

## IMPORTANT NOTICE

CQ3259

4369CK

Troponin I is stable for 1 hour after reconstitution and when stored refrigerated at +2°C to +8°C.

Troponin I is also stable for 2 weeks at -20°C if frozen within 1 hour after reconstitution and kept in the original container, free from contamination.

Authorised by: Gareth Little  
Serum QC Manager  
Date: 01 August 2019

Ref: CCS5712

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

**CAT. NO.** CQ3259

**LOT NO.** 4369CK, 4370CK, 4371CK

**SIZE:** 3 x 2 ml

**EXPIRY:** 2023-01-28

**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: All lots are stable for 5 days at +2°C to +8°C, with the exception of 4369CK which is stable for 1 hour after reconstitution and when stored refrigerated at +2°C to +8°C. Troponin I is also stable for 2 weeks frozen at -20°C, if frozen within 1 hour after reconstitution and kept in the original container 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. 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. 4369CK Size: 1 x 2 ml Expiry: 2023-01-28

Analyte	unit	Target	Range		methods
			low	high	
CK Total	U/l	86	71	101	CK-NAC substrate start (DGKC) 37°C
	U/l	54	44	64	CK-NAC substrate start (DGKC) 30°C
	U/l	37	30	44	CK-NAC substrate start (DGKC) 25°C
	U/l	103	84	122	Vitros 37°C
	U/l	84	69	99	CK-NAC (IFCC) 37°C
	U/l	53	43	63	CK-NAC (IFCC) 30°C
	U/l	36	29	43	CK-NAC (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	4.33	3.03	5.63	Siemens Dimension
	ng/ml = µg/l	7.78	5.45	10.1	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	5.66	3.96	7.36	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	6.78	4.75	8.81	Beckman Coulter Access
	ng/ml = µg/l	5.10	3.57	6.63	Abbott Architect
	ng/ml = µg/l	6.81	4.77	8.85	Beckman Dxl800
Homocysteine	µmol/l	10.8	8.64	13.0	Abbott Architect
	µmol/l	14.7	11.8	17.6	Roche Cobas 6000/8000
	µmol/l	16.0	12.8	19.2	Enzymatic
Myoglobin	ng/ml = µg/l	42.8	30.0	55.6	Roche Elecsys
	ng/ml = µg/l	36.7	25.7	47.7	Beckman Coulter Access
	ng/ml = µg/l	57.1	40.0	74.2	Abbott Architect
	ng/ml = µg/l	36.2	25.3	47.1	Beckman Dxl800
	ng/ml = µg/l	66.5	46.6	86.5	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.215	0.172	0.258	Siemens Immulite 1000
	ng/l = pg/ml	215	172	258	
	ng/ml = µg/l	0.352	0.282	0.422	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	352	282	422	
	ng/ml = µg/l	0.309	0.247	0.371	Ortho Vitros ECi
	ng/l = pg/ml	309	247	371	
	ng/ml = µg/l	0.184	0.147	0.221	Abbott Architect
	ng/l = pg/ml	184	147	221	
	ng/ml = µg/l	0.358	0.286	0.430	Abbott i STAT
	ng/l = pg/ml	358	286	430	
	ng/ml = µg/l	0.151	0.121	0.181	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	151	121	181	
	ng/ml = µg/l	0.077	0.062	0.092	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	77.0	62.0	92.0	
	ng/ml = µg/l	0.207	0.166	0.248	Siemens Dimension Exl LOCI
	ng/l = pg/ml	207	166	248	
	ng/ml = µg/l	0.186	0.149	0.223	Abbott Architect STAT hs
	ng/l = pg/ml	186	149	223	
	ng/ml = µg/l	0.070	0.056	0.084	Beckman Access - AccuTnl+3
	ng/l = pg/ml	70.0	56.0	84.0	
ng/ml = µg/l	0.273	0.218	0.328	Siemens Centaur CP	
ng/l = pg/ml	273	218	328		

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

Cat. No. CQ3259 Lot No. 4369CK Size: 1 x 2 ml Expiry: 2023-01-28

Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	0.321	0.257	0.385	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	321	257	385	
	ng/ml = µg/l	0.463	0.370	0.556	Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH)
	ng/l = pg/ml	463	370	556	
Troponin I	ng/ml = µg/l	0.100	0.080	0.120	Beckman Access 2 / DxC 600i Hs
	ng/l = pg/ml	100	80.0	120	
Troponin T	ng/ml = µg/l	0.014	0.010	0.018	Roche Cobas Troponin T HS
	ng/l = pg/ml	14.0	10.0	18.0	
	ng/ml = µg/l	0.040	0.028	0.052	Roche h232
	ng/l = pg/ml	40.0	28.0	52.0	
Troponin T	ng/ml = µg/l	0.013	0.009	0.017	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	13.0	9.00	17.0	

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

Cat. No. CQ3259 Lot No. 4370CK Size: 1 x 2 ml Expiry: 2023-01-28

Analyte	unit	Target	Range		methods
			low	high	
CK Total	U/l	251	206	296	CK-NAC substrate start (DGKC) 37°C
	U/l	157	129	185	CK-NAC substrate start (DGKC) 30°C
	U/l	107	88	126	CK-NAC substrate start (DGKC) 25°C
	U/l	331	271	391	Vitros 37°C
	U/l	243	199	287	CK-NAC (IFCC) 37°C
	U/l	152	125	179	CK-NAC (IFCC) 30°C
	U/l	103	85	121	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	29.2	23.4	35.0	Vitros 37°C
	U/l	28.9	23.1	34.7	Immunoinhibition substrate start 37°C
	U/l	16.8	13.4	20.2	Immunoinhibition substrate start 30°C
	U/l	10.3	8.20	12.4	Immunoinhibition substrate start 25°C
	U/l	28.0	22.4	33.6	Immunoinhibition serum start 37°C
	U/l	16.3	13.0	19.6	Immunoinhibition serum start 30°C
	U/l	9.94	7.95	11.9	Immunoinhibition serum start 25°C
	U/l	27.2	21.8	32.6	Immunoinhibition (IFCC) 37°C
	U/l	15.8	12.7	18.9	Immunoinhibition (IFCC) 30°C
	U/l	9.66	7.74	11.6	Immunoinhibition (IFCC) 25°C
	U/l	29.7	23.8	35.6	Randox Immunoinhibition substrate start 37°C
	U/l	17.3	13.8	20.8	Randox Immunoinhibition substrate start 30°C
	U/l	10.5	8.45	12.6	Randox Immunoinhibition substrate start 25°C
	U/l	28.7	23.0	34.4	Randox Immunoinhibition serum start 37°C
U/l	16.7	13.4	20.0	Randox Immunoinhibition serum start 30°C	
U/l	10.2	8.17	12.2	Randox Immunoinhibition serum start 25°C	
CK-MB Mass	ng/ml = µg/l	27.3	19.1	35.5	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	20.9	14.6	27.2	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	28.8	20.2	37.4	Beckman Coulter Access
	ng/ml = µg/l	22.1	15.5	28.7	Abbott Architect
	ng/ml = µg/l	30.7	21.5	39.9	Beckman Dxl800
	ng/ml = µg/l	19.6	13.7	25.5	Abbott i STAT
Homocysteine	µmol/l	18.5	14.8	22.2	Abbott Architect
	µmol/l	27.1	21.7	32.5	Roche Cobas 6000/8000
	µmol/l	22.9	18.3	27.5	Enzymatic
Myoglobin	ng/ml = µg/l	122	85.4	159	Roche Elecsys
	ng/ml = µg/l	101	70.7	131	Beckman Coulter Access
	ng/ml = µg/l	169	118	220	Abbott Architect
	ng/ml = µg/l	200	140	260	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	7.98	6.38	9.58	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	7980	6380	9580	
	ng/ml = µg/l	10.9	8.72	13.1	Ortho Vitros ECi
	ng/l = pg/ml	10900	8720	13100	
	ng/ml = µg/l	1.33	1.06	1.60	Abbott Architect
ng/l = pg/ml	1330	1060	1600		

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

Cat. No. CQ3259 Lot No. 4370CK Size: 1 x 2 ml Expiry: 2023-01-28

Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	7.23	5.78	8.68	Abbott i STAT
	ng/l = pg/ml	7230	5780	8680	
	ng/ml = µg/l	2.20	1.76	2.64	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	2200	1760	2640	
	ng/ml = µg/l	1.68	1.34	2.02	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	1680	1340	2020	
	ng/ml = µg/l	1.98	1.58	2.38	Siemens Dimension Exl LOCI
	ng/l = pg/ml	1980	1580	2380	
	ng/ml = µg/l	1.39	1.11	1.67	Abbott Architect STAT hs
	ng/l = pg/ml	1390	1110	1670	
	ng/ml = µg/l	0.875	0.700	1.05	Beckman Dxl - AccuTnl+3
	ng/l = pg/ml	875	700	1050	
	ng/ml = µg/l	0.979	0.783	1.17	Beckman Access - AccuTnl+3
	ng/l = pg/ml	979	783	1175	
	ng/ml = µg/l	6.65	5.32	7.98	Siemens Centaur CP
	ng/l = pg/ml	6650	5320	7980	
ng/ml = µg/l	8.54	6.83	10.2	bioMerieux VIDAS hs Troponin I	
ng/l = pg/ml	8540	6830	10200		
ng/ml = µg/l	6.82	5.46	8.18	Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH)	
ng/l = pg/ml	6820	5460	8180		
ng/ml = µg/l	2.91	2.33	3.50	Beckman Access 2 / DxC 600i Hs	
ng/l = pg/ml	2914	2330	3500		
Troponin T	ng/ml = µg/l	0.430	0.301	0.559	Roche Cobas Troponin T HS
	ng/l = pg/ml	430	301	559	
	ng/ml = µg/l	0.174	0.122	0.226	Roche h232
	ng/l = pg/ml	174	122	226	
ng/ml = µg/l	0.384	0.269	0.499	Roche Cobas Troponin T hs STAT	
ng/l = pg/ml	384	269	499		

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

Cat. No. CQ3259 Lot No. 4371CK Size: 1 x 2 ml Expiry: 2023-01-28

Analyte	unit	Target	Range		methods
			low	high	
CK Total	U/l	623	511	735	CK-NAC substrate start (DGKC) 37°C
	U/l	390	320	460	CK-NAC substrate start (DGKC) 30°C
	U/l	265	217	313	CK-NAC substrate start (DGKC) 25°C
	U/l	819	672	966	Vitros 37°C
	U/l	644	528	760	CK-NAC (IFCC) 37°C
	U/l	403	331	475	CK-NAC (IFCC) 30°C
	U/l	274	224	324	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	147	118	176	Vitros 37°C
	U/l	149	119	179	Immunoinhibition substrate start 37°C
	U/l	86.6	69.2	104	Immunoinhibition substrate start 30°C
	U/l	52.9	42.2	63.6	Immunoinhibition substrate start 25°C
	U/l	152	122	182	Immunoinhibition serum start 37°C
	U/l	88.3	70.9	106	Immunoinhibition serum start 30°C
	U/l	54.0	43.3	64.7	Immunoinhibition serum start 25°C
	U/l	147	118	176	Immunoinhibition (IFCC) 37°C
	U/l	85.4	68.6	102	Immunoinhibition (IFCC) 30°C
	U/l	52.2	41.9	62.5	Immunoinhibition (IFCC) 25°C
	U/l	150	120	180	Randox Immunoinhibition substrate start 37°C
	U/l	87.2	69.7	105	Randox Immunoinhibition substrate start 30°C
	U/l	53.3	42.6	64.0	Randox Immunoinhibition substrate start 25°C
	U/l	144	115	173	Randox Immunoinhibition serum start 37°C
U/l	83.7	66.8	101	Randox Immunoinhibition serum start 30°C	
U/l	51.1	40.8	61.4	Randox Immunoinhibition serum start 25°C	
CK-MB Mass	ng/ml = µg/l	169	118	220	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	140	98.0	182	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	199	139	259	Beckman Coulter Access
	ng/ml = µg/l	145	102	189	Abbott Architect
	ng/ml = µg/l	202	141	263	Beckman DxI800
	ng/ml = µg/l	139	97.3	181	Abbott i STAT
Homocysteine	µmol/l	34.7	27.8	41.6	Abbott Architect
	µmol/l	61.4	49.1	73.7	Roche Cobas 6000/8000
	µmol/l	41.0	32.8	49.2	Enzymatic
Myoglobin	ng/ml = µg/l	182	127	237	Roche Elecsys
	ng/ml = µg/l	152	106	198	Beckman Coulter Access
	ng/ml = µg/l	251	176	326	Abbott Architect
	ng/ml = µg/l	163	114	212	Beckman DxI800
	ng/ml = µg/l	307	215	399	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	30.0	24.0	36.0	Siemens Immulite 1000
	ng/l = pg/ml	30000	24000	36000	
	ng/ml = µg/l	37.8	30.2	45.4	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	37800	30200	45400	
	ng/ml = µg/l	75.1	60.1	90.1	Ortho Vitros Eci
	ng/l = pg/ml	75100	60100	90100	

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

Cat. No. CQ3259 Lot No. 4371CK Size: 1 x 2 ml Expiry: 2023-01-28

Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	8.77	7.02	10.5	Abbott Architect
	ng/l = pg/ml	8770	7020	10500	
	ng/ml = µg/l	40.6	32.5	48.7	Abbott i STAT
	ng/l = pg/ml	40600	32500	48700	
	ng/ml = µg/l	10.5	8.40	12.6	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	10500	8400	12600	
	ng/ml = µg/l	15.7	12.6	18.8	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	15700	12600	18800	
	ng/ml = µg/l	9.94	7.95	11.9	Siemens Dimension Exl LOCI
	ng/l = pg/ml	9940	7950	11900	
	ng/ml = µg/l	8.05	6.44	9.66	Abbott Architect STAT hs
	ng/l = pg/ml	8050	6440	9660	
	ng/ml = µg/l	5.86	4.69	7.03	Beckman Dxl - AccuTnl+3
	ng/l = pg/ml	5860	4690	7030	
ng/ml = µg/l	6.58	5.26	7.90	Beckman Access - AccuTnl+3	
ng/l = pg/ml	6580	5260	7900		
ng/ml = µg/l	24.5	19.6	29.4	Beckman Access 2 / DxC 600i Hs	
ng/l = pg/ml	24500	19600	29400		
Troponin T	ng/ml = µg/l	1.130	0.791	1.470	Roche Cobas Troponin T HS
	ng/l = pg/ml	1130	791	1469	
	ng/ml = µg/l	0.568	0.398	0.738	Roche h232
	ng/l = pg/ml	568	398	738	
ng/ml = µg/l	1.060	0.742	1.380	Roche Cobas Troponin T hs STAT	
ng/l = pg/ml	1060	742	1378		