RANDOX

PRODUCT INFORMATION

CQ3259

4487CK, 4488CK, 4489CK

The reconstituted stability for Cardiac Control Level 1 - lot 4487CK for Troponin I is 1 day at +2°C to +8°C, or 2 weeks when frozen once at –20°C.

The reconstituted stabilities for Cardiac Controls - lots 4488CK and 4489CK for Troponin I are unchanged at 5 days at +2°C to +8°C, or 2 weeks when frozen once at –20°C.

Please note targets and ranges are currently not available for Myoglobin in 4487CK. These will be updated in due course.

CCS6817

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

CAT. NO. CQ3259
SIZE: 3 x 2 ml
GTIN: 05055273201857
LOT NOS. 4487CK, 4488CK, 4489CK
EXPIRY: 2024-05-28

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 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 to +8°C). The reconstituted stability for lot: 4487CK for Troponin I is1 day at +2°C to +8°C, or 2 weeks when frozen once at –20°C. The reconstituted stabilities for lots: 4488CK and 4489CK for Troponin I are 5 days at +2°C to +8°C, or 2 weeks when frozen once at –20°C. 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 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. 4487CK Size: 1 x 2 ml Expiry: 2024-05-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK Total	U/l	87	71	103	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	105	86	124	Vitros 37°C
	U/l	86	71	101	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	6.03	4.22	7.84	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	4.51	3.16	5.86	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	3.73	2.61	4.85	Abbott Architect
	ng/ml = µg/l	3.48	2.44	4.52	Abbott i STAT
Homocysteine	µmol/l	10.1	8.08	12.1	Abbott Architect
	µmol/l	15.3	12.2	18.4	Roche Cobas 6000/8000
	µmol/l	15.7	12.6	18.8	Enzymatic
Myoglobin	ng/ml = µg/l	67.4	47.2	87.6	Roche Elecsys
	ng/ml = µg/l	49.6	34.7	64.5	Abbott Architect
Troponin I	ng/ml = µg/l	0.261	0.209	0.313	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	261	209	313	
	ng/ml = µg/l	0.335	0.268	0.402	Ortho Vitros ECi
	ng/l = pg/ml	335	268	402	
	ng/ml = µg/l	0.691	0.553	0.829	Tosoh Series
	ng/l = pg/ml	691	553	829	
	ng/ml = µg/l	0.203	0.162	0.244	Abbott Architect
	ng/l = pg/ml	203	162	244	
	ng/ml = µg/l	0.330	0.264	0.396	Abbott i STAT
	ng/l = pg/ml	330	264	396	
	ng/ml = µg/l	0.142	0.114	0.170	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	142	114	170	
	ng/ml = µg/l	0.195	0.156	0.234	Abbott Architect STAT hs
	ng/l = pg/ml	195	156	234	
	ng/ml = µg/l	0.162	0.130	0.194	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	162	130	194	
	ng/ml = µg/l	0.310	0.248	0.372	Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH)
	ng/l = pg/ml	310	248	372	
	ng/ml = µg/l	0.093	0.074	0.112	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	93.0	74.0	112	
	ng/ml = µg/l	0.104	0.083	0.125	Beckman DxI Hs
	ng/l = pg/ml	104	83.0	125	
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	0.015	0.011	0.020	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	15.0	11.0	19.0	

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CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot No. 4488CK Size: 1 x 2 ml Expiry: 2024-05-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK Total	U/l	232	190	274	CK-NAC substrate start (DGKC) 37°C
	U/l	145	119	171	CK-NAC substrate start (DGKC) 30°C
	U/l	99	81	117	CK-NAC substrate start (DGKC) 25°C
	U/l	314	257	371	Vitros 37°C
	U/l	221	181	261	CK-NAC (IFCC) 37°C
	U/l	138	113	163	CK-NAC (IFCC) 30°C
	U/l	94	77	111	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	17.8	14.2	21.4	Vitros 37°C
	U/l	20.2	16.2	24.2	Immunoinhibition substrate start 37°C
	U/l	11.7	9.42	14.0	Immunoinhibition substrate start 30°C
	U/l	7.17	5.75	8.59	Immunoinhibition substrate start 25°C
	U/l	20.4	16.3	24.5	Immunoinhibition serum start 37°C
	U/l	11.9	9.47	14.3	Immunoinhibition serum start 30°C
	U/l	7.24	5.79	8.69	Immunoinhibition serum start 25°C
	U/l	19.6	15.7	23.5	Immunoinhibition (IFCC) 37°C
	U/l	11.4	9.12	13.7	Immunoinhibition (IFCC) 30°C
	U/l	6.96	5.57	8.35	Immunoinhibition (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	22.6	15.8	29.4	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	17.3	12.1	22.5	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	17.2	12.0	22.4	Abbott Architect
	ng/ml = µg/l	19.0	13.3	24.7	Abbott i STAT
Homocysteine	µmol/l	17.7	14.2	21.2	Abbott Architect
	µmol/l	28.2	22.6	33.8	Roche Cobas 6000/8000
	µmol/l	22.9	18.3	27.5	Enzymatic
Myoglobin	ng/ml = µg/l	210	147	273	Roche Elecsys
	ng/ml = µg/l	147	103	191	Abbott Architect
	ng/ml = µg/l	195	137	254	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	8.83	7.06	10.6	Ortho Vitros ECi
	ng/l = pg/ml	8830	7060	10600	
	ng/ml = µg/l	1.70	1.36	2.04	Abbott Architect
	ng/l = pg/ml	1700	1360	2040	
	ng/ml = µg/l	6.36	5.09	7.63	Abbott i STAT
	ng/l = pg/ml	6360	5090	7630	
	ng/ml = µg/l	1.62	1.30	1.94	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	1620	1300	1940	
	ng/ml = µg/l	1.63	1.30	1.96	Abbott Architect STAT hs
	ng/l = pg/ml	1630	1300	1960	
	ng/ml = µg/l	4.67	3.74	5.60	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	4670	3740	5600	
	ng/ml = µg/l	5.58	4.46	6.70	Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH)
	ng/l = pg/ml	5580	4460	6700	
	ng/ml = µg/l	2.18	1.74	2.62	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	2180	1740	2620	

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CARDIAC CONTROL - LEVEL 2 (CRD CONTROL 2)

Cat. No. CQ3259 Lot No. 4488CK Size: 1 x 2 ml Expiry: 2024-05-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Troponin I	ng/ml = µg/l	2.42	1.94	2.90	Beckman DxI Hs
	ng/l = pg/ml	2420	1940	2900	
Troponin T	ng/ml = µg/l	0.403	0.282	0.524	Roche Cobas Troponin T HS
	ng/l = pg/ml	403	282	524	
	ng/ml = µg/l	0.220	0.154	0.286	Roche h232
	ng/l = pg/ml	220	154	286	
	ng/ml = µg/l	0.382	0.267	0.497	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	382	267	497	

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CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot No. 4489CK Size: 1 x 2 ml Expiry: 2024-05-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK Total	U/l	618	507	729	CK-NAC substrate start (DGKC) 37°C
	U/l	387	317	457	CK-NAC substrate start (DGKC) 30°C
	U/l	263	215	311	CK-NAC substrate start (DGKC) 25°C
	U/l	762	625	899	Vitros 37°C
	U/l	612	502	722	CK-NAC (IFCC) 37°C
	U/l	383	314	452	CK-NAC (IFCC) 30°C
	U/l	260	213	307	CK-NAC (IFCC) 25°C
CK-MB Activity	U/l	128	102	154	Vitros 37°C
	U/l	120	96.0	144	Immunoinhibition substrate start 37°C
	U/l	69.7	55.8	83.6	Immunoinhibition substrate start 30°C
	U/l	42.6	34.1	51.1	Immunoinhibition substrate start 25°C
	U/l	122	97.6	146	Immunoinhibition serum start 37°C
	U/l	70.9	56.7	85.1	Immunoinhibition serum start 30°C
	U/l	43.3	34.6	52.0	Immunoinhibition serum start 25°C
	U/l	123	98.4	148	Immunoinhibition (IFCC) 37°C
	U/l	71.5	57.2	85.8	Immunoinhibition (IFCC) 30°C
	U/l	43.7	34.9	52.5	Immunoinhibition (IFCC) 25°C
CK-MB Mass	ng/ml = µg/l	175	123	228	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	126	88.2	164	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	132	92.4	172	Abbott Architect
	ng/ml = µg/l	133	93.1	173	Abbott i STAT
Homocysteine	µmol/l	34.2	27.4	41.0	Abbott Architect
	µmol/l	59.6	47.7	71.5	Roche Cobas 6000/8000
	µmol/l	38.6	30.9	46.3	Enzymatic
Myoglobin	ng/ml = µg/l	314	220	408	Roche Elecsys
	ng/ml = µg/l	219	153	285	Abbott Architect
	ng/ml = µg/l	306	214	398	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	45.6	36.5	54.7	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	45600	36500	54700	
	ng/ml = µg/l	61.7	49.4	74.0	Ortho Vitros ECi
	ng/l = pg/ml	61700	49400	74000	
	ng/ml = µg/l	63.7	51.0	76.4	Tosoh Series
	ng/l = pg/ml	63700	51000	76400	
	ng/ml = µg/l	8.44	6.75	10.1	Abbott Architect
	ng/l = pg/ml	8440	6750	10100	
	ng/ml = µg/l	45.4	36.3	54.5	Abbott i STAT
	ng/l = pg/ml	45400	36300	54500	
	ng/ml = µg/l	7.16	5.73	8.59	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	7160	5730	8590	
	ng/ml = µg/l	8.76	7.01	10.5	Abbott Architect STAT hs
	ng/l = pg/ml	8760	7010	10500	
	ng/ml = µg/l	38.4	30.7	46.1	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	38400	30700	46100	

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CARDIAC CONTROL - LEVEL 3 (CRD CONTROL 3)

Cat. No. CQ3259 Lot No. 4489CK Size: 1 x 2 ml Expiry: 2024-05-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Troponin I	ng/ml = µg/l	26.1	20.9	31.3	Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH)
	ng/l = pg/ml	26100	20900	31300	
	ng/ml = µg/l	19.4	15.5	23.3	Beckman Access 2/DxC600i Hs
	ng/l = pg/ml	19400	15500	23300	
	ng/ml = µg/l	19.4	15.5	23.3	Beckman DxI Hs
	ng/l = pg/ml	19400	15500	23300	
Troponin T	ng/ml = µg/l	1.140	0.798	1.480	Roche Cobas Troponin T HS
	ng/l = pg/ml	1140	798	1482	
	ng/ml = µg/l	0.759	0.531	0.987	Roche h232
	ng/l = pg/ml	759	531	987	
	ng/ml = µg/l	1.080	0.756	1.400	Roche Cobas Troponin T hs STAT
	ng/l = pg/ml	1080	756	1404	