

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

CAT. NO. CQ3259 **LOT NOS.** 3845CK, 3846CK, 3847CK

SIZE: 3 x 2 ml **EXPIRY:** 2019-06

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°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 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 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. 3845CK Size: 1 x 2 ml Expiry: 2019-06

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	74	61	87	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	99	81	117	Vitros 37°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	77	63	91	Monothioglycerol 37°C
	U/l	48	39	57	Monothioglycerol 30°C
	U/l	33	27	39	Monothioglycerol 25°C
CK-MB Mass	ng/ml = µg/l	4.51	3.61	5.41	Siemens Dimension
	ng/ml = µg/l	6.42	5.14	7.70	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	5.23	4.18	6.28	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	7.20	5.76	8.64	Beckman Coulter Access
	ng/ml = µg/l	4.62	3.70	5.54	Ortho Vitros ECI
	ng/ml = µg/l	8.14	6.51	9.77	BioMerieux Vidas
	ng/ml = µg/l	4.91	3.93	5.89	Abbott Architect
	ng/ml = µg/l	7.01	5.61	8.41	Beckman Dxl800
Homocysteine	µmol/l	9.75	7.80	11.7	Abbott Architect
	µmol/l	9.75	7.80	11.7	IL ACL Elite/Elite Pro/8/9/10000
	µmol/l	13.5	10.8	16.2	Enzymatic
Myoglobin	ng/ml = µg/l	37.7	30.2	45.2	Roche Elecsys
	ng/ml = µg/l	29.0	23.2	34.8	Beckman Coulter Access
	ng/ml = µg/l	29.8	23.8	35.8	BioMerieux Vidas
	ng/ml = µg/l	51.0	40.8	61.2	Abbott Architect
	ng/ml = µg/l	30.5	24.4	36.6	Beckman Dxl800
	ng/ml = µg/l	56.1	44.9	67.3	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.109	0.087	0.131	Beckman Coulter Access
	ng/ml = µg/l	0.600	0.480	0.720	Siemens Immulite 1000
	ng/ml = µg/l	0.457	0.366	0.548	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	1.32	1.06	1.58	Ortho Vitros ECI
	ng/ml = µg/l	0.785	0.628	0.942	BioMerieux Vidas
	ng/ml = µg/l	2.09	1.67	2.51	Tosoh AIA360
	ng/ml = µg/l	1.59	1.27	1.91	Abbott Architect
	ng/ml = µg/l	0.767	0.614	0.920	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.188	0.150	0.226	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	0.228	0.182	0.274	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.206	0.165	0.247	Siemens Dimension Exl LOCI
	ng/ml = µg/l	0.357	0.286	0.428	Abbott Architect STAT hs
	ng/ml = µg/l	0.117	0.094	0.140	Beckman Access - A78803
	ng/ml = µg/l	0.118	0.094	0.142	Beckman Access - AccuTnl+3
Troponin T	µg/l	0.061	0.046	0.076	Roche Cobas Troponin T HS

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot No. 3846CK Size: 1 x 2 ml Expiry: 2019-06

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	352	289	415	Vitros 37°C
	U/l	253	207	299	CK-NAC (IFCC) 37°C
	U/l	158	130	186	CK-NAC (IFCC) 30°C
	U/l	108	88	128	CK-NAC (IFCC) 25°C
	U/l	264	216	312	Monothioglycerol 37°C
	U/l	165	135	195	Monothioglycerol 30°C
	U/l	112	92	132	Monothioglycerol 25°C
CK-MB Activity	U/l	17.6	14.1	21.1	Vitros 37°C
	U/l	27.9	22.3	33.5	Immunoinhibition substrate start 37°C
	U/l	16.2	13.0	19.4	Immunoinhibition substrate start 30°C
	U/l	9.90	7.92	11.9	Immunoinhibition substrate start 25°C
	U/l	27.5	22.0	33.0	Immunoinhibition serum start 37°C
	U/l	16.0	12.8	19.2	Immunoinhibition serum start 30°C
	U/l	9.76	7.81	11.7	Immunoinhibition serum start 25°C
	U/l	26.9	21.5	32.3	Immunoinhibition (IFCC) 37°C
	U/l	15.6	12.5	18.7	Immunoinhibition (IFCC) 30°C
	U/l	9.55	7.63	11.5	Immunoinhibition (IFCC) 25°C
	U/l	26.1	20.9	31.3	Randox Immunoinhibition serum start 37°C
	U/l	15.2	12.1	18.2	Randox Immunoinhibition serum start 30°C
	U/l	9.27	7.42	11.1	Randox Immunoinhibition serum start 25°C
	U/l	25.0	20.0	30.0	Randox Immunoinhibition substrate start 37°C
	U/l	14.5	11.6	17.4	Randox Immunoinhibition substrate start 30°C
	U/l	8.88	7.10	10.7	Randox Immunoinhibition substrate start 25°C
CK-MB Mass	ng/ml = µg/l	18.4	14.7	22.1	Siemens Dimension
	ng/ml = µg/l	24.0	19.2	28.8	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	18.0	14.4	21.6	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	27.6	22.1	33.1	Beckman Coulter Access
	ng/ml = µg/l	17.9	14.3	21.5	Ortho Vitros ECI
	ng/ml = µg/l	30.2	24.2	36.2	BioMerieux Vidas
	ng/ml = µg/l	18.9	15.1	22.7	Abbott Architect
	ng/ml = µg/l	28.1	22.5	33.7	Beckman Dxl800
	ng/ml = µg/l	6.05	4.84	7.26	Biosite Triage Meter Plus
Homocysteine	µmol/l	17.9	14.3	21.5	Abbott Architect
	µmol/l	17.5	14.0	21.0	IL ACL Elite/Elite Pro/8/9/10000
	µmol/l	20.8	16.6	25.0	Enzymatic
Myoglobin	ng/ml = µg/l	128	102	154	Roche Elecsys
	ng/ml = µg/l	100	80.0	120	Beckman Coulter Access
	ng/ml = µg/l	112	89.6	134	BioMerieux Vidas
	ng/ml = µg/l	185	148	222	Abbott Architect

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot No. 3846CK Size: 1 x 2 ml Expiry: 2019-06

Range					
Analyte	unit	Target	low	high	methods
Myoglobin	ng/ml = µg/l	99.0	79.2	119	Beckman DxI800
	ng/ml = µg/l	195	156	234	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.373	0.298	0.448	Siemens Stratus CS
	ng/ml = µg/l	0.470	0.376	0.564	Beckman Coulter Access
	ng/ml = µg/l	2.73	2.18	3.28	Siemens Immulite 1000
	ng/ml = µg/l	2.24	1.79	2.69	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	6.28	5.02	7.54	Ortho Vitros ECI
	ng/ml = µg/l	2.54	2.03	3.05	BioMerieux Vidas
	ng/ml = µg/l	9.09	7.27	10.9	Tosoh AIA360
	ng/ml = µg/l	6.51	5.21	7.81	Abbott Architect
	ng/ml = µg/l	2.58	2.06	3.10	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.514	0.411	0.617	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	1.32	1.06	1.58	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.581	0.465	0.697	Siemens Dimension Exl LOCI
	ng/ml = µg/l	1.23	0.984	1.48	Abbott Architect STAT hs
	ng/ml = µg/l	0.462	0.370	0.554	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	0.424	0.339	0.509	Beckman Access - A78803
	ng/ml = µg/l	0.423	0.338	0.508	Beckman Access - AccuTnl+3
Troponin T	µg/l	0.536	0.402	0.670	Roche Cobas Troponin T HS
	µg/l	0.269	0.202	0.336	Roche h232

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot No. 3847CK Size: 1 x 2 ml Expiry: 2019-06

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	552	453	651	CK-NAC substrate start (DGKC) 37°C
	U/l	346	284	408	CK-NAC substrate start (DGKC) 30°C
	U/l	235	193	277	CK-NAC substrate start (DGKC) 25°C
	U/l	780	640	920	Vitros 37°C
	U/l	577	473	681	CK-NAC (IFCC) 37°C
	U/l	361	296	426	CK-NAC (IFCC) 30°C
	U/l	245	201	289	CK-NAC (IFCC) 25°C
	U/l	584	479	689	Monothioglycerol 37°C
	U/l	366	300	432	Monothioglycerol 30°C
	U/l	248	204	292	Monothioglycerol 25°C
CK-MB Activity	U/l	123	98.4	148	Vitros 37°C
	U/l	136	109	163	Immunoinhibition substrate start 37°C
	U/l	79.0	63.4	94.6	Immunoinhibition substrate start 30°C
	U/l	48.3	38.7	57.9	Immunoinhibition substrate start 25°C
	U/l	134	107	161	Immunoinhibition serum start 37°C
	U/l	77.9	62.2	93.6	Immunoinhibition serum start 30°C
	U/l	47.6	38.0	57.2	Immunoinhibition serum start 25°C
	U/l	134	107	161	Immunoinhibition (IFCC) 37°C
	U/l	77.9	62.2	93.6	Immunoinhibition (IFCC) 30°C
	U/l	47.6	38.0	57.2	Immunoinhibition (IFCC) 25°C
	U/l	134	107	161	Randox Immunoinhibition serum start 37°C
	U/l	77.9	62.2	93.6	Randox Immunoinhibition serum start 30°C
	U/l	47.6	38.0	57.2	Randox Immunoinhibition serum start 25°C
	U/l	134	107	161	Randox Immunoinhibition substrate start 37°C
	U/l	77.9	62.2	93.6	Randox Immunoinhibition substrate start 30°C
	U/l	47.6	38.0	57.2	Randox Immunoinhibition substrate start 25°C
CK-MB Mass	ng/ml = µg/l	155	124	186	Siemens Dimension
	ng/ml = µg/l	172	138	206	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	126	101	151	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	218	174	262	Beckman Coulter Access
	ng/ml = µg/l	119	95.2	143	Ortho Vitros ECI
	ng/ml = µg/l	172	138	206	BioMerieux Vidas
	ng/ml = µg/l	138	110	166	Abbott Architect
	ng/ml = µg/l	196	157	235	Beckman Dxl800
	ng/ml = µg/l	38.1	30.5	45.7	Biosite Triage Meter Plus
Homocysteine	µmol/l	33.3	26.6	40.0	Abbott Architect
	µmol/l	28.2	22.6	33.8	IL ACL Elite/Elite Pro/8/9/10000
	µmol/l	36.2	29.0	43.4	Enzymatic
Myoglobin	ng/ml = µg/l	209	167	251	Roche Elecsys
	ng/ml = µg/l	172	138	206	Beckman Coulter Access
	ng/ml = µg/l	174	139	209	BioMerieux Vidas
	ng/ml = µg/l	320	256	384	Abbott Architect

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot No. 3847CK Size: 1 x 2 ml Expiry: 2019-06

Range					
Analyte	unit	Target	low	high	methods
Myoglobin	ng/ml = µg/l	335	268	402	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	1.44	1.15	1.73	Siemens Stratus CS
	ng/ml = µg/l	1.95	1.56	2.34	Beckman Coulter Access
	ng/ml = µg/l	12.6	10.1	15.1	Siemens Immulite 1000
	ng/ml = µg/l	13.1	10.5	15.7	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	31.3	25.0	37.6	Ortho Vitros ECI
	ng/ml = µg/l	11.1	8.88	13.3	BioMerieux Vidas
	ng/ml = µg/l	39.7	31.8	47.6	Tosoh AIA360
	ng/ml = µg/l	27.3	21.8	32.8	Abbott Architect
	ng/ml = µg/l	10.6	8.48	12.7	Biomerieux Vidas Ultra
	ng/ml = µg/l	1.62	1.30	1.94	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	6.63	5.30	7.96	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	1.83	1.46	2.20	Siemens Dimension Exl LOCI
	ng/ml = µg/l	3.54	2.83	4.25	Abbott Architect STAT hs
	ng/ml = µg/l	1.87	1.50	2.24	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	1.79	1.43	2.15	Beckman Access - A78803
	ng/ml = µg/l	1.84	1.47	2.21	Beckman Access - AccuTnl+3
Troponin T	µg/l	1.440	1.080	1.800	Roche Cobas Troponin T HS
	µg/l	0.764	0.573	0.955	Roche h232