

PRODUCT INFORMATION

CQ3100

4490CK

Troponin I is stable for 2 days 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.

CCS6460

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

CAT NO. CQ3100 **LOT NO.** 4490CK-4491CK-4492CK
SIZE: 3 x 1 ml **EXPIRY:** 2021-11-28
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. After reconstitution, troponin I in **Cardiac Control Level I (4490CK)** is stable for **2 days** at +2°C to +8°C if kept capped in original container and free from contamination. For **all levels**, Troponin I is stable for 2 weeks at -20°C if frozen within 1 hour of reconstitution and kept capped in 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°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.

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CARDIAC CONTROL LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3100 Lot. No. 4490CK Size 1 x 1ml Expiry 2021-11-28

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	123	101	145	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	7.14	5.00	9.28	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	5.31	3.72	6.90	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	4.93	3.45	6.41	Abbott Architect
	ng/ml = µg/l	4.28	3.00	5.56	Abbott i STAT
Homocysteine	µmol/l	11.1	8.88	13.3	Abbott Architect
	µmol/l	14.3	11.4	17.2	Roche Cobas 6000/8000
	µmol/l	15.1	12.1	18.1	Enzymatic
Myoglobin	ng/ml = µg/l	67.0	46.9	87.1	Roche Elecsys
	ng/ml = µg/l	50.1	35.1	65.1	Abbott Architect
	ng/ml = µg/l	64.2	44.9	83.5	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.235	0.188	0.282	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	235	188	282	
	ng/ml = µg/l	0.275	0.220	0.330	Ortho Vitros ECI
	ng/l = pg/ml	275	220	330	
	ng/ml = µg/l	0.170	0.136	0.204	Abbott Architect
	ng/l = pg/ml	170	136	204	
	ng/ml = µg/l	0.216	0.173	0.259	Abbott i STAT
	ng/l = pg/ml	216	173	259	
	ng/ml = µg/l	0.110	0.088	0.132	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	110	88.0	132	
	ng/ml = µg/l	0.064	0.051	0.077	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	64.0	51.0	77.0	
	ng/ml = µg/l	0.168	0.134	0.202	Abbott Architect STAT hs
	ng/l = pg/ml	168	134	202	
	ng/ml = µg/l	0.148	0.118	0.178	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	148	118	178	
ng/ml = µg/l	0.313	0.250	0.376	Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH)	
ng/l = pg/ml	313	250	376		
ng/ml = µg/l	0.068	0.054	0.082	Beckman Access 2/DxC600i Hs	
ng/l = pg/ml	68.0	54.0	82.0		
ng/ml = µg/l	0.081	0.065	0.097	Beckman Dxl Hs	
ng/l = pg/ml	81.0	65.0	97.0		
Troponin T	ng/ml = µg/l	0.016	0.011	0.021	Roche Cobas Troponin T HS
	ng/l = pg/ml	16.0	11.0	21.0	
	ng/ml = µg/l	0.040	0.028	0.052	Roche h232
	ng/l = pg/ml	40.0	28.0	52.0	

CARDIAC CONTROL LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3100 Lot. No. 4490CK Size 1 x 1ml Expiry 2021-11-28

Range

Analyte	unit	Target	low	high	methods
Troponin T	ng/ml = µg/l	0.016	0.011	0.021	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	16.0	11.0	21.0	

CARDIAC CONTROL LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3100 Lot. No. 4491CK Size 1 x 1ml Expiry 2021-11-28

Analyte	unit	Target	Range		methods
			low	high	
CK Total	U/l	236	194	278	CK-NAC substrate start (DGKC) 37°C
	U/l	148	121	175	CK-NAC substrate start (DGKC) 30°C
	U/l	100	82	118	CK-NAC substrate start (DGKC) 25°C
	U/l	309	253	365	Vitros 37°C
	U/l	225	185	266	CK-NAC (IFCC) 37°C
	U/l	141	116	166	CK-NAC (IFCC) 30°C
	U/l	96	79	113	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	24.2	19.4	29.0	Vitros 37°C
	U/l	22.3	17.8	26.8	Immunoinhibition substrate start 37°C
	U/l	13.0	10.3	15.7	Immunoinhibition substrate start 30°C
	U/l	7.92	6.32	9.52	Immunoinhibition substrate start 25°C
	U/l	22.4	17.9	26.9	Immunoinhibition serum start 37°C
	U/l	13.0	10.4	15.6	Immunoinhibition serum start 30°C
	U/l	7.95	6.35	9.55	Immunoinhibition serum start 25°C
	U/l	22.6	18.1	27.1	Immunoinhibition (IFCC) 37°C
	U/l	13.1	10.5	15.7	Immunoinhibition (IFCC) 30°C
	U/l	8.02	6.43	9.61	Immunoinhibition (IFCC) 25°C
	U/l	23.9	19.1	28.7	Randox Immunoinhibition substrate start 37°C
	U/l	13.9	11.1	16.7	Randox Immunoinhibition substrate start 30°C
	U/l	8.48	6.78	10.2	Randox Immunoinhibition substrate start 25°C
	U/l	22.6	18.1	27.1	Randox Immunoinhibition serum start 37°C
U/l	13.1	10.5	15.8	Randox Immunoinhibition serum start 30°C	
U/l	8.02	6.43	9.62	Randox Immunoinhibition serum start 25°C	
CK-MB Mass	ng/ml = µg/l	26.9	18.8	35.0	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	19.1	13.4	24.8	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	20.1	14.1	26.1	Abbott Architect
Homocysteine	µmol/l	18.6	14.9	22.3	Abbott Architect
	µmol/l	26.3	21.0	31.6	Roche Cobas 6000/8000
	µmol/l	22.8	18.2	27.4	Enzymatic
Myoglobin	ng/ml = µg/l	183	128	238	Roche Elecsys
	ng/ml = µg/l	139	97.3	181	Abbott Architect
	ng/ml = µg/l	175	123	228	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	4.44	3.55	5.33	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	4440	3550	5330	
	ng/ml = µg/l	6.00	4.80	7.20	Ortho Vitros Eci
	ng/l = pg/ml	6000	4800	7200	
	ng/ml = µg/l	1.65	1.32	1.98	Abbott Architect
	ng/l = pg/ml	1650	1320	1980	
	ng/ml = µg/l	3.64	2.91	4.37	Abbott i STAT
	ng/l = pg/ml	3640	2910	4370	
	ng/ml = µg/l	1.29	1.03	1.55	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	1290	1030	1550	

CARDIAC CONTROL LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3100 Lot. No. 4491CK Size 1 x 1ml Expiry 2021-11-28

Range						
Analyte	unit	Target	low	high	methods	
Troponin I	ng/ml = µg/l	1.35	1.08	1.62	Siemens Dimension Exl LOCI	
	ng/l = pg/ml	1350	1080	1620		
	ng/ml = µg/l	1.67	1.34	2.00	Abbott Architect STAT hs	
	ng/l = pg/ml	1670	1340	2000		
	ng/ml = µg/l	0.788	0.630	0.946	Beckman Access - AccuTnl+3	
	ng/l = pg/ml	788	630	946		
	ng/ml = µg/l	4.60	3.68	5.52	Siemens Centaur CP	
	ng/l = pg/ml	4600	3680	5520		
	ng/ml = µg/l	3.47	2.78	4.16	bioMerieux VIDAS hs Troponin I	
	ng/l = pg/ml	3470	2780	4160		
	ng/ml = µg/l	4.34	3.47	5.21	Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH)	
	ng/l = pg/ml	4340	3470	5210		
Troponin T	ng/ml = µg/l	1.45	1.16	1.74	Beckman Access 2/DxC600i Hs	
	ng/l = pg/ml	1450	1160	1740		
	ng/ml = µg/l	1.57	1.26	1.88	Beckman Dxl Hs	
	ng/l = pg/ml	1570	1260	1880		
	Troponin T	ng/ml = µg/l	0.468	0.328	0.608	Roche Cobas Troponin T HS
		ng/l = pg/ml	468	328	608	
		ng/ml = µg/l	0.312	0.218	0.406	Roche h232
		ng/l = pg/ml	312	218	406	
		ng/ml = µg/l	0.468	0.328	0.608	Roche Cobas Troponin T hs STAT
		ng/l = pg/ml	468	328	608	

CARDIAC CONTROL LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3100 Lot. No. 4492CK

Size 1 x 1ml Expiry 2021-11-28

Analyte	unit	Target	Range		methods
			low	high	
CK Total	U/l	680	558	802	CK-NAC substrate start (DGKC) 37°C
	U/l	426	349	503	CK-NAC substrate start (DGKC) 30°C
	U/l	289	237	341	CK-NAC substrate start (DGKC) 25°C
	U/l	623	511	735	CK-NAC (IFCC) 37°C
	U/l	390	320	460	CK-NAC (IFCC) 30°C
	U/l	265	217	313	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	132	106	158	Vitros 37°C
	U/l	135	108	162	Immuno-inhibition substrate start 37°C
	U/l	78.5	62.8	94.2	Immuno-inhibition substrate start 30°C
	U/l	47.9	38.3	57.5	Immuno-inhibition substrate start 25°C
	U/l	137	110	164	Immuno-inhibition serum start 37°C
	U/l	79.6	63.9	95.3	Immuno-inhibition serum start 30°C
	U/l	48.6	39.1	58.1	Immuno-inhibition serum start 25°C
	U/l	134	107	161	Immuno-inhibition (IFCC) 37°C
	U/l	77.9	62.2	93.6	Immuno-inhibition (IFCC) 30°C
	U/l	47.6	38.0	57.2	Immuno-inhibition (IFCC) 25°C
	U/l	135	108	162	Randox Immuno-inhibition substrate start 37°C
	U/l	78.5	62.8	94.2	Randox Immuno-inhibition substrate start 30°C
	U/l	47.9	38.3	57.5	Randox Immuno-inhibition substrate start 25°C
	U/l	131	105	157	Randox Immuno-inhibition serum start 37°C
U/l	76.1	61.0	91.2	Randox Immuno-inhibition serum start 30°C	
U/l	46.5	37.3	55.7	Randox Immuno-inhibition serum start 25°C	
CK-MB Mass	ng/ml = µg/l	178	125	231	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	141	98.7	183	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	153	107	199	Abbott Architect
	ng/ml = µg/l	144	101	187	Abbott i STAT
Homocysteine	µmol/l	35.3	28.2	42.4	Abbott Architect
	µmol/l	55.8	44.6	67.0	Roche Cobas 6000/8000
	µmol/l	39.7	31.8	47.6	Enzymatic
Myoglobin	ng/ml = µg/l	282	197	367	Roche Elecsys
	ng/ml = µg/l	207	145	269	Abbott Architect
	ng/ml = µg/l	270	189	351	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	35.5	28.4	42.6	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	35500	28400	42600	
	ng/ml = µg/l	49.3	39.4	59.2	Ortho Vitros ECI
	ng/l = pg/ml	49300	39400	59200	
	ng/ml = µg/l	8.31	6.65	9.97	Abbott Architect
	ng/l = pg/ml	8310	6650	9970	
	ng/ml = µg/l	31.3	25.0	37.6	Abbott i STAT
	ng/l = pg/ml	31300	25000	37600	
	ng/ml = µg/l	6.01	4.81	7.21	Roche Elecsys/E170/c6000/e411
ng/l = pg/ml	6010	4810	7210		

CARDIAC CONTROL LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3100 Lot. No. 4492CK

Size 1 x 1ml Expiry 2021-11-28

Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	12.6	10.1	15.1	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	12600	10100	15100	
	ng/ml = µg/l	7.34	5.87	8.81	Siemens Dimension Exl LOCI
	ng/l = pg/ml	7340	5870	8810	
	ng/ml = µg/l	8.26	6.61	9.91	Abbott Architect STAT hs
	ng/l = pg/ml	8260	6610	9910	
	ng/ml = µg/l	5.58	4.46	6.70	Beckman Access - AccuTnl+3
	ng/l = pg/ml	5580	4460	6700	
	ng/ml = µg/l	41.7	33.4	50.0	Siemens Centaur CP
	ng/l = pg/ml	41700	33400	50000	
	ng/ml = µg/l	34.6	27.7	41.5	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	34600	27700	41500	
	ng/ml = µg/l	25.4	20.3	30.5	Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH)
	ng/l = pg/ml	25400	20300	30500	
ng/ml = µg/l	14.5	11.6	17.4	Beckman Access 2/DxC600i Hs	
ng/l = pg/ml	14500	11600	17400		
ng/ml = µg/l	14.2	11.4	17.0	Beckman Dxl Hs	
ng/l = pg/ml	14200	11400	17000		
Troponin T	ng/ml = µg/l	1.310	0.917	1.700	Roche Cobas Troponin T HS
	ng/l = pg/ml	1310	917	1703	
	ng/ml = µg/l	0.819	0.573	1.060	Roche h232
	ng/l = pg/ml	819	573	1065	
ng/ml = µg/l	1.320	0.924	1.720	Roche Cobas Troponin T hs STAT	
ng/l = pg/ml	1320	924	1716		