

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

CAT NO. CQ3100 **LOT NO.** 4794CK, 4795CK, 4796CK
SIZE: 3 x 1 ml **EXPIRY:** 2027-01-28
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 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°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.

EC	REP
----	-----

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

08 Jun '23 me

CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3100 Lot. No. 4794CK Size 1 x 1 ml Expiry 2027-01-28

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	105	86	124	Vitros 37°C
	U/l	77	63	91	CK-NAC (IFCC) 37°C
	U/l	48	39	57	CK-NAC (IFCC) 30°C
	U/l	33	27	39	CK-NAC (IFCC) 25°C
	U/l	79	65	93	CK-NAC substrate start (DGKC) 37°C
	U/l	49	41	57	CK-NAC substrate start (DGKC) 30°C
	U/l	34	28	40	CK-NAC substrate start (DGKC) 25°C
CK-MB Mass	ng/ml = µg/l	5.52	3.86	7.18	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	4.94	3.46	6.42	Abbott Architect / Alinity
Homocysteine	µmol/l	10.1	8.08	12.1	Abbott Architect
	µmol/l	16.4	13.1	19.7	Roche Cobas 6000/8000
	µmol/l	15.0	12.0	18.0	Enzymatic
Myoglobin	ng/ml = µg/l	67.0	46.9	87.1	Abbott Architect
Troponin I	ng/ml = µg/l	0.370	0.296	0.444	Ortho Vitros ECI
	ng/l = pg/ml	370	296	444	
	ng/ml = µg/l	0.113	0.090	0.136	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	113	90.0	136	
	ng/ml = µg/l	0.243	0.194	0.292	Abbott Architect STAT hs
	ng/l = pg/ml	243	194	292	
	ng/ml = µg/l	0.246	0.197	0.295	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	246	197	295	
	ng/ml = µg/l	0.265	0.212	0.318	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	265	212	318	
	ng/ml = µg/l	0.097	0.078	0.116	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	97.0	78.0	116	
	ng/ml = µg/l	0.265	0.210	0.320	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	265	210	320	
Troponin T	ng/ml = µg/l	0.013	0.009	0.017	Roche Cobas Troponin T HS
	ng/l = pg/ml	13.0	9.00	17.0	
	ng/ml = µg/l	0.012	0.008	0.016	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	12.0	8.00	16.0	

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3100 Lot. No. 4795CK Size 1 x 1 ml Expiry 2027-01-28

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	224	184	264	CK-NAC substrate start (DGKC) 37°C
	U/l	140	115	165	CK-NAC substrate start (DGKC) 30°C
	U/l	95	78	112	CK-NAC substrate start (DGKC) 25°C
	U/l	309	253	365	Vitros 37°C
	U/l	218	179	257	CK-NAC (IFCC) 37°C
	U/l	136	112	160	CK-NAC (IFCC) 30°C
	U/l	93	76	110	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	21.8	17.4	26.2	Immunoinhibition substrate start 37°C
	U/l	12.7	10.1	15.3	Immunoinhibition substrate start 30°C
	U/l	7.74	6.18	9.30	Immunoinhibition substrate start 25°C
	U/l	22.3	17.8	26.8	Immunoinhibition (IFCC) 37°C
	U/l	13.0	10.3	15.7	Immunoinhibition (IFCC) 30°C
	U/l	7.92	6.32	9.52	Immunoinhibition (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	20.7	14.5	26.9	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	20.2	14.1	26.3	Abbott Architect / Alinity
Homocysteine	µmol/l	17.8	14.2	21.4	Abbott Architect
	µmol/l	29.8	23.8	35.8	Roche Cobas 6000/8000
	µmol/l	21.6	17.3	25.9	Enzymatic
Myoglobin	ng/ml = µg/l	198	139	257	Abbott Architect
Troponin I	ng/ml = µg/l	11.1	8.88	13.3	Ortho Vitros ECI
	ng/l = pg/ml	11100	8880	13320	
	ng/ml = µg/l	0.930	0.744	1.12	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	930	744	1116	
	ng/ml = µg/l	2.17	1.74	2.60	Abbott Architect STAT hs
	ng/l = pg/ml	2170	1740	2600	
	ng/ml = µg/l	7.45	5.96	8.94	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	7450	5960	8940	
	ng/ml = µg/l	5.70	4.56	6.84	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	5700	4560	6840	
Troponin T	ng/ml = µg/l	2.20	1.76	2.64	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	2200	1760	2640	
	ng/ml = µg/l	0.360	0.252	0.468	Roche Cobas Troponin T HS
	ng/l = pg/ml	360	252	468	
	ng/ml = µg/l	0.220	0.154	0.286	Roche Cobas h232
	ng/l = pg/ml	220	154	286	
	ng/ml = µg/l	0.340	0.238	0.442	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	340	238	442	

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3100 Lot. No. 4796CK Size 1 x 1 ml Expiry 2027-01-28

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	576	472	680	CK-NAC substrate start (DGKC) 37°C
	U/l	361	295	427	CK-NAC substrate start (DGKC) 30°C
	U/l	245	201	289	CK-NAC substrate start (DGKC) 25°C
	U/l	764	626	902	Vitros 37°C
	U/l	558	458	658	CK-NAC (IFCC) 37°C
	U/l	349	287	411	CK-NAC (IFCC) 30°C
	U/l	237	195	279	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	120	96.0	144	Vitros 37°C
	U/l	103	82.4	124	Immunoinhibition substrate start 37°C
	U/l	59.9	47.9	71.9	Immunoinhibition substrate start 30°C
	U/l	36.6	29.3	43.9	Immunoinhibition substrate start 25°C
	U/l	99.0	79.2	119	Immunoinhibition serum start 37°C
	U/l	57.5	46.0	69.0	Immunoinhibition serum start 30°C
	U/l	35.1	28.1	42.1	Immunoinhibition serum start 25°C
	U/l	102	81.6	122	Immunoinhibition (IFCC) 37°C
	U/l	59.3	47.4	71.2	Immunoinhibition (IFCC) 30°C
	U/l	36.2	29.0	43.4	Immunoinhibition (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	108	75.6	140	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	108	75.6	140	Abbott Architect / Alinity
Homocysteine	µmol/l	35.5	28.4	42.6	Abbott Architect
	µmol/l	58.7	47.0	70.4	Roche Cobas 6000/8000
	µmol/l	36.5	29.2	43.8	Enzymatic
Myoglobin	ng/ml = µg/l	285	200	371	Abbott Architect
Troponin I	ng/ml = µg/l	45.1	36.1	54.1	Ortho Vitros ECI
	ng/l = pg/ml	45100	36100	54100	
	ng/ml = µg/l	7.40	5.92	8.88	Abbott Architect
	ng/l = pg/ml	7400	5920	8880	
	ng/ml = µg/l	2.61	2.09	3.13	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	2610	2090	3130	
	ng/ml = µg/l	6.86	5.49	8.23	Abbott Architect STAT hs
	ng/l = pg/ml	6860	5490	8230	
	ng/ml = µg/l	22.3	17.8	26.8	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	22300	17800	26800	
	ng/ml = µg/l	11.9	9.52	14.3	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	11900	9520	14280	
	ng/ml = µg/l	12.8	10.2	15.4	Beckman Dxl Hs
	ng/l = pg/ml	12800	10200	15400	
Troponin T	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	0.649	0.454	0.844	Roche Cobas h232
	ng/l = pg/ml	649	454	844	
	ng/ml = µg/l	1.020	0.714	1.330	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	1020	714	1326	