

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

CAT. NO. CQ3259 **LOT NO.** 4646CK, 4647CK, 4648CK
SIZE 3 x 2 ml **EXPIRY:** 2025-12-28
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.

EC	REP
----	-----

Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

05 May '22 me

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot. No. 4647CK Size 1 x 2ml Expiry 2025-12-28

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	306	251	361	Vitros 37°C
	U/l	224	184	264	CK-NAC (IFCC) 37°C
	U/l	140	115	165	CK-NAC (IFCC) 30°C
	U/l	95	78	112	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	19.3	15.4	23.2	Immunoinhibition substrate start 37°C
	U/l	11.2	8.95	13.5	Immunoinhibition substrate start 30°C
	U/l	6.85	5.47	8.23	Immunoinhibition substrate start 25°C
	U/l	16.7	13.4	20.0	Immunoinhibition serum start 37°C
	U/l	9.71	7.79	11.6	Immunoinhibition serum start 30°C
	U/l	5.93	4.76	7.10	Immunoinhibition serum start 25°C
	U/l	20.0	16.0	24.0	Immunoinhibition (IFCC) 37°C
	U/l	11.6	9.30	13.9	Immunoinhibition (IFCC) 30°C
CK-MB Mass	ng/ml = µg/l	16.1	11.3	20.9	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	15.8	11.1	20.5	Abbott Architect / Alinity
Homocysteine	µmol/l	19.6	15.7	23.5	Abbott Architect
	µmol/l	31.9	25.5	38.3	Roche Cobas 6000/8000
	µmol/l	22.9	18.3	27.5	Enzymatic
Myoglobin	ng/ml = µg/l	155	109	202	Abbott Architect
Troponin I	ng/ml = µg/l	13.0	10.4	15.6	Ortho Vitros ECi
	ng/l = pg/ml	13000	10400	15600	
	ng/ml = µg/l	2.55	2.04	3.06	Abbott Architect
	ng/l = pg/ml	2550	2040	3060	
	ng/ml = µg/l	10.2	8.16	12.2	Abbott i STAT
	ng/l = pg/ml	10200	8160	12200	
	ng/ml = µg/l	1.16	0.928	1.39	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	1160	928	1392	
	ng/ml = µg/l	2.45	1.96	2.94	Abbott Architect STAT hs
	ng/l = pg/ml	2450	1960	2940	
	ng/ml = µg/l	11.7	9.36	14.0	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	11700	9360	14000	
	ng/ml = µg/l	6.89	5.51	8.27	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	6890	5510	8270	
Troponin T	ng/ml = µg/l	0.244	0.171	0.317	Roche Cobas h232
	ng/l = pg/ml	244	171	317	
	ng/ml = µg/l	0.331	0.232	0.430	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	331	232	430	
	ng/ml = µg/l	0.411	0.288	0.534	Roche Cobas e801 TnT hs
	ng/l = pg/ml	411	288	534	

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot. No. 4648CK Size 1 x 2ml Expiry 2025-12-28

Analyte	unit	Target	Range		methods
			low	high	
CK Total	U/l	870	713	1027	Vitros 37°C
	U/l	661	542	780	CK-NAC (IFCC) 37°C
	U/l	414	339	489	CK-NAC (IFCC) 30°C
	U/l	281	230	332	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	104	83.2	125	Immunoinhibition substrate start 37°C
	U/l	60.4	48.4	72.4	Immunoinhibition substrate start 30°C
	U/l	36.9	29.5	44.3	Immunoinhibition substrate start 25°C
	U/l	102	81.6	122	Immunoinhibition serum start 37°C
	U/l	59.3	47.4	71.2	Immunoinhibition serum start 30°C
	U/l	36.2	29.0	43.4	Immunoinhibition serum start 25°C
	U/l	108	86.4	130	Immunoinhibition (IFCC) 37°C
	U/l	62.8	50.2	75.4	Immunoinhibition (IFCC) 30°C
CK-MB Mass	ng/ml = µg/l	108	75.6	140	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	113	79.1	147	Abbott Architect / Alinity
Homocysteine	µmol/l	39.4	31.5	47.3	Abbott Architect
	µmol/l	67.6	54.1	81.1	Roche Cobas 6000/8000
	µmol/l	40.3	32.2	48.4	Enzymatic
Myoglobin	ng/ml = µg/l	270	189	351	Abbott Architect
Troponin I	ng/ml = µg/l	51.1	40.9	61.3	Ortho Vitros ECI
	ng/l = pg/ml	51100	40900	61300	
	ng/ml = µg/l	46.9	37.5	56.3	Tosoh Series
	ng/l = pg/ml	46900	37500	56300	
	ng/ml = µg/l	44.0	35.2	52.8	Abbott i STAT
	ng/l = pg/ml	44000	35200	52800	
	ng/ml = µg/l	3.14	2.51	3.77	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	3140	2510	3770	
	ng/ml = µg/l	7.93	6.34	9.52	Abbott Architect STAT hs
	ng/l = pg/ml	7930	6340	9520	
	ng/ml = µg/l	23.0	18.4	27.6	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	23000	18400	27600	
	ng/ml = µg/l	12.8	10.2	15.4	Beckman Access 2/DxC600i Hs
ng/l = pg/ml	12800	10200	15400		
Troponin T	ng/ml = µg/l	0.992	0.694	1.290	Roche Cobas Troponin T HS
	ng/l = pg/ml	992	694	1290	
	ng/ml = µg/l	0.592	0.414	0.770	Roche Cobas h232
	ng/l = pg/ml	592	414	770	
	ng/ml = µg/l	0.977	0.684	1.270	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	977	684	1270	
	ng/ml = µg/l	1.230	0.861	1.600	Roche Cobas e801 TnT hs
	ng/l = pg/ml	1230	861	1599	