

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

**CAT. NO.** CQ3259 **LOT NO.** 4783CK, 4784CK, 4785CK  
**SIZE** 3 x 2 ml **EXPIRY:** 2027-06-28  
**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 and 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](mailto:Technical.Services@randox.com).

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## CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3259 Lot. No. 4783CK Size 1 x 2 ml Expiry 2027-06-28

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	116	95	137	Vitros 37°C
	U/l	87	71	103	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	3.70	2.59	4.81	Abbott Architect / Alinity
	ng/ml = µg/l	5.49	3.84	7.14	Siemens Atellica IM
Homocysteine	µmol/l	12.6	10.1	15.1	Abbott Architect
	µmol/l	16.5	13.2	19.8	Enzymatic
Myoglobin	ng/ml = µg/l	47.9	33.5	62.3	Abbott Architect
Troponin I	ng/ml = µg/l	0.190	0.152	0.228	Ortho Vitros ECI
	ng/l = pg/ml	190	152	228	
	ng/ml = µg/l	0.540	0.432	0.648	Tosoh Series
	ng/l = pg/ml	540	432	648	
	ng/ml = µg/l	0.220	0.176	0.264	Abbott Architect
	ng/l = pg/ml	220	176	264	
	ng/ml = µg/l	0.210	0.168	0.252	Abbott Architect STAT hs
	ng/l = pg/ml	210	168	252	
	ng/ml = µg/l	0.180	0.144	0.216	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	180	144	216	
	ng/ml = µg/l	0.290	0.232	0.348	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	290	232	348	
	ng/ml = µg/l	0.070	0.056	0.084	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	70.0	56.0	84.0	
Troponin T	ng/ml = µg/l	0.300	0.240	0.360	Siemens Atellica IM
	ng/l = pg/ml	300	240	360	
	ng/ml = µg/l	0.010	0.007	0.013	Roche Cobas Troponin T HS
	ng/l = pg/ml	10.0	7.00	13.0	
	ng/ml = µg/l	0.010	0.007	0.013	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	10.0	7.00	13.0	
	ng/ml = µg/l	0.010	0.007	0.013	Roche Cobas e801 TnT hs
	ng/l = pg/ml	10.0	7.00	13.0	
	ng/ml = µg/l	0.010	0.007	0.013	Roche Cobas e801 TnT hs STAT
	ng/l = pg/ml	10.0	7.00	13.0	

## CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot. No. 4784CK Size 1 x 2 ml Expiry 2027-06-28

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	296	243	349	Vitros 37°C
	U/l	209	171	247	CK-NAC (IFCC) 37°C
	U/l	131	107	155	CK-NAC (IFCC) 30°C
	U/l	89	73	105	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	22.5	18.0	27.0	Immunoinhibition (IFCC) 37°C
	U/l	13.1	10.5	15.7	Immunoinhibition (IFCC) 30°C
	U/l	7.99	6.39	9.59	Immunoinhibition (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	26.9	18.8	35.0	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	20.1	14.1	26.1	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	19.3	13.5	25.1	Abbott Architect / Alinity
Homocysteine	µmol/l	20.5	16.4	24.6	Abbott Architect
	µmol/l	26.7	21.4	32.0	Roche Cobas 6000/8000
	µmol/l	23.2	18.6	27.8	Enzymatic
Myoglobin	ng/ml = µg/l	141	98.7	183	Abbott Architect
Troponin I	ng/ml = µg/l	1.81	1.45	2.17	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	1810	1450	2170	
	ng/ml = µg/l	1.43	1.14	1.72	Abbott Architect STAT hs
	ng/l = pg/ml	1430	1140	1720	
	ng/ml = µg/l	10.7	8.56	12.8	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	10700	8560	12800	
	ng/ml = µg/l	7.13	5.70	8.56	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	7130	5700	8560	
	ng/ml = µg/l	2.80	2.24	3.36	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	2800	2240	3360	
Troponin T	ng/ml = µg/l	7.83	6.26	9.40	Siemens Atellica IM
	ng/l = pg/ml	7830	6260	9400	
	ng/ml = µg/l	0.290	0.203	0.377	Roche Cobas Troponin T HS
	ng/l = pg/ml	290	203	377	
	ng/ml = µg/l	0.260	0.182	0.338	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	260	182	338	
	ng/ml = µg/l	0.300	0.210	0.390	Roche Cobas e801 TnT hs
	ng/l = pg/ml	300	210	390	
	ng/ml = µg/l	0.300	0.210	0.390	Roche Cobas e801 TnT hs STAT
	ng/l = pg/ml	300	210	390	

## CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot. No. 4785CK Size 1 x 2 ml Expiry 2027-06-28

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	791	649	933	Vitros 37°C
	U/l	597	490	704	CK-NAC (IFCC) 37°C
	U/l	374	307	441	CK-NAC (IFCC) 30°C
	U/l	254	208	300	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	93.4	74.7	112	Immunoinhibition (IFCC) 37°C
	U/l	54.3	43.4	65.1	Immunoinhibition (IFCC) 30°C
	U/l	33.2	26.5	39.8	Immunoinhibition (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	131	91.7	170	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	101	70.7	131	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	97.7	68.4	127	Abbott Architect / Alinity
	ng/ml = µg/l	129	90.3	168	Siemens Atellica IM
Homocysteine	µmol/l	35.8	28.6	43.0	Abbott Architect
	µmol/l	59.4	47.5	71.3	Roche Cobas 6000/8000
	µmol/l	36.7	29.4	44.0	Enzymatic
Myoglobin	ng/ml = µg/l	376	263	489	Abbott Architect
Troponin I	ng/ml = µg/l	28.5	22.8	34.2	Ortho Vitros ECI
	ng/l = pg/ml	28500	22800	34200	
	ng/ml = µg/l	29.2	23.4	35.0	Tosoh Series
	ng/l = pg/ml	29200	23400	35000	
	ng/ml = µg/l	2.82	2.26	3.38	Abbott Architect
	ng/l = pg/ml	2820	2260	3380	
	ng/ml = µg/l	2.54	2.03	3.05	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	2540	2030	3050	
	ng/ml = µg/l	2.99	2.39	3.59	Abbott Architect STAT hs
	ng/l = pg/ml	2990	2390	3590	
	ng/ml = µg/l	28.6	22.9	34.3	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	28600	22900	34300	
	ng/ml = µg/l	14.7	11.8	17.6	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	14700	11800	17600	
	ng/ml = µg/l	6.89	5.51	8.27	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	6890	5510	8270	
Troponin T	ng/ml = µg/l	15.4	12.3	18.5	Siemens Atellica IM
	ng/l = pg/ml	15400	12300	18500	
	ng/ml = µg/l	0.860	0.602	1.120	Roche Cobas Troponin T HS
	ng/l = pg/ml	860	602	1118	
	ng/ml = µg/l	0.720	0.504	0.936	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	720	504	936	
	ng/ml = µg/l	0.710	0.497	0.923	Roche Cobas e801 TnT hs
	ng/l = pg/ml	710	497	923	
	ng/ml = µg/l	0.760	0.532	0.988	Roche Cobas e801 TnT hs STAT
	ng/l = pg/ml	760	532	988	