

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

CAT. NO. CQ3259

LOT NO. 4097CK, 4098CK, 4099CK

SIZE: 3 x 2 ml

EXPIRY: 2021-01-28

GTIN: 05055273201857

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.

- 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.
- Refer to the Control section of the individual analyser application.
- 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. 4097CK Size: 1 x 2 ml Expiry: 2021-01-28

Analyte	unit	Target	Range		methods
			low	high	
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 serum start (DGKC) 37°C
	U/l	47	39	55	CK-NAC serum start (DGKC) 30°C
	U/l	32	26	38	CK-NAC serum start (DGKC) 25°C
	U/l	74	61	87	CK-NAC (IFCC) 37°C
	U/l	46	38	54	CK-NAC (IFCC) 30°C
	U/l	31	26	36	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	
CK-MB Mass	ng/ml = µg/l	5.58	4.46	6.70	Siemens Dimension
	ng/ml = µg/l	8.13	6.50	9.76	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	6.82	5.46	8.18	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	8.52	6.82	10.2	Beckman Coulter Access
	ng/ml = µg/l	9.79	7.83	11.7	BioMerieux Vidas
	ng/ml = µg/l	6.37	5.10	7.64	Abbott Architect
	ng/ml = µg/l	9.10	7.28	10.9	Beckman Dxl800
Homocysteine	µmol/l	11.5	9.20	13.8	Siemens Immulite 2000/2500
	µmol/l	10.4	8.32	12.5	Abbott Architect
	µmol/l	13.4	10.7	16.1	Roche Cobas 6000/8000
	µmol/l	15.3	12.2	18.4	Enzymatic
Myoglobin	ng/ml = µg/l	49.1	34.4	63.8	Roche Elecsys
	ng/ml = µg/l	53.8	37.7	69.9	Siemens Dimension
	ng/ml = µg/l	38.3	26.8	49.8	Beckman Coulter Access
	ng/ml = µg/l	43.2	30.2	56.2	BioMerieux Vidas
	ng/ml = µg/l	59.3	41.5	77.1	Abbott Architect
	ng/ml = µg/l	41.7	29.2	54.2	Beckman Dxl800
	ng/ml = µg/l	21.2	14.8	27.6	Biosite Triage Meter Plus
	ng/ml = µg/l	71.3	49.9	92.7	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.124	0.099	0.149	Siemens Stratus CS
	ng/l = pg/ml	124	99.0	149	
	ng/ml = µg/l	0.683	0.546	0.820	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	683	546	820	
	ng/ml = µg/l	1.26	1.01	1.51	Ortho Vitros ECi
	ng/l = pg/ml	1260	1010	1510	
	ng/ml = µg/l	0.776	0.621	0.931	Biomerieux Vidas Ultra
	ng/l = pg/ml	776	621	931	
	ng/ml = µg/l	0.203	0.162	0.244	Beckman DXi800 1st gen
ng/l = pg/ml	203	162	244		

CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3259 Lot No. 4097CK Size: 1 x 2 ml Expiry: 2021-01-28

Analyte	unit	Target	Range		methods
			low	high	
Troponin I	ng/ml = µg/l	0.273	0.218	0.328	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	273	218	328	
	ng/ml = µg/l	0.232	0.186	0.278	Siemens Dimension Exl LOCI
	ng/l = pg/ml	232	186	278	
	ng/ml = µg/l	0.511	0.409	0.613	Abbott Architect STAT hs
	ng/l = pg/ml	511	409	613	
	ng/ml = µg/l	0.188	0.150	0.226	Beckman Dxl - AccuTnl+3
	ng/l = pg/ml	188	150	226	
	ng/ml = µg/l	0.194	0.155	0.233	Beckman Access - A78803
	ng/l = pg/ml	194	155	233	
	ng/ml = µg/l	0.209	0.167	0.251	Beckman Access - AccuTnl+3
	ng/l = pg/ml	209	167	251	
ng/ml = µg/l	0.541	0.433	0.649	Siemens Centaur CP	
ng/l = pg/ml	541	433	649		
ng/ml = µg/l	0.847	0.678	1.02	bioMerieux VIDAS hs Troponin I	
ng/l = pg/ml	847	678	1016		
Troponin T	ng/ml = µg/l	0.063	0.047	0.079	Roche Cobas Troponin T HS
	ng/l = pg/ml	63.0	47.0	79.0	
	ng/ml = µg/l	0.054	0.041	0.068	Roche h232
	ng/l = pg/ml	54.0	41.0	67.0	
	ng/ml = µg/l	0.062	0.047	0.078	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	62.0	47.0	77.0	

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot No. 4098CK Size: 1 x 2 ml Expiry: 2021-01-28

Analyte	unit	Target	Range		methods
			low	high	
CK Total	U/l	238	195	281	CK-NAC substrate start (DGKC) 37°C
	U/l	149	122	176	CK-NAC substrate start (DGKC) 30°C
	U/l	101	83	119	CK-NAC substrate start (DGKC) 25°C
	U/l	322	264	380	Vitros 37°C
	U/l	226	185	267	CK-NAC serum start (DGKC) 37°C
	U/l	141	116	166	CK-NAC serum start (DGKC) 30°C
	U/l	96	79	113	CK-NAC serum start (DGKC) 25°C
	U/l	228	187	269	CK-NAC (IFCC) 37°C
	U/l	143	117	169	CK-NAC (IFCC) 30°C
	U/l	97	79	115	CK-NAC (IFCC) 25°C
	U/l	232	190	274	Monothioglycerol 37°C
	U/l	145	119	171	Monothioglycerol 30°C
	U/l	99	81	117	Monothioglycerol 25°C
CK-MB Activity	U/l	14.9	11.9	17.9	Vitros 37°C
	U/l	22.0	17.6	26.4	Immunoinhibition substrate start 37°C
	U/l	12.8	10.2	15.4	Immunoinhibition substrate start 30°C
	U/l	7.81	6.25	9.37	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	21.9	17.5	26.3	Immunoinhibition (IFCC) 37°C
	U/l	12.7	10.2	15.2	Immunoinhibition (IFCC) 30°C
	U/l	7.77	6.21	9.33	Immunoinhibition (IFCC) 25°C
	U/l	22.5	18.0	27.0	Randox Immunoinhibition substrate start 37°C
	U/l	13.1	10.5	15.7	Randox Immunoinhibition substrate start 30°C
	U/l	7.99	6.39	9.59	Randox Immunoinhibition substrate start 25°C
	U/l	22.4	17.9	26.9	Randox Immunoinhibition serum start 37°C
U/l	13.0	10.4	15.6	Randox Immunoinhibition serum start 30°C	
U/l	7.95	6.35	9.55	Randox Immunoinhibition serum start 25°C	
CK-MB Mass	ng/ml = µg/l	18.7	15.0	22.4	Siemens Dimension
	ng/ml = µg/l	23.3	18.6	28.0	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	17.7	14.2	21.2	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	25.4	20.3	30.5	Beckman Coulter Access
	ng/ml = µg/l	25.3	20.2	30.4	BioMerieux Vidas
	ng/ml = µg/l	18.1	14.5	21.7	Abbott Architect
	ng/ml = µg/l	25.8	20.6	31.0	Beckman Dxl800
Homocysteine	µmol/l	21.4	17.1	25.7	Siemens Immulite 2000/2500
	µmol/l	18.2	14.6	21.8	Abbott Architect
	µmol/l	24.3	19.4	29.2	Roche Cobas 6000/8000
	µmol/l	22.7	18.2	27.2	Enzymatic
Myoglobin	ng/ml = µg/l	128	89.6	166	Roche Elecsys
	ng/ml = µg/l	162	113	211	Siemens Dimension

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot No. 4098CK Size: 1 x 2 ml Expiry: 2021-01-28

Analyte	unit	Target	Range		methods
			low	high	
Myoglobin	ng/ml = µg/l	102	71.4	133	Beckman Coulter Access
	ng/ml = µg/l	110	77.0	143	BioMerieux Vidas
	ng/ml = µg/l	179	125	233	Abbott Architect
	ng/ml = µg/l	117	81.9	152	Beckman Dxl800
	ng/ml = µg/l	67.0	46.9	87.1	Biosite Triage Meter Plus
	ng/ml = µg/l	201	141	261	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.464	0.371	0.557	Siemens Stratus CS
	ng/l = pg/ml	464	371	557	
	ng/ml = µg/l	3.60	2.88	4.32	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	3600	2880	4320	
	ng/ml = µg/l	6.34	5.07	7.61	Ortho Vitros ECI
	ng/l = pg/ml	6340	5070	7610	
	ng/ml = µg/l	2.46	1.97	2.95	Biomerieux Vidas Ultra
	ng/l = pg/ml	2460	1970	2950	
	ng/ml = µg/l	0.770	0.616	0.924	Beckman DXI800 1st gen
	ng/l = pg/ml	770	616	924	
	ng/ml = µg/l	0.464	0.371	0.557	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	464	371	557	
	ng/ml = µg/l	1.38	1.10	1.66	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	1380	1100	1660	
	ng/ml = µg/l	0.617	0.494	0.740	Siemens Dimension Exl LOCI
	ng/l = pg/ml	617	494	740	
	ng/ml = µg/l	1.70	1.36	2.04	Abbott Architect STAT hs
	ng/l = pg/ml	1700	1360	2040	
	ng/ml = µg/l	0.718	0.574	0.862	Beckman Dxl - AccuTnl+3
	ng/l = pg/ml	718	574	862	
ng/ml = µg/l	0.792	0.634	0.950	Beckman Access - A78803	
ng/l = pg/ml	792	634	950		
ng/ml = µg/l	0.776	0.621	0.931	Beckman Access - AccuTnl+3	
ng/l = pg/ml	776	621	931		
ng/ml = µg/l	2.89	2.31	3.47	Siemens Centaur CP	
ng/l = pg/ml	2890	2310	3470		
ng/ml = µg/l	4.76	3.81	5.71	bioMerieux VIDAS hs Troponin I	
ng/l = pg/ml	4760	3810	5710		
Troponin T	ng/ml = µg/l	0.443	0.332	0.554	Roche Cobas Troponin T HS
	ng/l = pg/ml	443	332	554	
	ng/ml = µg/l	0.267	0.200	0.334	Roche h232
	ng/l = pg/ml	267	200	334	
	ng/ml = µg/l	0.431	0.323	0.539	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	431	323	539	

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot No. 4099CK Size: 1 x 2 ml Expiry: 2021-01-28

Analyte	unit	Target	Range		methods
			low	high	
CK Total	U/l	536	440	632	CK-NAC substrate start (DGKC) 37°C
	U/l	336	275	397	CK-NAC substrate start (DGKC) 30°C
	U/l	228	187	269	CK-NAC substrate start (DGKC) 25°C
	U/l	714	585	843	Vitros 37°C
	U/l	536	440	632	CK-NAC serum start (DGKC) 37°C
	U/l	336	275	397	CK-NAC serum start (DGKC) 30°C
	U/l	228	187	269	CK-NAC serum start (DGKC) 25°C
	U/l	535	439	631	CK-NAC (IFCC) 37°C
	U/l	335	275	395	CK-NAC (IFCC) 30°C
	U/l	227	187	267	CK-NAC (IFCC) 25°C
	U/l	546	448	644	Monothioglycerol 37°C
	U/l	342	280	404	Monothioglycerol 30°C
	U/l	232	190	274	Monothioglycerol 25°C
CK-MB Activity	U/l	108	86.4	130	Vitros 37°C
	U/l	122	97.6	146	Immunoinhibition substrate start 37°C
	U/l	70.9	56.7	85.1	Immunoinhibition substrate start 30°C
	U/l	43.3	34.6	52.0	Immunoinhibition substrate start 25°C
	U/l	117	93.6	140	Immunoinhibition serum start 37°C
	U/l	68.0	54.4	81.6	Immunoinhibition serum start 30°C
	U/l	41.5	33.2	49.8	Immunoinhibition serum start 25°C
	U/l	116	92.8	139	Immunoinhibition (IFCC) 37°C
	U/l	67.4	53.9	80.9	Immunoinhibition (IFCC) 30°C
	U/l	41.2	32.9	49.5	Immunoinhibition (IFCC) 25°C
	U/l	117	93.6	140	Randox Immunoinhibition substrate start 37°C
	U/l	68.0	54.4	81.4	Randox Immunoinhibition substrate start 30°C
	U/l	41.5	33.2	49.7	Randox Immunoinhibition substrate start 25°C
	U/l	117	93.6	140	Randox Immunoinhibition serum start 37°C
	U/l	68.0	54.4	81.4	Randox Immunoinhibition serum start 30°C
U/l	41.5	33.2	49.7	Randox Immunoinhibition serum start 25°C	
CK-MB Mass	ng/ml = µg/l	153	122	184	Siemens Dimension
	ng/ml = µg/l	164	131	197	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	120	96.0	144	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	168	134	202	Beckman Coulter Access
	ng/ml = µg/l	155	124	186	BioMerieux Vidas
	ng/ml = µg/l	125	100	150	Abbott Architect
	ng/ml = µg/l	180	144	216	Beckman Dxl800
Homocysteine	µmol/l	42.1	33.7	50.5	Siemens Immulite 2000/2500
	µmol/l	36.4	29.1	43.7	Abbott Architect
	µmol/l	50.8	40.6	61.0	Roche Cobas 6000/8000
	µmol/l	39.9	31.9	47.9	Enzymatic
Myoglobin	ng/ml = µg/l	220	154	286	Roche Elecsys
	ng/ml = µg/l	170	119	221	Beckman Coulter Access

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot No. 4099CK Size: 1 x 2 ml Expiry: 2021-01-28

Range					
Analyte	unit	Target	low	high	methods
Myoglobin	ng/ml = µg/l	186	130	242	BioMerieux Vidas
	ng/ml = µg/l	309	216	402	Abbott Architect
	ng/ml = µg/l	197	138	256	Beckman Dxl800
	ng/ml = µg/l	387	271	503	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	2.15	1.72	2.58	Siemens Stratus CS
	ng/l = pg/ml	2150	1720	2580	
	ng/ml = µg/l	23.1	18.5	27.7	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	23100	18500	27700	
	ng/ml = µg/l	32.1	25.7	38.5	Ortho Vitros ECI
	ng/l = pg/ml	32100	25700	38500	
	ng/ml = µg/l	9.77	7.82	11.7	Biomerieux Vidas Ultra
	ng/l = pg/ml	9770	7820	11700	
	ng/ml = µg/l	4.78	3.82	5.74	Beckman DXI800 1st gen
	ng/l = pg/ml	4780	3820	5740	
	ng/ml = µg/l	1.53	1.22	1.84	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	1530	1220	1840	
	ng/ml = µg/l	9.30	7.44	11.2	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	9300	7440	11200	
	ng/ml = µg/l	2.62	2.10	3.14	Siemens Dimension Exl LOCI
	ng/l = pg/ml	2620	2100	3140	
	ng/ml = µg/l	5.95	4.76	7.14	Abbott Architect STAT hs
	ng/l = pg/ml	5950	4760	7140	
	ng/ml = µg/l	4.31	3.45	5.17	Beckman Dxl - AccuTnl+3
	ng/l = pg/ml	4310	3450	5170	
ng/ml = µg/l	4.72	3.78	5.66	Beckman Access - A78803	
ng/l = pg/ml	4720	3780	5660		
ng/ml = µg/l	4.51	3.61	5.41	Beckman Access - AccuTnl+3	
ng/l = pg/ml	4510	3610	5410		
ng/ml = µg/l	17.3	13.8	20.8	Siemens Centaur CP	
ng/l = pg/ml	17300	13800	20800		
ng/ml = µg/l	31.6	25.3	37.9	bioMerieux VIDAS hs Troponin I	
ng/l = pg/ml	31600	25300	37900		
Troponin T	ng/ml = µg/l	1.230	0.923	1.540	Roche Cobas Troponin T HS
	ng/l = pg/ml	1230	923	1537	
	ng/ml = µg/l	0.784	0.588	0.980	Roche h232
	ng/l = pg/ml	784	588	980	
ng/ml = µg/l	1.240	0.930	1.550	Roche Cobas Troponin T hs STAT	
ng/l = pg/ml	1240	930	1550		