

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

CAT. NO. CQ3259

LOT NO. 3923CK, 3924CK, 3925CK

SIZE: 3 x 2 ml

EXPIRY: 2020-01-28

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, CK-MB 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.

1. 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.
2. Refer to the Control section of the individual analyser application.
3. 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.

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CARDIAC CONTROL - LEVEL 1 (CRD CONTROL 1)

Cat. No. CQ3259 Lot No. 3923CK Size: 1 x 2 ml Expiry: 2020-01-28

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	80	66	94	CK-NAC substrate start (DGKC) 37°C
	U/l	50	41	59	CK-NAC substrate start (DGKC) 30°C
	U/l	34	28	40	CK-NAC substrate start (DGKC) 25°C
	U/l	109	89	129	Vitros 37°C
	U/l	78	64	92	CK-NAC (IFCC) 37°C
	U/l	49	40	58	CK-NAC (IFCC) 30°C
	U/l	33	27	39	CK-NAC (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	4.45	3.56	5.34	Siemens Dimension
	ng/ml = µg/l	7.04	5.63	8.45	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	5.29	4.23	6.35	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	7.53	6.02	9.04	Beckman Coulter Access
	ng/ml = µg/l	5.47	4.38	6.56	Ortho Vitros ECI
	ng/ml = µg/l	8.81	7.05	10.6	BioMerieux Vidas
	ng/ml = µg/l	5.00	4.00	6.00	Abbott Architect
Homocysteine	µmol/l	10.9	8.72	13.1	Siemens Immulite 2000/2500
	µmol/l	9.47	7.58	11.4	Abbott Architect
	µmol/l	14.5	11.6	17.4	Roche Cobas 6000/8000
	µmol/l	10.1	8.08	12.1	IL ACL Elite/Elite Pro/8/9/10000
	µmol/l	12.6	10.1	15.1	Enzymatic
Myoglobin	ng/ml = µg/l	44.4	35.5	53.3	Roche Elecsys
	ng/ml = µg/l	35.7	28.6	42.8	Beckman Coulter Access
	ng/ml = µg/l	38.5	30.8	46.2	BioMerieux Vidas
	ng/ml = µg/l	57.2	45.8	68.6	Abbott Architect
	ng/ml = µg/l	65.0	52.0	78.0	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.682	0.546	0.818	Siemens Immulite 1000
	ng/ml = µg/l	0.477	0.382	0.572	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	1.49	1.19	1.79	Ortho Vitros ECI
	ng/ml = µg/l	0.751	0.601	0.901	BioMerieux Vidas
	ng/ml = µg/l	1.52	1.22	1.82	Abbott Architect
	ng/ml = µg/l	0.719	0.575	0.863	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.107	0.086	0.128	Beckman DXi800 1st gen
	ng/ml = µg/l	0.189	0.151	0.227	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	0.265	0.212	0.318	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.192	0.154	0.230	Siemens Dimension Exl LOCI
	ng/ml = µg/l	0.276	0.221	0.331	Abbott Architect STAT hs
	ng/ml = µg/l	0.107	0.086	0.128	Beckman Access - AccuTnl+3
Troponin T	µg/l	0.044	0.033	0.055	Roche Cobas Troponin T HS
	µg/l	0.040	0.030	0.050	Roche h232

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot No. 3924CK Size: 1 x 2 ml Expiry: 2020-01-28

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	214	175	253	CK-NAC substrate start (DGKC) 37°C
	U/l	134	110	158	CK-NAC substrate start (DGKC) 30°C
	U/l	91	74	108	CK-NAC substrate start (DGKC) 25°C
	U/l	318	261	375	Vitros 37°C
	U/l	222	182	262	CK-NAC (IFCC) 37°C
	U/l	139	114	164	CK-NAC (IFCC) 30°C
	U/l	94	77	111	CK-NAC (IFCC) 25°C
	U/l	227	186	268	Monothioglycerol 37°C
	U/l	142	116	168	Monothioglycerol 30°C
	U/l	96	79	113	Monothioglycerol 25°C
CK-MB Activity	U/l	12.2	9.76	14.6	Vitros 37°C
	U/l	24.1	19.3	28.9	Immunoinhibition substrate start 37°C
	U/l	14.0	11.2	16.8	Immunoinhibition substrate start 30°C
	U/l	8.56	6.85	10.3	Immunoinhibition substrate start 25°C
	U/l	24.0	19.2	28.8	Immunoinhibition serum start 37°C
	U/l	13.9	11.2	16.6	Immunoinhibition serum start 30°C
	U/l	8.52	6.82	10.2	Immunoinhibition serum start 25°C
	U/l	23.9	19.1	28.7	Immunoinhibition (IFCC) 37°C
	U/l	13.9	11.1	16.7	Immunoinhibition (IFCC) 30°C
	U/l	8.48	6.78	10.2	Immunoinhibition (IFCC) 25°C
	U/l	25.3	20.2	30.4	Randox Immunoinhibition substrate start 37°C
	U/l	14.7	11.7	17.7	Randox Immunoinhibition substrate start 30°C
	U/l	8.98	7.17	10.8	Randox Immunoinhibition substrate start 25°C
	U/l	25.0	20.0	30.0	Randox Immunoinhibition serum start 37°C
	U/l	14.5	11.6	17.4	Randox Immunoinhibition serum start 30°C
	U/l	8.88	7.10	10.7	Randox Immunoinhibition serum start 25°C
CK-MB Mass	ng/ml = µg/l	16.1	12.9	19.3	Siemens Dimension
	ng/ml = µg/l	22.7	18.2	27.2	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	17.3	13.8	20.8	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	27.1	21.7	32.5	Beckman Coulter Access
	ng/ml = µg/l	17.0	13.6	20.4	Ortho Vitros ECI
	ng/ml = µg/l	27.6	22.1	33.1	BioMerieux Vidas
	ng/ml = µg/l	18.5	14.8	22.2	Abbott Architect
	ng/ml = µg/l	27.0	21.6	32.4	Beckman Dxl800
Homocysteine	µmol/l	20.3	16.2	24.4	Siemens Immulite 2000/2500
	µmol/l	17.7	14.2	21.2	Abbott Architect
	µmol/l	28.5	22.8	34.2	Roche Cobas 6000/8000
	µmol/l	20.7	16.6	24.8	Enzymatic
Myoglobin	ng/ml = µg/l	128	102	154	Roche Elecsys
	ng/ml = µg/l	102	81.6	122	Beckman Coulter Access
	ng/ml = µg/l	119	95.2	143	BioMerieux Vidas
	ng/ml = µg/l	177	142	212	Abbott Architect

CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot No. 3924CK Size: 1 x 2 ml Expiry: 2020-01-28

Range					
Analyte	unit	Target	low	high	methods
Myoglobin	ng/ml = µg/l	195	156	234	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.330	0.264	0.396	Siemens Stratus CS
	ng/ml = µg/l	2.55	2.04	3.06	Siemens Immulite 1000
	ng/ml = µg/l	2.17	1.74	2.60	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	6.31	5.05	7.57	Ortho Vitros ECI
	ng/ml = µg/l	2.31	1.85	2.77	BioMerieux Vidas
	ng/ml = µg/l	6.03	4.82	7.24	Abbott Architect
	ng/ml = µg/l	2.46	1.97	2.95	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.386	0.309	0.463	Beckman DXi800 1st gen
	ng/ml = µg/l	0.478	0.382	0.574	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	1.31	1.05	1.57	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.519	0.415	0.623	Siemens Dimension Exl LOCI
	ng/ml = µg/l	0.876	0.701	1.05	Abbott Architect STAT hs
	ng/ml = µg/l	0.412	0.330	0.494	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	0.405	0.324	0.486	Beckman Access - AccuTnl+3
Troponin T	µg/l	0.372	0.279	0.465	Roche Cobas Troponin T HS
	µg/l	0.190	0.143	0.238	Roche h232

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot No. 3925CK Size: 1 x 2 ml Expiry: 2020-01-28

Range					
Analyte	unit	Target	low	high	methods
CK Total	U/l	510	418	602	CK-NAC substrate start (DGKC) 37°C
	U/l	319	262	376	CK-NAC substrate start (DGKC) 30°C
	U/l	217	178	256	CK-NAC substrate start (DGKC) 25°C
	U/l	737	604	870	Vitros 37°C
	U/l	541	444	638	CK-NAC (IFCC) 37°C
	U/l	339	278	400	CK-NAC (IFCC) 30°C
	U/l	230	189	271	CK-NAC (IFCC) 25°C
	U/l	541	444	638	Monothioglycerol 37°C
	U/l	339	278	400	Monothioglycerol 30°C
	U/l	230	189	271	Monothioglycerol 25°C
CK-MB Activity	U/l	119	95.2	143	Vitros 37°C
	U/l	122	97.6	146	Immunoinhibition substrate start 37°C
	U/l	70.9	56.7	85.1	Immunoinhibition substrate start 30°C
	U/l	43.3	34.6	52.0	Immunoinhibition substrate start 25°C
	U/l	124	99.0	149	Immunoinhibition serum start 37°C
	U/l	72.1	57.5	86.7	Immunoinhibition serum start 30°C
	U/l	44.0	35.1	52.9	Immunoinhibition serum start 25°C
	U/l	124	99.0	149	Immunoinhibition (IFCC) 37°C
	U/l	72.1	57.5	86.7	Immunoinhibition (IFCC) 30°C
	U/l	44.0	35.1	52.9	Immunoinhibition (IFCC) 25°C
	U/l	121	96.8	145	Randox Immunoinhibition substrate start 37°C
	U/l	70.3	56.3	84.3	Randox Immunoinhibition substrate start 30°C
	U/l	43.0	34.4	51.6	Randox Immunoinhibition substrate start 25°C
	U/l	122	97.6	146	Randox Immunoinhibition serum start 37°C
	U/l	70.9	56.7	84.9	Randox Immunoinhibition serum start 30°C
	U/l	43.3	34.6	51.8	Randox Immunoinhibition serum start 25°C
CK-MB Mass	ng/ml = µg/l	158	126	190	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	118	94.4	142	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	186	149	223	Beckman Coulter Access
	ng/ml = µg/l	110	88.0	132	Ortho Vitros Eci
	ng/ml = µg/l	180	144	216	BioMerieux Vidas
	ng/ml = µg/l	128	102	154	Abbott Architect
	ng/ml = µg/l	199	159	239	Beckman Dxl800
Homocysteine	µmol/l	40.6	32.5	48.7	Siemens Immulite 2000/2500
	µmol/l	35.0	28.0	42.0	Abbott Architect
	µmol/l	58.8	47.0	70.6	Roche Cobas 6000/8000
	µmol/l	37.1	29.7	44.5	IL ACL Elite/Elite Pro/8/9/10000
	µmol/l	39.2	31.4	47.0	Enzymatic
Myoglobin	ng/ml = µg/l	214	171	257	Roche Elecsys
	ng/ml = µg/l	177	142	212	Beckman Coulter Access
	ng/ml = µg/l	201	161	241	BioMerieux Vidas
	ng/ml = µg/l	311	249	373	Abbott Architect

CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot No. 3925CK Size: 1 x 2 ml Expiry: 2020-01-28

Range					
Analyte	unit	Target	low	high	methods
Myoglobin	ng/ml = µg/l	345	276	414	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	1.61	1.29	1.93	Siemens Stratus CS
	ng/ml = µg/l	12.8	10.2	15.4	Siemens Immulite 1000
	ng/ml = µg/l	14.4	11.5	17.3	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	32.5	26.0	39.0	Ortho Vitros ECI
	ng/ml = µg/l	10.4	8.32	12.5	BioMerieux Vidas
	ng/ml = µg/l	26.2	21.0	31.4	Abbott Architect
	ng/ml = µg/l	10.7	8.56	12.8	Biomerieux Vidas Ultra
	ng/ml = µg/l	1.90	1.52	2.28	Beckman DXi800 1st gen
	ng/ml = µg/l	1.68	1.34	2.02	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	7.29	5.83	8.75	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	1.98	1.58	2.38	Siemens Dimension Exl LOCI
	ng/ml = µg/l	3.23	2.58	3.88	Abbott Architect STAT hs
	ng/ml = µg/l	2.03	1.62	2.44	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	1.91	1.53	2.29	Beckman Access - AccuTnl+3
Troponin T	µg/l	1.170	0.878	1.460	Roche Cobas Troponin T HS
	µg/l	0.570	0.428	0.713	Roche h232