

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

CAT. NO. CQ3259 **LOT NO.** 4681CK, 4682CK, 4683CK
SIZE: 3 x 2 ml **EXPIRY:** 2026-08-28
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.



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CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3259 Lot. No. 4681CK Size 1 x 2ml Expiry 2026-08-28

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	89	73	105	CK-NAC substrate start (DGKC) 37°C
	U/l	56	46	66	CK-NAC substrate start (DGKC) 30°C
	U/l	38	31	45	CK-NAC substrate start (DGKC) 25°C
	U/l	107	88	126	Vitros 37°C
	U/l	82	67	97	CK-NAC (IFCC) 37°C
	U/l	51	42	60	CK-NAC (IFCC) 30°C
	U/l	35	28	42	CK-NAC (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	3.69	2.58	4.80	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	3.06	2.14	3.98	Abbott Architect / Alinity
Homocysteine	µmol/l	11.0	8.80	13.2	Abbott Architect
	µmol/l	15.7	12.6	18.8	Roche Cobas 6000/8000
	µmol/l	15.6	12.5	18.7	Enzymatic
Myoglobin	ng/ml = µg/l	67.5	47.3	87.8	Abbott Architect
Troponin I	ng/ml = µg/l	0.341	0.273	0.409	Ortho Vitros ECi
	ng/l = pg/ml	341	273	409	
	ng/ml = µg/l	0.575	0.460	0.690	Tosoh Series
	ng/l = pg/ml	575	460	690	
	ng/ml = µg/l	0.107	0.086	0.128	Abbott Architect
	ng/l = pg/ml	107	86.0	128	
	ng/ml = µg/l	0.398	0.318	0.478	Abbott i STAT
	ng/l = pg/ml	398	318	478	
	ng/ml = µg/l	0.110	0.088	0.132	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	110	88.0	132	
	ng/l = pg/ml	0.047	0.037	0.057	
	ng/ml = µg/l	0.109	0.087	0.131	Abbott Architect STAT hs
	ng/l = pg/ml	109	87.0	131	
	ng/ml = µg/l	0.244	0.195	0.293	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	244	195	293	
	ng/ml = µg/l	0.170	0.136	0.204	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	170	136	204	
	ng/ml = µg/l	0.056	0.045	0.067	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	56.0	45.0	67.0	
Troponin T	ng/ml = µg/l	0.014	0.010	0.018	Roche Cobas Troponin T HS
	ng/l = pg/ml	14.2	10.0	18.4	
	ng/ml = µg/l	0.013	0.009	0.017	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	13.4	9.00	17.8	
	ng/ml = µg/l	0.015	0.010	0.019	Roche Cobas e801 TnT hs
	ng/l = pg/ml	14.6	10.0	19.2	
	ng/ml = µg/l	0.014	0.010	0.018	Roche Cobas e801 TnT hs STAT
	ng/l = pg/ml	13.9	10.0	17.8	

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot. No. 4682CK Size 1 x 2ml Expiry 2026-08-28

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	78.0	112	CK-NAC substrate start (DGKC) 25°C
	U/l	285	234	336	Vitros 37°C
	U/l	219	180	258	CK-NAC (IFCC) 37°C
	U/l	137	113	161	CK-NAC (IFCC) 30°C
	U/l	93	77	109	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	12.7	10.2	15.2	Vitros 37°C
	U/l	19.9	15.9	23.9	Immunoinhibition substrate start 37°C
	U/l	11.6	9.24	14.0	Immunoinhibition substrate start 30°C
	U/l	7.06	5.64	8.48	Immunoinhibition substrate start 25°C
	U/l	18.1	14.5	21.7	Immunoinhibition serum start 37°C
	U/l	10.5	8.43	12.6	Immunoinhibition serum start 30°C
	U/l	6.43	5.15	7.71	Immunoinhibition serum start 25°C
	U/l	18.8	15.0	22.6	Immunoinhibition (IFCC) 37°C
	U/l	10.9	8.72	13.1	Immunoinhibition (IFCC) 30°C
	U/l	6.67	5.33	8.01	Immunoinhibition (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	16.5	11.6	21.5	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	16.7	11.7	21.7	Abbott Architect / Alinity
Homocysteine	µmol/l	20.1	16.1	24.1	Abbott Architect
	µmol/l	31.0	24.8	37.2	Roche Cobas 6000/8000
	µmol/l	24.1	19.3	28.9	Enzymatic
Myoglobin	ng/ml = µg/l	192	134	250	Abbott Architect
Troponin I	ng/ml = µg/l	10.1	8.08	12.1	Ortho Vitros ECi
	ng/l = pg/ml	10100	8080	12120	
	ng/ml = µg/l	1.63	1.30	1.96	Abbott Architect
	ng/l = pg/ml	1630	1300	1960	
	ng/ml = µg/l	9.67	7.74	11.6	Abbott i STAT
	ng/l = pg/ml	9670	7740	11600	
	ng/ml = µg/l	0.580	0.470	0.700	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	583	466	700	
	ng/ml = µg/l	1.61	1.29	1.93	Abbott Architect STAT hs
	ng/l = pg/ml	1610	1290	1930	
	ng/ml = µg/l	8.15	6.52	9.78	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	8150	6520	9780	
	ng/ml = µg/l	4.78	3.82	5.74	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	4780	3820	5740	
	ng/ml = µg/l	1.48	1.18	1.78	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	1480	1180	1780	
	ng/ml = µg/l	5.08	4.06	6.10	Siemens Atellica IM
	ng/l = pg/ml	5080	4060	6100	
Troponin T	ng/ml = µg/l	0.340	0.238	0.442	Roche Cobas Troponin T HS
	ng/l = pg/ml	340	238	442	

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot. No. 4682CK Size 1 x 2ml Expiry 2026-08-28

Range					
Analyte	unit	Target	low	high	methods
Troponin T	ng/ml = µg/l	0.161	0.113	0.209	Roche Cobas h232
	ng/l = pg/ml	161	113	209	
	ng/ml = µg/l	0.313	0.219	0.407	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	313	219	407	
	ng/ml = µg/l	0.339	0.237	0.441	Roche Cobas e801 TnT hs
	ng/l = pg/ml	339	237	441	
	ng/ml = µg/l	0.359	0.251	0.467	Roche Cobas e801 TnT hs STAT
	ng/l = pg/ml	359	251	467	

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot. No. 4683CK Size 1 x 2ml Expiry 2026-08-28

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	744	610	878	Vitros 37°C
	U/l	566	464	668	CK-NAC (IFCC) 37°C
	U/l	354	290	418	CK-NAC (IFCC) 30°C
	U/l	241	197	285	CK-NAC (IFCC) 25°C
	U/l	586	481	691	CK-NAC substrate start (DGKC) 37°C
	U/l	367	301	433	CK-NAC substrate start (DGKC) 30°C
	U/l	249	204	294	CK-NAC substrate start (DGKC) 25°C
CK-MB Activity	U/l	89.4	71.5	107	Vitros 37°C
	U/l	94.9	75.9	114	Immunoinhibition substrate start 37°C
	U/l	55.2	44.1	66.3	Immunoinhibition substrate start 30°C
	U/l	33.7	26.9	40.5	Immunoinhibition substrate start 25°C
	U/l	99.4	79.5	119	Immunoinhibition serum start 37°C
	U/l	57.8	46.2	69.4	Immunoinhibition serum start 30°C
	U/l	35.3	28.2	42.4	Immunoinhibition serum start 25°C
	U/l	95.0	76.0	114	Immunoinhibition (IFCC) 37°C
	U/l	55.2	44.2	66.2	Immunoinhibition (IFCC) 30°C
	U/l	33.7	27.0	40.4	Immunoinhibition (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	101	70.7	131	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	104	72.8	135	Abbott Architect / Alinity
Homocysteine	µmol/l	35.0	28.0	42.0	Abbott Architect
	µmol/l	57.9	46.3	69.5	Roche Cobas 6000/8000
	µmol/l	38.9	31.1	46.7	Enzymatic
Myoglobin	ng/ml = µg/l	291	204	378	Abbott Architect
Troponin I	ng/ml = µg/l	43.7	35.0	52.4	Ortho Vitros ECi
	ng/l = pg/ml	43700	35000	52400	
	ng/ml = µg/l	46.4	37.1	55.7	Tosoh Series
	ng/l = pg/ml	46400	37100	55700	
	ng/ml = µg/l	5.60	4.48	6.72	Abbott Architect
	ng/l = pg/ml	5600	4480	6720	
	ng/ml = µg/l	38.3	30.6	46.0	Abbott i STAT
	ng/l = pg/ml	38300	30600	46000	
	ng/ml = µg/l	1.73	1.38	2.08	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	1730	1380	2080	
	ng/ml = µg/l	5.58	4.46	6.70	Abbott Architect STAT hs
	ng/l = pg/ml	5580	4460	6700	
	ng/ml = µg/l	38.2	30.6	45.8	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	38160	30600	46000	
	ng/ml = µg/l	20.6	16.5	24.7	Siemens Centaur CP/XP/XPT TNIH
	ng/l = pg/ml	20600	16500	24700	
	ng/ml = µg/l	8.47	6.78	10.2	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	8470	6780	10160	
	ng/ml = µg/l	21.5	17.2	25.8	Siemens Atellica IM
	ng/l = pg/ml	21500	17200	25800	

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot. No. 4683CK Size 1 x 2ml Expiry 2026-08-28

Range					
Analyte	unit	Target	low	high	methods
Troponin T	ng/ml = µg/l	0.735	0.515	0.956	Roche Cobas Troponin T HS
	ng/l = pg/ml	735	515	955	
	ng/ml = µg/l	0.444	0.311	0.577	Roche Cobas h232
	ng/l = pg/ml	0.189	0.132	0.246	
	ng/ml = µg/l	0.730	0.511	0.949	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	730	511	949	
	ng/ml = µg/l	0.853	0.597	1.110	Roche Cobas e801 TnT hs
	ng/l = pg/ml	853	597	1109	
	ng/ml = µg/l	0.897	0.628	1.170	Roche Cobas e801 TnT hs STAT
	ng/l = pg/ml	897	628	1166	