	106	160	BioMerieux Vidas
	ng/ml = μg/l	128	102	154	Tosoh AIA360
	ng/ml = μg/l	201	161	241	Abbott Architect
	ng/ml = μg/l	112	89.6	134	Beckman Dxl800
	ng/ml = μg/l	74.0	59.2	88.8	Biosite Triage Meter Plus
	ng/ml = μg/l	206	165	247	Randox Immunoturbidimetric
Troponin I	ng/ml = μg/l	0.315	0.252	0.378	Siemens Dimension
	ng/ml = μg/l	0.410	0.328	0.492	Siemens Stratus
	ng/ml = μg/l	0.570	0.456	0.684	Beckman Coulter Access
	ng/ml = μg/l	2.02	1.62	2.42	Siemens Advia Centaur
	ng/ml = μg/l	5.34	4.27	6.41	Ortho Vitros ECI
	ng/ml = μg/l	2.12	1.70	2.54	BioMerieux Vidas
	ng/ml = μg/l	7.40	5.65	9.15	Tosoh AIA360
	ng/ml = μg/l	4.71	3.77	5.65	Abbott Architect
	ng/ml = μg/l	2.34	1.87	2.81	Biomerieux Vidas Ultra
	ng/ml = μg/l	0.684	0.547	0.821	Siemens/Dade Dimension EXL/Vista
	ng/ml = μg/l	0.682	0.497	0.867	Roche Elecsys/E170/c6000/e411
	ng/ml = μg/l	1.28	0.971	1.59	Mitsubishi Chemical Pathfast
Troponin T	μg/l	0.420	0.336	0.504	Roche Modular E170/Roche Cobas c501 Troponin T HS
	μg/l	0.424	0.339	0.509	Roche Elecsys/Roche Cobas e411 Troponin T HS
	μg/l	0.445	0.356	0.534	Roche Cobas TroponinT

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot No. 3454CK Size: 1 x 2 ml Expiry: 2016-12

Range					
Analyte	unit	target	low	high	methods
CK Total	U/l	554	454	654	CK-NAC substrate start (DGKC) 37°C
	U/l	347	284	410	CK-NAC substrate start (DGKC) 30°C
	U/l	235	193	277	CK-NAC substrate start (DGKC) 25°C
	U/l	758	622	894	Vitros 37°C
	U/l	595	488	702	CK-NAC serum start (DGKC) 37°C
	U/l	372	305	439	CK-NAC serum start (DGKC) 30°C
	U/l	253	207	299	CK-NAC serum start (DGKC) 25°C
	U/l	594	487	701	CK-NAC (IFCC) 37°C
	U/l	372	305	439	CK-NAC (IFCC) 30°C
	U/l	252	207	297	CK-NAC (IFCC) 25°C
	U/l	589	483	695	Monothioglycerol 37°C
	U/l	369	302	436	Monothioglycerol 30°C
	U/l	250	205	295	Monothioglycerol 25°C
	U/l	627	514	740	Dithioerythritol (DTE) IFCC correlated 37°C
	U/l	393	322	464	Dithioerythritol (DTE) IFCC correlated 30°C
	U/l	266	218	314	Dithioerythritol (DTE) IFCC correlated 25°C
CK-MB Activity	U/l	140	112	168	Vitros 37°C
	U/l	141	113	169	Immunoinhibition substrate start 37°C
	U/l	81.9	65.7	98.1	Immunoinhibition substrate start 30°C
	U/l	50.1	40.1	60.1	Immunoinhibition substrate start 25°C
	U/l	141	113	169	Immunoinhibition serum start 37°C
	U/l	81.9	65.7	98.1	Immunoinhibition serum start 30°C
	U/l	50.1	40.1	60.1	Immunoinhibition serum start 25°C
	U/l	143	114	172	Immunoinhibition (IFCC) 37°C
	U/l	83.1	66.3	100	Immunoinhibition (IFCC) 30°C
	U/l	50.8	40.5	61.1	Immunoinhibition (IFCC) 25°C
	U/l	138	110	166	Randox Immunoinhibition serum start 37°C
	U/l	80.2	63.9	96.5	Randox Immunoinhibition serum start 30°C
	U/l	49.0	39.1	58.9	Randox Immunoinhibition serum start 25°C
	U/l	138	110	166	Randox Immunoinhibition substrate start 37°C
	U/l	80.2	63.9	96.5	Randox Immunoinhibition substrate start 30°C
	U/l	49.0	39.1	58.9	Randox Immunoinhibition substrate start 25°C
CK-MB Mass	ng/ml = µg/l	190	152	228	Siemens Dimension
	ng/ml = µg/l	160	128	192	Siemens Advia Centaur
	ng/ml = µg/l	153	122	184	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	243	194	292	Beckman Coulter Access
	ng/ml = µg/l	136	109	163	Ortho Vitros Eci
	ng/ml = µg/l	233	186	280	BioMerieux Vidas
	ng/ml = µg/l	163	130	196	Abbott Architect
Homocysteine	µmol/l	42.9	34.1	51.7	Siemens Immulite 2000/2500
	µmol/l	36.4	28.9	43.9	Abbott AXSYM
	µmol/l	38.5	30.8	46.2	Abbott Architect

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot No. 3454CK Size: 1 x 2 ml Expiry: 2016-12

Range					
Analyte	unit	target	low	high	methods
Myoglobin	ng/ml = µg/l	285	228	342	Roche Elecsys
	ng/ml = µg/l	190	152	228	Beckman Coulter Access
	ng/ml = µg/l	235	188	282	BioMerieux Vidas
	ng/ml = µg/l	234	187	281	Tosoh AIA360
	ng/ml = µg/l	365	292	438	Abbott Architect
	ng/ml = µg/l	367	294	440	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	1.78	1.42	2.14	Siemens Dimension
	ng/ml = µg/l	2.23	1.78	2.68	Siemens Stratus
	ng/ml = µg/l	3.62	2.90	4.34	Beckman Coulter Access
	ng/ml = µg/l	15.3	12.2	18.4	Siemens Advia Centaur
	ng/ml = µg/l	34.9	27.9	41.9	Ortho Vitros ECI
	ng/ml = µg/l	36.5	29.2	43.8	Tosoh AIA360
	ng/ml = µg/l	27.2	21.8	32.6	Abbott Architect
	ng/ml = µg/l	11.3	9.04	13.6	Biomerieux Vidas Ultra
	ng/ml = µg/l	2.80	2.24	3.36	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	3.05	2.30	3.80	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	8.39	6.71	10.1	Mitsubishi Chemical Pathfast
Troponin T	µg/l	1.319	1.060	1.580	Roche Modular E170/Roche Cobas c501 Troponin T HS
	µg/l	1.360	1.088	1.632	Roche Elecsys/Roche Cobas e411 Troponin T HS
	µg/l	1.381	1.100	1.660	Roche Cobas TroponinT