

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

CAT NO. CQ3100

LOT NO. 4270CK, 4271CK, 4272CK

SIZE: 3 x 1 ml

EXPIRY: 2020-02-28

GTIN: 05055273201840

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: All lots are stable for 5 days at +2°C to +8°C, with the exception of 4270CK, which is stable for 2 days at +2°C to +8°C or 2 weeks frozen 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.

- 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.
- 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 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.

(S) 12 Oct 18 pq

CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3100 Lot No. 4270CK Size: 1 x 1 ml Expiry: 2020-02-28

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	88	72	104	CK-NAC substrate start (DGKC) 37°C
	U/l	55	45	65	CK-NAC substrate start (DGKC) 30°C
	U/l	37	31	43	CK-NAC substrate start (DGKC) 25°C
	U/l	122	100	144	Vitros 37°C
	U/l	86	71	101	CK-NAC (IFCC) 37°C
	U/l	54	44	64	CK-NAC (IFCC) 30°C
	U/l	37	30	44	CK-NAC (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	4.20	2.94	5.46	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	4.86	3.40	6.32	Beckman Coulter Access
	ng/ml = µg/l	3.62	2.53	4.71	Abbott Architect
	ng/ml = µg/l	5.05	3.54	6.57	Beckman Dxl800
Homocysteine	µmol/l	11.0	8.80	13.2	Abbott Architect
	µmol/l	16.9	13.5	20.3	Roche Cobas 6000/8000
	µmol/l	17.0	13.6	20.4	Enzymatic
Myoglobin	ng/ml = µg/l	52.7	36.9	68.5	Roche Elecsys
	ng/ml = µg/l	40.4	28.3	52.5	Beckman Coulter Access
	ng/ml = µg/l	72.2	50.5	93.9	Abbott Architect
	ng/ml = µg/l	41.5	29.1	54.0	Beckman Dxl800
	ng/ml = µg/l	27.2	19.0	35.4	Biosite Triage Meter Plus
	ng/ml = µg/l	85.1	59.6	111	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.800	0.640	0.960	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	800	640	960	
	ng/ml = µg/l	1.45	1.16	1.74	Ortho Vitros ECi
	ng/l = pg/ml	1450	1160	1740	
	ng/ml = µg/l	0.108	0.086	0.130	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	108	86.0	130	
	ng/ml = µg/l	0.267	0.214	0.320	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	267	214	320	
	ng/ml = µg/l	0.191	0.153	0.229	Siemens Dimension Exl LOCI
	ng/l = pg/ml	191	153	229	
	ng/ml = µg/l	0.572	0.458	0.686	Abbott Architect STAT hs
	ng/l = pg/ml	572	458	686	
	ng/ml = µg/l	0.263	0.210	0.316	Beckman Dxl - AccuTnl+3
	ng/l = pg/ml	263	210	316	
Troponin T	ng/ml = µg/l	0.069	0.048	0.090	Roche Cobas Troponin T HS
	ng/l = pg/ml	69.0	48.0	90.0	
	ng/ml = µg/l	0.055	0.039	0.072	Roche h232
	ng/l = pg/ml	55.0	39.0	71.0	

CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3100 Lot No. 4270CK Size: 1 x 1 ml Expiry: 2020-02-28

Analyte	unit	Target	Range		methods
			low	high	
Troponin T	ng/ml = µg/l	0.066	0.046	0.086	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	66.0	46.0	86.0	

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3100 Lot No. 4271CK Size: 1 x 1 ml Expiry: 2020-02-28

Analyte	unit	Target	Range		methods
			low	high	
CK Total	U/l	270	221	319	CK-NAC substrate start (DGKC) 37°C
	U/l	169	138	200	CK-NAC substrate start (DGKC) 30°C
	U/l	115	94	136	CK-NAC substrate start (DGKC) 25°C
	U/l	358	294	422	Vitros 37°C
	U/l	250	205	295	CK-NAC (IFCC) 37°C
	U/l	157	128	186	CK-NAC (IFCC) 30°C
	U/l	106	87	125	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	19.6	15.7	23.5	Vitros 37°C
	U/l	20.6	16.5	24.7	Immunoinhibition substrate start 37°C
	U/l	12.0	9.59	14.4	Immunoinhibition substrate start 30°C
	U/l	7.31	5.86	8.76	Immunoinhibition substrate start 25°C
	U/l	22.2	17.8	26.6	Immunoinhibition serum start 37°C
	U/l	12.9	10.3	15.5	Immunoinhibition serum start 30°C
	U/l	7.88	6.32	9.44	Immunoinhibition serum start 25°C
	U/l	21.6	17.3	25.9	Immunoinhibition (IFCC) 37°C
	U/l	12.6	10.1	15.1	Immunoinhibition (IFCC) 30°C
	U/l	7.67	6.14	9.20	Immunoinhibition (IFCC) 25°C
	U/l	23.3	18.6	28.0	Randox Immunoinhibition substrate start 37°C
	U/l	13.5	10.8	16.3	Randox Immunoinhibition substrate start 30°C
	U/l	8.27	6.60	9.94	Randox Immunoinhibition substrate start 25°C
	U/l	22.3	17.8	26.8	Randox Immunoinhibition serum start 37°C
U/l	13.0	10.3	15.6	Randox Immunoinhibition serum start 30°C	
U/l	7.92	6.32	9.51	Randox Immunoinhibition serum start 25°C	
CK-MB Mass	ng/ml = µg/l	15.4	10.8	20.0	Siemens Dimension
	ng/ml = µg/l	20.5	14.4	26.7	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	16.5	11.6	21.5	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	22.9	16.0	29.8	Beckman Coulter Access
	ng/ml = µg/l	17.1	12.0	22.2	Abbott Architect
	ng/ml = µg/l	22.9	16.0	29.8	Beckman DxI800
Homocysteine	µmol/l	21.8	17.4	26.2	Siemens Immulite 2000/2500
	µmol/l	18.2	14.6	21.8	Abbott Architect
	µmol/l	30.3	24.2	36.4	Roche Cobas 6000/8000
	µmol/l	23.6	18.9	28.3	Enzymatic
Myoglobin	ng/ml = µg/l	104	72.8	135	Roche Elecsys
	ng/ml = µg/l	84.9	59.4	110	Beckman Coulter Access
	ng/ml = µg/l	149	104	194	Abbott Architect
	ng/ml = µg/l	86.7	60.7	113	Beckman DxI800
	ng/ml = µg/l	174	122	226	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	4.65	3.72	5.58	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	4650	3720	5580	
	ng/ml = µg/l	6.77	5.42	8.12	Ortho Vitros ECI
	ng/l = pg/ml	6770	5420	8120	

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3100 Lot No. 4271CK Size: 1 x 1 ml Expiry: 2020-02-28

Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	1.46	1.17	1.75	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	1460	1170	1750	
	ng/ml = µg/l	0.540	0.432	0.648	Siemens Dimension Exl LOCI
	ng/l = pg/ml	540	432	648	
	ng/ml = µg/l	2.10	1.68	2.52	Abbott Architect STAT hs
	ng/l = pg/ml	2100	1680	2520	
	ng/ml = µg/l	1.25	1.00	1.50	Beckman Dxl - AccuTnl+3
	ng/l = pg/ml	1250	1000	1500	
ng/ml = µg/l	1.36	1.09	1.63	Beckman Access - AccuTnl+3	
ng/l = pg/ml	1360	1090	1630		
Troponin T	ng/ml = µg/l	6.08	4.86	7.30	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	6080	4860	7300	
	ng/ml = µg/l	0.390	0.273	0.507	Roche Cobas Troponin T HS
	ng/l = pg/ml	390	273	507	
	ng/ml = µg/l	0.201	0.141	0.261	Roche h232
	ng/l = pg/ml	201	141	261	
	ng/ml = µg/l	0.367	0.257	0.477	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	367	257	477	

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3100 Lot No. 4272CK Size: 1 x 1 ml Expiry: 2020-02-28

Analyte	unit	Target	Range		methods
			low	high	
CK Total	U/l	690	566	814	CK-NAC substrate start (DGKC) 37°C
	U/l	432	354	510	CK-NAC substrate start (DGKC) 30°C
	U/l	293	241	345	CK-NAC substrate start (DGKC) 25°C
	U/l	933	765	1101	Vitros 37°C
	U/l	673	552	794	CK-NAC (IFCC) 37°C
	U/l	421	346	496	CK-NAC (IFCC) 30°C
	U/l	286	235	337	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	121	96.8	145	Vitros 37°C
	U/l	125	100	150	Immunoinhibition substrate start 37°C
	U/l	72.7	58.1	87.3	Immunoinhibition substrate start 30°C
	U/l	44.4	35.5	53.3	Immunoinhibition substrate start 25°C
	U/l	123	98.4	148	Immunoinhibition serum start 37°C
	U/l	71.5	57.2	85.8	Immunoinhibition serum start 30°C
	U/l	43.7	34.9	52.5	Immunoinhibition serum start 25°C
	U/l	122	97.6	146	Immunoinhibition (IFCC) 37°C
	U/l	70.9	56.7	85.1	Immunoinhibition (IFCC) 30°C
	U/l	43.3	34.6	52.0	Immunoinhibition (IFCC) 25°C
	U/l	121	96.8	145	Randox Immunoinhibition serum start 37°C
	U/l	70.3	56.3	84.3	Randox Immunoinhibition serum start 30°C
	U/l	43.0	34.4	51.5	Randox Immunoinhibition serum start 25°C
	U/l	122	97.6	146	Randox Immunoinhibition substrate start 37°C
U/l	70.9	56.7	84.9	Randox Immunoinhibition substrate start 30°C	
U/l	43.3	34.6	51.8	Randox Immunoinhibition substrate start 25°C	
CK-MB Mass	ng/ml = µg/l	159	111	207	Siemens Dimension
	ng/ml = µg/l	175	123	228	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	126	88.2	164	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	183	128	238	Beckman Coulter Access
	ng/ml = µg/l	130	91.0	169	Abbott Architect
	ng/ml = µg/l	187	131	243	Beckman DxI800
Homocysteine	µmol/l	48.5	38.8	58.2	Siemens Immulite 2000/2500
	µmol/l	37.9	30.3	45.5	Abbott Architect
	µmol/l	64.5	51.6	77.4	Roche Cobas 6000/8000
	µmol/l	43.7	35.0	52.4	Enzymatic
Myoglobin	ng/ml = µg/l	233	163	303	Roche Elecsys
	ng/ml = µg/l	182	127	237	Beckman Coulter Access
	ng/ml = µg/l	330	231	429	Abbott Architect
	ng/ml = µg/l	196	137	255	Beckman DxI800
	ng/ml = µg/l	111	77.7	144	Biosite Triage Meter Plus
	ng/ml = µg/l	392	274	510	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	46.7	37.4	56.0	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	46700	37400	56000	
	ng/ml = µg/l	53.4	42.7	64.1	Ortho Vitros ECI
	ng/l = pg/ml	53400	42700	64100	

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3100 Lot No. 4272CK Size: 1 x 1 ml Expiry: 2020-02-28

Analyte	unit	Target	Range		methods
			low	high	
Troponin I	ng/ml = µg/l	1.11	0.888	1.33	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	1110	888	1332	
	ng/ml = µg/l	15.0	12.0	18.0	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	15000	12000	18000	
	ng/ml = µg/l	2.73	2.18	3.28	Siemens Dimension Exl LOCI
	ng/l = pg/ml	2730	2180	3280	
	ng/ml = µg/l	14.6	11.7	17.5	Abbott Architect STAT hs
	ng/l = pg/ml	14600	11700	17500	
	ng/ml = µg/l	13.6	10.9	16.3	Beckman Dxl - AccuTnl+3
	ng/l = pg/ml	13600	10900	16300	
Troponin T	ng/ml = µg/l	12.7	10.2	15.2	Beckman Access - AccuTnl+3
	ng/l = pg/ml	12700	10200	15200	
	ng/ml = µg/l	40.7	32.6	48.8	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	40700	32600	48800	
	ng/ml = µg/l	1.150	0.805	1.500	Roche Cobas Troponin T HS
	ng/l = pg/ml	1150	805	1495	
	ng/ml = µg/l	0.643	0.450	0.836	Roche h232
	ng/l = pg/ml	643	450	836	
	ng/ml = µg/l	1.100	0.770	1.430	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	1100	770	1430	