RANDOX

Urgent Field Safety Notice

Randox Laboratories Ltd
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United Kingdom BT29 4QY
technical.services@randox.com
Tel: +44 (0) 28 9445 1070

Date Issued: 01 Oct 2019
Complaint Reference: REC414

Action Type: Device Modification

Detail on Affected Devices:

Our records indicate that your facility may have received the following product

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry date	Manufacturing date
Liquid Cardiac Control	CQ5051	05055273207446	4243CK	28 Nov 2019	May 2018
			4246CK	28 Nov 2019	May 2018
			4249CK	28 Nov 2019	Feb 2018
			4260CK	28 Nov 2019	Apr 2019
			4311CK	28 May 2020	Sep 2018
			4314CK	28 May 2020	Apr 2019
			4317CK	28 May 2020	Apr 2019
	CQ5052	05055273207453	4244CK	28 Nov 2019	Feb 2018
			4247CK	28 Nov 2019	Oct 2018
			4261CK	28 Nov 2019	Apr 2019
			4312CK	28 Jun 2020	Sep 2018
			4315CK	28 Jun 2020	Apr 2019
	CQ5053	05055273207460	4245CK	28 Nov 2019	Feb 2018
			4248CK	28 Nov 2019	Sep 2018
			4313CK	28 Jun 2020	Apr 2019
			4316CK	28 Jun 2020	Sep 2018

Reason for Action:

Randox has observed a decrease in recovery for N-Terminal Pro-Brain Natriuretic Peptide (NT-proBNP) in recent lots of Liquid Cardiac Controls CQ5051, CQ5052 and CQ5053. We have therefore taken the decision to remove all NT-proBNP claims in these lots of control.

Risk to Health:

Quality control results which are not within range can lead to a delay in reporting results however NTproBNP is used in conjunction with other results and indicators to diagnose and monitor heart failure in patients. This therefore should not pose a serious risk to health.

Form No. 6307-TS
REVISION (10)
4th Feb 2019

Last printed: 01 October 2019

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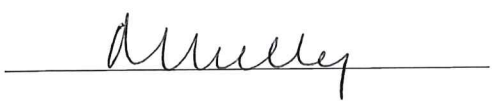
Action to be taken:

- Inspect your stock and quarantine affected stock.
- Replace the value sheet in the kit with the revised value sheet provided.
- Randox is not recommending a review of previous results as changes in quality control recovery would be reviewed at the time of occurrence.
- Discuss the contents of this notice with your Medical Director.
- Complete and return the response form 12187-QA to technical.services@randox.com within five working days.

Transmission of Field Safety Notice: Send a copy of the FSN to all affected customers and to those who need to be aware within your organisation.

Please accept our apologies for any inconvenience caused. Thank you for your patience and understanding. If you have any questions or concerns please contact Randox Technical Services.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency



Last printed: 01 October 2019

Form No. 6307-TS
REVISION (10)
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Response Form

Randox Laboratories Ltd
55 Diamond Road, Crumlin
United Kingdom BT29 4QY
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Please complete this form *even if you do not have any affected stock*.

Date Issued: 01 Oct 2019
Complaint Reference: REC414 **Action Type:** Device Modification

Detail on Affected Devices:
Our records indicate that your facility may have received the following product

Device Name	Catalogue Number	GTIN	Batch / Lot number	Expiry date	Manufacturing date
Liquid Cardiac Control	CQ5051	05055273207446	4243CK 4246CK 4249CK 4260CK 4311CK 4314CK 4317CK	28 Nov 2019 28 Nov 2019 28 Nov 2019 28 Nov 2019 28 May 2020 28 May 2020 28 May 2020	May 2018 May 2018 Feb 2018 Apr 2019 Sep 2018 Apr 2019 Apr 2019
	CQ5052	05055273207453	4244CK 4247CK 4261CK 4312CK 4315CK	28 Nov 2019 28 Nov 2019 28 Nov 2019 28 Jun 2020 28 Jun 2020	Feb 2018 Oct 2018 Apr 2019 Sep 2018 Apr 2019
	CQ5053	05055273207460	4245CK 4248CK 4313CK 4316CK	28 Nov 2019 28 Nov 2019 28 Jun 2020 28 Jun 2020	Feb 2018 Sep 2018 Apr 2019 Sep 2018

Please check ALL appropriate boxes.

- ❑ I have read and understand the instructions provided in the Field Safety Notice.
- ❑ I have checked my stock and identified the affected kits.
- ❑ I have notified all those who need to be aware of this notice within the organisation.
- ❑ Field Safety Notice is not applicable to my use of the product.

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Response Form

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Indicate disposition of affected product:

- ❑ no affected stock
- ❑ relabelled (*specify quantity and date*);
- ❑ quarantined pending correction (*specify quantity*);

Customer Details

Company Name	
Address	

Total Quantity

Received	
Distributed	

Completed By	Print Name: Signature:	Date	
Contact Telephone			
Contact Email			

Complete and return the response form to technical.services@randox.com within five working days.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your regulatory authority requires your response form as evidence of the effectiveness of the corrective actions detailed in the FSN.

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Response Form

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PART 2 (To be completed by Distributors and Randox Offices only)

Area of Distribution

- ❑ I have identified and notified my customers that were shipped or may have been shipped this product by (*specify date and method of notification*);

  OR

- ❑ Detailed below is a list of customers who received/may have received this product. Please notify my customers. (List of customers may also be sent in a separate attachment)

Consignee	Country	Quantity Received	Analyser / Kit Serial / Lot Number	Replacements Required

Have your customers notified you of any adverse events associated with recalled product?

- ❑ YES
- ❑ NO

If yes, please explain: _____

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IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 1
(CRD LIQ CONTROL 1)

CAT. NO. CQ5051 **LOT NO.** 4243CK
SIZE: 3 x 3 ml **EXPIRY:** 2019-11-28

GTIN: 05055273207446

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 1 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Rev. 05 Sep 19 pq

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LIQUID CARDIAC CONTROL - LEVEL 1 (CRD LIQ CONTROL 1)

Cat. No. CQ5051 Lot No. 4243CK Size: 3 x 3 ml Expiry: 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	2.60	1.82	3.38	Abbott Architect
	ng/ml = µg/l	4.27	2.99	5.55	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	2.56	1.79	3.33	Siemens Dimension
	ng/ml = µg/l	2.80	1.96	3.64	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	3.78	2.65	4.91	Beckman Coulter Access
	ng/ml = µg/l	2.86	2.00	3.72	Siemens Stratus CS
	ng/ml = µg/l	4.53	3.17	5.89	BioMerieux Vidas
	ng/ml = µg/l	3.81	2.67	4.95	Beckman DxI800
	ng/ml = µg/l	2.81	1.97	3.65	Roche h232
	ng/ml = µg/l	4.73	3.31	6.15	Radiometer AQT90 Flex
D-Dimer	µg/l FEU	944	708	1180	Biomerieux Vidas Exclusion II
	µg/l FEU	3018	2264	3773	Mitsubishi Pathfast D-Dimer
	µg/l	391	293	489	Roche/ Stago STA-R Evolution
	µg/l	538	404	673	Roche Cobas h232 D-Dimer
	µg/l	263	197	329	Roche Integra D-DI 2
	µg/l	611	458	764	Alere Biosite Triage D-Dimer
	µg/l	532	399	665	Abbott Architect Quantia D-Dimer
	µg/l	578	434	723	Siemens Stratus CS
	µg/l	574	431	718	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1294	971	1618	Siemens Innovance D-Dimer
	µg/l	157	118	196	Roche Cobas D-DI 2
	µg/l FEU	1540	1155	1925	HemosIL D-Dimer HS 500
	µg/l	453	340	566	HemosIL D-Dimer
	µg/l	520	390	650	HemosIL D-Dimer HS
Digoxin	nmol/l	0.986	0.789	1.18	Chemiluminescence
	ng/ml	0.770	0.616	0.924	
	nmol/l	0.884	0.707	1.06	Enzyme Immunoassay
	ng/ml	0.690	0.552	0.828	
	nmol/l	0.844	0.675	1.01	Turbidimetric
	ng/ml	0.659	0.527	0.791	
	nmol/l	0.807	0.646	0.968	KIMS
	ng/ml	0.630	0.505	0.755	
	nmol/l	0.880	0.704	1.06	Enzyme Linked Flourescent assay
	ng/ml	0.687	0.550	0.824	
hsCRP	mg/l	0.760	0.608	0.912	Nephelometric (IFCC Cal.)
	mg/l	0.788	0.630	0.946	Nephelometric (Non IFCC Cal.)
	mg/l	0.868	0.694	1.04	Turbidimetric (IFCC Cal.)
	mg/l	0.876	0.701	1.05	Turbidimetric (Non IFCC Cal.)
	mg/l	0.885	0.708	1.06	Chemiluminescence (IFCC Cal.)
	mg/l	0.831	0.660	1.00	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	66.1	46.3	85.9	Abbott Architect
	ng/ml = µg/l	48.3	33.8	62.8	Siemens/Dade Behring Nephelometer

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LIQUID CARDIAC CONTROL - LEVEL 1 (CRD LIQ CONTROL 1)

Cat. No. CQ5051 Lot No. 4243CK Size: 3 x 3 ml Expiry: 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Myoglobin	ng/ml = µg/l	50.9	35.6	66.2	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	50.2	35.1	65.3	Siemens Dimension
	ng/ml = µg/l	37.6	26.3	48.9	Beckman DxI800
	ng/ml = µg/l	45.7	32.0	59.4	Roche Elecsys
	ng/ml = µg/l	52.7	36.9	68.5	Roche Hitachi
	ng/ml = µg/l	37.7	26.4	49.0	Beckman Coulter Access
	ng/ml = µg/l	28.4	19.9	36.9	Siemens Stratus CS
	ng/ml = µg/l	35.0	24.5	45.5	BioMerieux Vidas
	ng/ml = µg/l	45.1	31.6	58.6	Siemens Dimension Vista LOCI
	ng/ml = µg/l	47.3	33.1	61.5	Siemens Centaur CP
	ng/ml = µg/l	67.6	47.3	87.9	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.036	0.028	0.043	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	35.6	28.0	43.2	
	ng/ml = µg/l	0.022	0.018	0.026	Beckman Coulter Access
	ng/l = pg/ml	21.9	18.0	25.8	
	ng/ml = µg/l	0.024	0.019	0.028	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	23.5	19.0	28.0	
	ng/ml = µg/l	0.042	0.033	0.050	Abbott Architect STAT hs
	ng/l = pg/ml	41.8	33.0	50.6	
	ng/ml = µg/l	0.030	0.024	0.036	Siemens Centaur CP
	ng/l = pg/ml	29.9	24.0	35.8	
	ng/ml = µg/l	0.229	0.183	0.275	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	229	183	275	
	ng/ml = µg/l	0.023	0.020	0.030	Beckman DxI - AccuTnI+3
	ng/l = pg/ml	22.9	20.0	30.0	
	ng/ml = µg/l	0.023	0.020	0.030	Beckman Access - AccuTnI+3
	ng/l = pg/ml	22.5	20.0	30.0	
	ng/ml = µg/l	0.301	0.240	0.360	Ortho Vitros 3600/5600/ECi
	ng/l = pg/ml	301	240	360	
	ng/ml = µg/l	0.048	0.038	0.057	Siemens Dimension EXL high sensitivity Troponin I
	ng/l = pg/ml	47.5	38.0	57.0	
	ng/ml = µg/l	0.054	0.040	0.060	Siemens Dimension Vista high sensitivity Troponin I
	ng/l = pg/ml	54.0	40.0	60.0	

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RANDOX

IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 2
(CRD LIQ CONTROL 2)

CAT NO. CQ5052 **LOT NO.** 4244CK
SIZE: 3 x 3 ml **EXPIRY:** 2019-11-28

GTIN: 05055273207453

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 2 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Rev. 05 Sep '19 pq

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LIQUID CARDIAC CONTROL LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot No. 4244CK Size: 3 x 3 ml Expiry: 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	13.6	9.52	17.7	Abbott Architect
	ng/ml = µg/l	19.0	13.3	24.7	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	14.9	10.4	19.4	Siemens Dimension
	ng/ml = µg/l	13.1	9.17	17.0	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	19.5	13.7	25.4	Beckman Coulter Access
	ng/ml = µg/l	14.1	9.87	18.3	Siemens Stratus CS
	ng/ml = µg/l	19.9	13.9	25.9	BioMerieux Vidas
	ng/ml = µg/l	19.5	13.7	25.4	Beckman DxI800
	ng/ml = µg/l	12.1	8.47	15.7	Roche h232
	ng/ml = µg/l	25.3	17.7	32.9	Radiometer AQT90 Flex
	ng/ml = µg/l	14.7	10.3	19.1	Siemens Dimension Vista LOCI
	ng/ml = µg/l	16.1	11.3	20.9	Siemens Centaur CP
D - Dimer	µg/l FEU	1154	866	1443	Biomerieux Vidas Exclusion II
	µg/l FEU	4298	3224	5373	Mitsubishi Pathfast D-Dimer
	µg/l	479	359	599	Roche/ Stago STA-R Evolution
	µg/l	681	511	851	Roche Cobas h232 D-Dimer
	µg/l	399	299	499	Roche Integra D-DI 2
	µg/l	835	626	1044	Alere Biosite Triage D-Dimer
	µg/l	618	464	773	Abbott Architect Quantia D-Dimer
	µg/l	854	641	1068	Siemens Stratus CS
	µg/l	238	179	298	Siemens Immulite 2000 D-Dimer
	µg/l	717	538	896	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1634	1226	2043	Siemens Innovance D-Dimer
	µg/l	301	226	376	Roche Cobas D-DI 2
	µg/l FEU	1886	1415	2358	HemosIL D-Dimer 500
	µg/l FEU	1884	1413	2355	HemosIL D-Dimer HS 500
	µg/l	543	407	679	HemosIL D-Dimer
Digoxin	nmol/l	2.13	1.70	2.56	Chemiluminescence
	ng/ml	1.66	1.33	1.99	
	nmol/l	2.03	1.62	2.44	Enzyme Immunoassay
	ng/ml	1.59	1.27	1.91	
	nmol/l	2.20	1.76	2.64	Turbidimetric
	ng/ml	1.72	1.37	2.07	
	nmol/l	2.10	1.68	2.52	KIMS
	ng/ml	1.64	1.31	1.97	
	nmol/l	2.13	1.70	2.56	Enzyme Linked Flourescent assay
	ng/ml	1.66	1.33	1.99	
hsCRP	mg/l	2.80	2.24	3.36	Nephelometric (IFCC Cal.)
	mg/l	2.84	2.27	3.41	Nephelometric (Non IFCC Cal.)
	mg/l	2.93	2.34	3.52	Turbidimetric (IFCC Cal.)
	mg/l	2.99	2.39	3.59	Turbidimetric (Non IFCC Cal.)
	mg/l	3.35	2.68	4.02	Chemiluminescence (IFCC Cal.)

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LIQUID CARDIAC CONTROL LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot No. 4244CK Size: 3 x 3 ml Expiry: 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
hsCRP	mg/l	2.81	2.25	3.37	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	171	120	222	Abbott Architect
	ng/ml = µg/l	129	90.3	168	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	140	98.0	182	Siemens Dimension
	ng/ml = µg/l	92.0	64.4	120	Beckman DxI800
	ng/ml = µg/l	115	80.5	150	Roche Elecsys
	ng/ml = µg/l	106	74.2	138	Roche Hitachi
	ng/ml = µg/l	89.4	62.6	116	Beckman Coulter Access
	ng/ml = µg/l	94.4	66.1	123	Siemens Stratus CS
	ng/ml = µg/l	85.0	59.5	111	BioMerieux Vidas
	ng/ml = µg/l	121	84.7	157	Siemens Dimension Vista LOCI
	ng/ml = µg/l	130	91.0	169	Siemens Centaur CP
	ng/ml = µg/l	163	114	212	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	1.15	0.920	1.38	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	1150	920	1380	
	ng/ml = µg/l	0.284	0.227	0.341	Siemens Dimension
	ng/l = pg/ml	284	227	341	
	ng/ml = µg/l	0.394	0.315	0.473	Beckman DXi800 1st gen
	ng/l = pg/ml	394	315	473	
	ng/ml = µg/l	0.407	0.326	0.488	Beckman Coulter Access
	ng/l = pg/ml	407	326	488	
	ng/ml = µg/l	0.376	0.301	0.451	Siemens Stratus CS
	ng/l = pg/ml	376	301	451	
	ng/ml = µg/l	0.231	0.185	0.277	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	231	185	277	
	ng/ml = µg/l	1.06	0.848	1.27	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	1060	848	1272	
	ng/ml = µg/l	0.333	0.266	0.400	Siemens/Dade Dimension EXL/Vista
	ng/l = pg/ml	333	266	400	
	ng/ml = µg/l	0.347	0.278	0.416	Siemens Dimension Exl LOCI
	ng/l = pg/ml	347	278	416	
	ng/ml = µg/l	0.670	0.536	0.804	Abbott Architect STAT hs
	ng/l = pg/ml	670	536	804	
	ng/ml = µg/l	0.363	0.290	0.436	Beckman Dxl - AccuTnI+3
	ng/l = pg/ml	363	290	436	
	ng/ml = µg/l	0.386	0.309	0.463	Beckman Access - AccuTnI+3
	ng/l = pg/ml	386	309	463	
	ng/ml = µg/l	0.925	0.740	1.11	Siemens Centaur CP
	ng/l = pg/ml	925	740	1110	
	ng/ml = µg/l	7.52	6.02	9.02	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	7520	6020	9020	

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RANDOX

IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 3 (CRD LIQ CONTROL 3)

CAT. NO. CQ5053 **LOT NO.** 4245CK
SIZE: 3 x 3 ml **EXPIRY:** 2019-11-28

GTIN: 05055273207460

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 3 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Rev. 05 Sep '19 pq

RANDOX

LIQUID CARDIAC CONTROL - LEVEL 3 (CRD LIQ CONTROL 3)

Cat. No. CQ5053 Lot No. 4245CK Size: 3 x 3 ml Expiry: 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	85.1	59.6	111	Abbott Architect
	ng/ml = µg/l	112	78.4	146	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	120	84.0	156	Siemens Dimension
	ng/ml = µg/l	73.4	51.4	95.4	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	124	86.8	161	Beckman Coulter Access
	ng/ml = µg/l	108	75.6	140	Siemens Stratus CS
	ng/ml = µg/l	122	85.4	159	BioMerieux Vidas
	ng/ml = µg/l	124	86.8	161	Beckman DxI800
	ng/ml = µg/l	49.6	34.7	64.5	Biosite Triage Meter Plus
	ng/ml = µg/l	34.8	24.4	45.2	Roche h232
	ng/ml = µg/l	147	103	191	Radiometer AQT90 Flex
	ng/ml = µg/l	112	78.4	146	Siemens Dimension Vista LOCI
	ng/ml = µg/l	97.5	68.3	127	Siemens Centaur CP
D-Dimer	µg/l FEU	2444	1833	3055	Biomerieux Vidas Exclusion II
	µg/l FEU	10946	8210	13682	Mitsubishi Pathfast D-Dimer
	µg/l	1043	782	1304	Roche/ Stago STA-R Evolution
	µg/l	1539	1154	1924	Roche Cobas h232 D-Dimer
	µg/l	1204	903	1505	Roche Integra D-DI 2
	µg/l	1777	1333	2221	Alere Biosite Triage D-Dimer
	µg/l	1194	896	1493	Abbott Architect Quantia D-Dimer
	µg/l	2119	1589	2649	Siemens Stratus CS
	µg/l	944	708	1180	Siemens Immulite 2000 D-Dimer
	µg/l	1426	1070	1783	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	3836	2877	4795	Siemens Innovance D-Dimer
	µg/l	1302	977	1628	Roche Cobas D-DI 2
	µg/l FEU	3610	2708	4513	HemosIL D-Dimer 500
	µg/l FEU	3890	2918	4863	HemosIL D-Dimer HS 500
	µg/l	1159	869	1449	HemosIL D-Dimer HS
Digoxin	nmol/l	3.48	2.78	4.18	Chemiluminescence
	ng/ml	2.72	2.17	3.27	
	nmol/l	3.41	2.73	4.09	Enzyme Immunoassay
	ng/ml	2.66	2.13	3.19	
	nmol/l	3.61	2.89	4.33	Turbidimetric
	ng/ml	2.82	2.26	3.38	
	nmol/l	3.41	2.73	4.09	KIMS
	ng/ml	2.66	2.13	3.19	
	nmol/l	3.62	2.90	4.34	Enzyme Linked Flourescent assay
	ng/ml	2.83	2.26	3.40	
hsCRP	mg/l	7.45	5.96	8.94	Nephelometric (IFCC Cal.)
	mg/l	7.49	5.99	8.99	Nephelometric (Non IFCC Cal.)
	mg/l	7.48	5.98	8.98	Turbidimetric (IFCC Cal.)
	mg/l	7.61	6.09	9.13	Turbidimetric (Non IFCC Cal.)

RANDOX

LIQUID CARDIAC CONTROL - LEVEL 3 (CRD LIQ CONTROL 3)

Cat. No. CQ5053 Lot No. 4245CK Size: 3 x 3 ml Expiry: 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
hsCRP	mg/l	8.37	6.70	10.0	Chemiluminescence (IFCC Cal.)
	mg/l	6.98	5.58	8.38	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	388	272	504	Abbott Architect
	ng/ml = µg/l	323	226	420	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	346	242	450	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	377	264	490	Siemens Dimension
	ng/ml = µg/l	240	168	312	Beckman DxI800
	ng/ml = µg/l	274	192	356	Roche Elecsys
	ng/ml = µg/l	270	189	351	Roche Hitachi
	ng/ml = µg/l	232	162	302	Beckman Coulter Access
	ng/ml = µg/l	215	151	280	Siemens Stratus CS
	ng/ml = µg/l	251	176	326	BioMerieux Vidas
	ng/ml = µg/l	331	232	430	Biosite Triage Meter Plus
	ng/ml = µg/l	324	227	421	Siemens Dimension Vista LOCI
	ng/ml = µg/l	357	250	464	Siemens Centaur CP
	ng/ml = µg/l	421	295	547	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	6.79	5.43	8.15	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	6790	5430	8150	
	ng/ml = µg/l	1.41	1.13	1.69	Siemens Dimension
	ng/l = pg/ml	1410	1130	1690	
	ng/ml = µg/l	1.93	1.54	2.32	Beckman DXi800 1st gen
	ng/l = pg/ml	1930	1540	2320	
	ng/ml = µg/l	1.77	1.42	2.12	Beckman Coulter Access
	ng/l = pg/ml	1770	1420	2120	
	ng/ml = µg/l	1.77	1.42	2.12	Siemens Stratus CS
	ng/l = pg/ml	1770	1420	2120	
	ng/ml = µg/l	31.3	25.0	37.6	Ortho Vitros ECi
	ng/l = pg/ml	31300	25000	37600	
	ng/ml = µg/l	15.7	12.6	18.8	Biomerieux Vidas Ultra
	ng/l = pg/ml	15700	12600	18800	
	ng/ml = µg/l	0.773	0.618	0.928	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	773	618	928	
	ng/ml = µg/l	6.30	5.04	7.56	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	6300	5040	7560	
	ng/ml = µg/l	1.66	1.33	1.99	Siemens/Dade Dimension EXL/Vista
	ng/l = pg/ml	1660	1330	1990	
	ng/ml = µg/l	1.69	1.35	2.03	Siemens Dimension Exl LOCI
	ng/l = pg/ml	1690	1350	2030	
	ng/ml = µg/l	2.73	2.18	3.28	Abbott Architect STAT hs
	ng/l = pg/ml	2730	2180	3280	
	ng/ml = µg/l	1.82	1.46	2.18	Beckman DxI - AccuTnI+3
	ng/l = pg/ml	1820	1460	2180	
	ng/ml = µg/l	1.81	1.45	2.17	Beckman Access - AccuTnI+3
	ng/l = pg/ml	1810	1450	2170	
	ng/ml = µg/l	5.86	4.69	7.03	Siemens Centaur CP
	ng/l = pg/ml	5860	4690	7030	

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RANDOX

IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 1
(CRD LIQ CONTROL 1)

CAT. NO. CQ5051 **LOT NO.** 4246CK
SIZE: 3 x 3 ml **EXPIRY:** 2019-11-28

GTIN: 05055273207446

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 1 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Revised 22 Jul 19 pq

LIQUID CARDIAC CONTROL - LEVEL 1 (CRD LIQ CONTROL 1)

Cat. No. CQ5051 Lot No. 4246CK **Size: 3 x 3 ml Expiry: 2019-11-28**

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	4.24	2.97	5.51	Abbott Architect
	ng/ml = µg/l	6.55	4.59	8.52	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	4.40	3.08	5.72	Siemens Dimension
	ng/ml = µg/l	4.18	2.93	5.43	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	6.01	4.21	7.81	Beckman Coulter Access
	ng/ml = µg/l	4.96	3.47	6.45	Siemens Stratus CS
	ng/ml = µg/l	7.34	5.14	9.54	BioMerieux Vidas
	ng/ml = µg/l	6.08	4.26	7.90	Beckman DxI800
	ng/ml = µg/l	4.12	2.88	5.36	Roche h232
	ng/ml = µg/l	7.86	5.50	10.2	Radiometer AQT90 Flex
	ng/ml = µg/l	4.49	3.14	5.84	Siemens Dimension Vista LOCI
	ng/ml = µg/l	4.09	2.86	5.32	Roche Cardiac Reader
	ng/ml = µg/l	5.30	3.71	6.89	Siemens Centaur CP
D - Dimer	µg/l FEU	920	690	1150	Biomerieux Vidas Exclusion II
	µg/l FEU	2816	2112	3520	Mitsubishi Pathfast D-Dimer
	µg/l	358	269	448	Roche/ Stago STA-R Evolution
	µg/l	537	403	671	Roche Cobas h232 D-Dimer
	µg/l	292	219	365	Roche Integra D-DI 2
	µg/l	586	440	733	Alere Biosite Triage D-Dimer
	µg/l	528	396	660	Abbott Architect Quantia D-Dimer
	µg/l	520	390	650	Siemens Stratus CS
	µg/l	113	84.8	141	Siemens Immulite 2000 D-Dimer
	µg/l	570	428	713	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1296	972	1620	Siemens Innovance D-Dimer
	µg/l	158	119	198	Roche Cobas D-DI 2
	µg/l FEU	1458	1094	1823	HemosIL D-Dimer 500
	µg/l FEU	1528	1146	1910	HemosIL D-Dimer HS 500
	µg/l	464	348	580	HemosIL D-Dimer
	µg/l	469	352	586	HemosIL D-Dimer HS
Digoxin	nmol/l	1.29	1.03	1.55	Chemiluminescence
	ng/ml	1.01	0.804	1.22	
	nmol/l	1.18	0.944	1.42	Enzyme Immunoassay
	ng/ml	0.922	0.737	1.11	
	nmol/l	1.22	0.976	1.46	Turbidimetric
	ng/ml	0.953	0.762	1.14	
	nmol/l	1.08	0.864	1.30	KIMS
	ng/ml	0.843	0.675	1.01	
	nmol/l	1.32	1.06	1.58	Enzyme Linked Flourescent assay
	ng/ml	1.03	0.828	1.23	
hsCRP	mg/l	1.31	1.05	1.57	Nephelometric (IFCC Cal.)
	mg/l	1.48	1.18	1.78	Turbidimetric (IFCC Cal.)
	mg/l	1.53	1.22	1.84	Turbidimetric (Non IFCC Cal.)

LIQUID CARDIAC CONTROL - LEVEL 1 (CRD LIQ CONTROL 1)

Cat. No. CQ5051 Lot No. 4246CK Size: 3 x 3 ml Expiry: 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
hsCRP	mg/l	1.56	1.25	1.87	Chemiluminescence (IFCC Cal.)
	mg/l	1.42	1.14	1.70	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	83.1	58.2	108	Abbott Architect
	ng/ml = µg/l	67.7	47.4	88.0	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	67.6	47.3	87.9	Siemens Dimension
	ng/ml = µg/l	49.3	34.5	64.1	Beckman DxI800
	ng/ml = µg/l	56.9	39.8	74.0	Roche Elecsys
	ng/ml = µg/l	63.4	44.4	82.4	Roche Hitachi
	ng/ml = µg/l	49.2	34.4	64.0	Beckman Coulter Access
	ng/ml = µg/l	36.2	25.3	47.1	Siemens Stratus CS
	ng/ml = µg/l	48.5	34.0	63.1	BioMerieux Vidas
	ng/ml = µg/l	58.0	40.6	75.4	Siemens Dimension Vista LOCI
	ng/ml = µg/l	62.0	43.4	80.6	Siemens Centaur CP
	ng/ml = µg/l	85.9	60.1	112	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.0036	0.0029	0.0043	Abbott Architect
	ng/l = pg/ml	3.57	2.86	4.28	
	ng/ml = µg/l	0.0087	0.0070	0.0105	BioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	8.73	6.98	10.5	
	ng/ml = µg/l	0.0035	0.0028	0.0042	Abbott Architect STAT hs
	ng/l = pg/ml	3.46	2.77	4.15	

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RANDOX

IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 2
(CRD LIQ CONTROL 2)

CAT. NO. CQ 5052 **LOT NO.** 4247CK
SIZE: 3 x 3 ml **EXPIRY:** 2019-11-28

GTIN: 05055273207453

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 2 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Rev. 19 Jul 19 pq

RANDOX

LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot No. 4247CK Size: 3 x 3 ml Expiry: 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	5.24	3.67	6.81	Abbott Architect
	ng/ml = µg/l	7.65	5.36	9.95	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	5.71	4.00	7.42	Siemens Dimension
	ng/ml = µg/l	5.15	3.61	6.70	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	7.63	5.34	9.92	Beckman Coulter Access
	ng/ml = µg/l	6.38	4.47	8.29	Siemens Stratus CS
	ng/ml = µg/l	8.81	6.17	11.5	BioMerieux Vidas
	ng/ml = µg/l	7.81	5.47	10.2	Beckman DxI800
	ng/ml = µg/l	4.63	3.24	6.02	Roche h232
	ng/ml = µg/l	9.40	6.58	12.2	Radiometer AQT90 Flex
	ng/ml = µg/l	6.14	4.30	7.98	Siemens Dimension Vista LOCI
	ng/ml = µg/l	6.93	4.85	9.01	Siemens Centaur CP
D-Dimer	µg/l FEU	1428	1071	1785	Biomerieux Vidas Exclusion II
	µg/l FEU	6236	4677	7795	Mitsubishi Pathfast D-Dimer
	µg/l	616	462	770	Roche/ Stago STA-R Evolution
	µg/l	844	633	1055	Roche Cobas h232 D-Dimer
	µg/l	636	477	795	Roche Integra D-DI 2
	µg/l	955	716	1194	Alere Biosite Triage D-Dimer
	µg/l	795	596	994	Abbott Architect Quantia D-Dimer
	µg/l	1121	841	1401	Siemens Stratus CS
	µg/l	326	245	408	Siemens Immulite 2000 D-Dimer
	µg/l	884	663	1105	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	2032	1524	2540	Siemens Innovance D-Dimer
	µg/l	584	438	730	Roche Cobas D-DI 2
	µg/l FEU	2242	1682	2803	HemosIL D-Dimer HS 500
	µg/l	672	504	840	HemosIL D-Dimer
	µg/l	713	535	891	HemosIL D-Dimer HS
Digoxin	nmol/l	1.31	1.05	1.57	Chemiluminescence
	ng/ml	1.02	0.820	1.22	
	nmol/l	1.16	0.928	1.39	Enzyme Immunoassay
	ng/ml	0.906	0.725	1.09	
	nmol/l	1.28	1.02	1.54	Turbidimetric
	ng/ml	1.00	0.797	1.20	
	nmol/l	1.10	0.880	1.32	KIMS
	ng/ml	0.859	0.687	1.03	
	nmol/l	1.21	0.968	1.45	Enzyme Linked Flourescent assay
	ng/ml	0.945	0.756	1.13	
hsCRP	mg/l	1.82	1.46	2.18	Nephelometric (IFCC Cal.)
	mg/l	1.96	1.57	2.35	Turbidimetric (IFCC Cal.)
	mg/l	2.02	1.62	2.42	Turbidimetric (Non IFCC Cal.)
	mg/l	1.92	1.54	2.30	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	96.9	67.8	126	Abbott Architect

RANDOX

LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot No. 4247CK Size: 3 x 3 ml Expiry: 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Myoglobin	ng/ml = µg/l	80.3	56.2	104	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	82.7	57.9	108	Siemens Dimension
	ng/ml = µg/l	58.6	41.0	76.2	Beckman DxI800
	ng/ml = µg/l	67.5	47.3	87.8	Roche Elecsys
	ng/ml = µg/l	73.5	51.5	95.6	Roche Hitachi
	ng/ml = µg/l	58.2	40.7	75.7	Beckman Coulter Access
	ng/ml = µg/l	43.7	30.6	56.8	Siemens Stratus CS
	ng/ml = µg/l	60.2	42.1	78.3	BioMerieux Vidas
	ng/ml = µg/l	69.2	48.4	90.0	Siemens Dimension Vista LOCI
	ng/ml = µg/l	70.8	49.6	92.0	Siemens Centaur CP
	ng/ml = µg/l	98.1	68.7	128	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.024	0.019	0.029	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	24.0	19.0	29.0	
	ng/ml = µg/l	0.010	0.008	0.012	Beckman Coulter Access
	ng/l = pg/ml	10.0	8.00	12.0	
	ng/ml = µg/l	0.206	0.165	0.247	Ortho Vitros ECi
	ng/l = pg/ml	206	165	247	
	ng/ml = µg/l	0.159	0.127	0.191	Biomerieux Vidas Ultra
	ng/l = pg/ml	159	127	191	
	ng/ml = µg/l	0.020	0.016	0.024	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	20.0	16.0	24.0	
	ng/ml = µg/l	0.029	0.023	0.035	Abbott Architect STAT hs
	ng/l = pg/ml	29.0	23.0	35.0	
	ng/ml = µg/l	0.022	0.018	0.026	Siemens Centaur CP
	ng/l = pg/ml	22.0	18.0	26.0	
	ng/ml = µg/l	0.156	0.125	0.187	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	156	125	187	

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RANDOX

IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 1
(CRD LIQ CONTROL 1)

CAT. NO. CQ5051 **LOT NO.** 4249CK
SIZE: 3 x 3 ml **EXPIRY:** 2019-11-28

GTIN: 05055273207446

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°C if kept capped in the 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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 1 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Rev 22 Jul 19 pq

RANDOX

LIQUID CARDIAC CONTROL LEVEL 1 (CRD LIQ CONTROL 1)

Cat. No. CQ5051 Lot. No. 4249CK Size 3 x 3ml Expiry 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	2.71	1.90	3.52	Abbott Architect
	ng/ml = µg/l	4.29	3.00	5.58	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	2.64	1.85	3.43	Siemens Dimension
	ng/ml = µg/l	2.80	1.96	3.64	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	3.83	2.68	4.98	Beckman Coulter Access
	ng/ml = µg/l	3.13	2.19	4.07	Siemens Stratus CS
	ng/ml = µg/l	4.84	3.39	6.29	BioMerieux Vidas
	ng/ml = µg/l	3.98	2.79	5.17	Beckman DxI800
	ng/ml = µg/l	2.73	1.91	3.55	Roche h232
	ng/ml = µg/l	4.86	3.40	6.32	Radiometer AQT90 Flex
	ng/ml = µg/l	2.72	1.90	3.54	Siemens Dimension Vista LOCI
	ng/ml = µg/l	2.59	1.81	3.37	Roche Cardiac Reader
	ng/ml = µg/l	3.53	2.47	4.59	Siemens Centaur CP
D - Dimer	µg/l FEU	1012	759	1265	Biomerieux Vidas Exclusion II
	µg/l FEU	2916	2187	3645	Mitsubishi Pathfast D-Dimer
	µg/l	371	278	464	Roche/ Stago STA-R Evolution
	µg/l	574	431	718	Roche Cobas h232 D-Dimer
	µg/l	279	209	349	Roche Integra D-DI 2
	µg/l	619	464	774	Alere Biosite Triage D-Dimer
	µg/l	535	401	669	Abbott Architect Quantia D-Dimer
	µg/l	618	464	773	Siemens Stratus CS
	µg/l	125	93.8	156	Siemens Immulite 2000 D-Dimer
	µg/l	576	432	720	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1450	1088	1813	Siemens Innovance D-Dimer
	µg/l	168	126	210	Roche Cobas D-DI 2
	µg/l FEU	1642	1232	2053	HemosIL D-Dimer HS 500
	µg/l	508	381	635	HemosIL D-Dimer
	µg/l	537	403	671	HemosIL D-Dimer HS
Digoxin	nmol/l	1.01	0.808	1.21	Chemiluminescence
	ng/ml	0.789	0.631	0.947	
	nmol/l	0.833	0.666	1.00	Enzyme Immunoassay
	ng/ml	0.651	0.520	0.782	
	nmol/l	0.821	0.657	0.985	Turbidimetric
	ng/ml	0.641	0.513	0.769	
	nmol/l	0.776	0.621	0.931	KIMS
	ng/ml	0.606	0.485	0.727	
	nmol/l	0.942	0.754	1.13	Enzyme Linked Flourescent assay
	ng/ml	0.736	0.589	0.883	
hsCRP	mg/l	0.825	0.660	0.990	Nephelometric (IFCC Cal.)
	mg/l	0.871	0.697	1.05	Turbidimetric (IFCC Cal.)
	mg/l	0.890	0.712	1.07	Turbidimetric (Non IFCC Cal.)
	mg/l	0.932	0.746	1.12	Chemiluminescence (IFCC Cal.)

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LIQUID CARDIAC CONTROL LEVEL 1 (CRD LIQ CONTROL 1)

Cat. No. CQ5051 Lot. No. 4249CK Size 3 x 3ml Expiry 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
hsCRP	mg/l	0.785	0.630	0.940	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	63.2	44.2	82.2	Abbott Architect
	ng/ml = µg/l	48.3	33.8	62.8	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	48.0	33.6	62.4	Siemens Dimension
	ng/ml = µg/l	37.3	26.1	48.5	Beckman DxI800
	ng/ml = µg/l	43.1	30.2	56.0	Roche Elecsys
	ng/ml = µg/l	50.0	35.0	65.0	Roche Hitachi
	ng/ml = µg/l	37.8	26.5	49.1	Beckman Coulter Access
	ng/ml = µg/l	26.6	18.6	34.6	Siemens Stratus CS
	ng/ml = µg/l	36.3	25.4	47.2	BioMerieux Vidas
	ng/ml = µg/l	42.6	29.8	55.4	Siemens Dimension Vista LOCI
	ng/ml = µg/l	45.3	31.7	58.9	Siemens Centaur CP
	ng/ml = µg/l	72.8	51.0	94.6	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.122	0.098	0.146	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	122	98.0	146	
	ng/ml = µg/l	0.046	0.037	0.055	Siemens Stratus CS
	ng/l = pg/ml	46.0	37.0	55.0	
	ng/ml = µg/l	0.868	0.694	1.04	Ortho Vitros ECi
	ng/l = pg/ml	868	694	1042	
	ng/ml = µg/l	0.061	0.049	0.073	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	61.0	49.0	73.0	
	ng/ml = µg/l	0.028	0.022	0.034	Siemens/Dade Dimension EXL/Vista
	ng/l = pg/ml	28.0	22.0	34.0	
	ng/ml = µg/l	0.043	0.034	0.052	Siemens Dimension Exl LOCI
	ng/l = pg/ml	43.0	34.0	52.0	
	ng/ml = µg/l	0.098	0.078	0.118	Abbott Architect STAT hs
	ng/l = pg/ml	98.0	78.0	118	
	ng/ml = µg/l	0.055	0.044	0.066	Beckman Dxl - AccuTnI+3
	ng/l = pg/ml	55.0	44.0	66.0	
	ng/ml = µg/l	0.054	0.043	0.065	Beckman Access - AccuTnI+3
	ng/l = pg/ml	54.0	43.0	65.0	
	ng/ml = µg/l	0.102	0.082	0.122	Siemens Centaur CP
	ng/l = pg/ml	102	82.0	122	
	ng/ml = µg/l	0.669	0.535	0.803	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	669	535	803	

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RANDOX

IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 1
(CRD LIQ CONTROL 1)

CAT. NO. CQ5051 **LOT NO.** 4260CK
SIZE: 3 x 3 ml **EXPIRY:** 2019-11-28

GTIN: 05055273207446

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 1 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Rev. 06 Aug 19 pq

LIQUID CARDIAC CONTROL - LEVEL 1 (CRD LIQ CONTROL 1)

Cat. No. CQ5051 Lot No. 4260CK

Size: 3 x 3 ml Expiry: 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	4.61	3.23	5.99	Siemens Centaur XP/XPT/Classic
D-Dimer	µg/l	923	692	1154	BioMerieux Vidas
Digoxin	nmol/l	0.70	0.56	0.84	Immunoturbidimetric
	ng/ml	0.54	0.44	0.64	
hsCRP	mg/l	0.76	0.61	0.92	Immunoturbidimetric
Myoglobin	ng/ml = µg/l	48.2	33.8	62.7	Siemens Centaur XP/XPT/Classic
Troponin I	ng/ml = µg/l	0.01	0.01	0.01	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	11.0	10.0	12.0	

RANDOX

IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

CAT. NO. CQ 5052 **LOT NO.** 4261CK
SIZE: 3 x 3 ml **EXPIRY:** 2019-11-28

GTIN: 05055273207453

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 2 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Rev. 06 Aug 19 pq

LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot No. 4261CK

Size: 3 x 3 ml Expiry: 2019-11-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	23.3	16.3	30.3	Siemens Centaur XP/XPT/Classic
D-Dimer	µg/l	1007	755	1259	BioMerieux Vidas
Digoxin	nmol/l	1.98	1.58	2.38	Immunoturbidimetric
	ng/ml	1.55	1.23	1.87	
hsCRP	mg/l	2.82	2.26	3.38	Immunoturbidimetric
Myoglobin	ng/ml = µg/l	137	95.8	178	Siemens Centaur XP/XPT/Classic
Troponin I	ng/ml = µg/l	0.05	0.04	0.06	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	47.7	40.0	55.4	

RANDOX

IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 1 (CRD LIQ CONTROL 1)

CAT. NO. CQ5051 **LOT NO.** 4311CK
SIZE: 3 x 3 ml **EXPIRY:** 2020-05-28

GTIN: 05055273207446

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 1 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Rev 22 Jul 19 pq

LIQUID CARDIAC CONTROL - LEVEL 1 (CRD LIQ CONTROL 1)

Cat. No. CQ5051 Lot No. 4311CK Size: 3 x 3 ml Expiry: 2020-05-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	2.77	1.94	3.60	Abbott Architect
	ng/ml = µg/l	4.37	3.06	5.68	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	2.83	1.98	3.68	Siemens Dimension
	ng/ml = µg/l	3.10	2.17	4.03	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	3.77	2.64	4.90	Beckman Coulter Access
	ng/ml = µg/l	3.38	2.37	4.39	Siemens Stratus CS
	ng/ml = µg/l	3.87	2.71	5.03	BioMerieux Vidas
	ng/ml = µg/l	3.89	2.72	5.06	Beckman DxI800
	ng/ml = µg/l	2.92	2.04	3.80	Roche h232
	ng/ml = µg/l	4.90	3.43	6.37	Radiometer AQT90 Flex
	ng/ml = µg/l	3.10	2.17	4.03	Siemens Dimension Vista LOCI
	ng/ml = µg/l	3.58	2.51	4.65	Siemens Centaur CP
D-Dimer	µg/l FEU	1220	915	1525	Biomerieux Vidas Exclusion II
	µg/l FEU	4490	3368	5613	Mitsubishi Pathfast D-Dimer
	µg/l	451	338	564	Roche/ Stago STA-R Evolution
	µg/l	724	543	905	Roche Cobas h232 D-Dimer
	µg/l	346	260	433	Roche Integra D-DI 2
	µg/l	649	487	811	Alere Biosite Triage D-Dimer
	µg/l	654	491	818	Abbott Architect Quantia D-Dimer
	µg/l	649	487	811	Siemens Stratus CS
	µg/l	161	121	201	Siemens Immulite 2000 D-Dimer
	µg/l	712	534	890	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1700	1275	2125	Siemens Innovance D-Dimer
	µg/l	216	162	270	Roche Cobas D-DI 2
	µg/l FEU	1820	1365	2275	HemosIL D-Dimer HS 500
	µg/l	574	431	718	HemosIL D-Dimer
	µg/l	657	493	821	HemosIL D-Dimer HS
	µg/l	804	603	1005	Diazyme D-Dimer
Digoxin	nmol/l	1.08	0.864	1.30	Chemiluminescence
	ng/ml	0.843	0.675	1.01	
	nmol/l	1.09	0.872	1.31	Enzyme Immunoassay
	ng/ml	0.851	0.681	1.02	
	nmol/l	0.913	0.730	1.10	Turbidimetric
	ng/ml	0.713	0.570	0.856	
	nmol/l	1.02	0.816	1.22	KIMS
	ng/ml	0.797	0.637	0.957	
	nmol/l	0.966	0.773	1.16	Enzyme Linked Flourescent assay
	ng/ml	0.754	0.604	0.904	
hsCRP	mg/l	0.940	0.752	1.13	Nephelometric (IFCC Cal.)
	mg/l	1.06	0.848	1.27	Turbidimetric (IFCC Cal.)
	mg/l	1.10	0.880	1.32	Turbidimetric (Non IFCC Cal.)
	mg/l	1.16	0.928	1.39	Chemiluminescence (IFCC Cal.)

LIQUID CARDIAC CONTROL - LEVEL 1 (CRD LIQ CONTROL 1)

Cat. No. CQ5051 Lot No. 4311CK Size: 3 x 3 ml Expiry: 2020-05-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
hsCRP	mg/l	0.932	0.750	1.12	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	57.8	40.5	75.1	Abbott Architect
	ng/ml = µg/l	46.8	32.8	60.8	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	50.7	35.5	65.9	Siemens Dimension
	ng/ml = µg/l	38.0	26.6	49.4	Beckman DxI800
	ng/ml = µg/l	43.2	30.2	56.2	Roche Elecsys
	ng/ml = µg/l	51.0	35.7	66.3	Roche Hitachi
	ng/ml = µg/l	37.1	26.0	48.2	Beckman Coulter Access
	ng/ml = µg/l	25.1	17.6	32.6	Siemens Stratus CS
	ng/ml = µg/l	42.6	29.8	55.4	BioMerieux Vidas
	ng/ml = µg/l	38.6	27.0	50.2	Siemens Dimension Vista LOCI
	ng/ml = µg/l	42.3	29.6	55.0	Siemens Centaur CP
	ng/ml = µg/l	66.1	46.3	85.9	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.083	0.066	0.100	Abbott Architect
	ng/l = pg/ml	83.0	66.0	100	
	ng/ml = µg/l	0.072	0.058	0.086	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	72.0	58.0	86.0	
	ng/ml = µg/l	0.332	0.266	0.398	Ortho Vitros ECi
	ng/l = pg/ml	332	266	398	
	ng/ml = µg/l	0.031	0.025	0.037	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	31.0	25.0	37.0	
	ng/ml = µg/l	0.025	0.020	0.030	Siemens/Dade Dimension EXL/Vista
	ng/l = pg/ml	25.0	20.0	30.0	
	ng/ml = µg/l	0.032	0.026	0.039	Siemens Dimension ExI LOCI
	ng/l = pg/ml	32.1	26.0	38.2	
	ng/ml = µg/l	0.080	0.064	0.096	Abbott Architect STAT hs
	ng/l = pg/ml	80.0	64.0	96.0	
	ng/ml = µg/l	0.044	0.035	0.053	Beckman DxI - AccuTnI+3
	ng/l = pg/ml	44.0	35.0	53.0	
	ng/ml = µg/l	0.047	0.038	0.056	Beckman Access - AccuTnI+3
	ng/l = pg/ml	47.0	38.0	56.0	
	ng/ml = µg/l	0.060	0.048	0.072	Siemens Centaur CP
	ng/l = pg/ml	60.0	48.0	72.0	
	ng/ml = µg/l	0.222	0.178	0.266	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	222	178	266	
	ng/ml = µg/l	0.115	0.092	0.138	Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH)
	ng/l = pg/ml	115	92.0	138	

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RANDOX

IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

CAT. NO. CQ 5052 **LOT NO.** 4312CK
SIZE: 3 x 3 ml **EXPIRY:** 2020-06-28

GTIN: 05055273207453

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 2 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Rev. 19 Jul 19 pq

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LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot No. 4312CK Size: 3 x 3 ml Expiry: 2020-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	16.5	11.6	21.5	Abbott Architect
	ng/ml = µg/l	22.9	16.0	29.8	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	22.3	15.6	29.0	Siemens Dimension
	ng/ml = µg/l	15.1	10.6	19.6	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	23.9	16.7	31.1	Beckman Coulter Access
	ng/ml = µg/l	21.5	15.1	28.0	Siemens Stratus CS
	ng/ml = µg/l	21.2	14.8	27.6	BioMerieux Vidas
	ng/ml = µg/l	24.0	16.8	31.2	Beckman DxI800
	ng/ml = µg/l	14.6	10.2	19.0	Roche h232
	ng/ml = µg/l	30.0	21.0	39.0	Radiometer AQT90 Flex
	ng/ml = µg/l	20.1	14.1	26.1	Siemens Centaur CP
D-Dimer	µg/l FEU	1384	1038	1730	Biomerieux Vidas Exclusion II
	µg/l FEU	5244	3933	6555	Mitsubishi Pathfast D-Dimer
	µg/l	539	404	674	Roche/ Stago STA-R Evolution
	µg/l	829	622	1036	Roche Cobas h232 D-Dimer
	µg/l	459	344	574	Roche Integra D-DI 2
	µg/l	712	534	890	Alere Biosite Triage D-Dimer
	µg/l	726	545	908	Abbott Architect Quantia D-Dimer
	µg/l	848	636	1060	Siemens Stratus CS
	µg/l	763	572	954	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1868	1401	2335	Siemens Innovance D-Dimer
	µg/l	351	263	439	Roche Cobas D-DI 2
	µg/l FEU	2122	1592	2653	HemosIL D-Dimer HS 500
	µg/l	549	412	686	HemosIL D-Dimer
Digoxin	nmol/l	2.28	1.82	2.74	Chemiluminescence
	ng/ml	1.78	1.42	2.14	
	nmol/l	2.19	1.75	2.63	Enzyme Immunoassay
	ng/ml	1.71	1.37	2.05	
	nmol/l	2.28	1.82	2.74	Turbidimetric
	ng/ml	1.78	1.42	2.14	
	nmol/l	2.17	1.74	2.60	KIMS
	ng/ml	1.69	1.36	2.02	
hsCRP	mg/l	2.85	2.28	3.42	Nephelometric (IFCC Cal.)
	mg/l	2.95	2.36	3.54	Turbidimetric (IFCC Cal.)
	mg/l	2.99	2.39	3.59	Turbidimetric (Non IFCC Cal.)
	mg/l	2.76	2.21	3.31	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	140	98.0	182	Abbott Architect
	ng/ml = µg/l	104	72.8	135	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	138	96.6	179	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	139	97.3	181	Siemens Dimension
	ng/ml = µg/l	95.6	66.9	124	Beckman DxI800
	ng/ml = µg/l	105	73.5	137	Roche Elecsys

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LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot No. 4312CK Size: 3 x 3 ml Expiry: 2020-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Myoglobin	ng/ml = µg/l	106	74.2	138	Roche Hitachi
	ng/ml = µg/l	93.7	65.6	122	Beckman Coulter Access
	ng/ml = µg/l	71.5	50.1	93.0	Siemens Stratus CS
	ng/ml = µg/l	108	75.6	140	BioMerieux Vidas
	ng/ml = µg/l	111	77.7	144	Siemens Dimension Vista LOCI
	ng/ml = µg/l	123	86.1	160	Siemens Centaur CP
	ng/ml = µg/l	155	109	202	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	2.02	1.62	2.42	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	2020	1620	2420	
	ng/ml = µg/l	1.10	0.880	1.32	Siemens Dimension
	ng/l = pg/ml	1100	880	1320	
	ng/ml = µg/l	1.21	0.968	1.45	Siemens Stratus CS
	ng/l = pg/ml	1210	968	1452	
	ng/ml = µg/l	8.76	7.01	10.5	Ortho Vitros ECi
	ng/l = pg/ml	8760	7010	10510	
	ng/ml = µg/l	7.87	6.30	9.44	Biomerieux Vidas Ultra
	ng/l = pg/ml	7870	6300	9440	
	ng/ml = µg/l	0.603	0.482	0.724	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	603	482	724	
	ng/ml = µg/l	0.721	0.577	0.865	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	721	577	865	
	ng/ml = µg/l	0.949	0.759	1.14	Siemens/Dade Dimension EXL/Vista
	ng/l = pg/ml	949	759	1139	
	ng/ml = µg/l	1.04	0.832	1.25	Siemens Dimension Exl LOCI
	ng/l = pg/ml	1040	832	1248	
	ng/ml = µg/l	1.65	1.32	1.98	Abbott Architect STAT hs
	ng/l = pg/ml	1650	1320	1980	
	ng/ml = µg/l	0.958	0.766	1.15	Beckman Dxl - AccuTnI+3
	ng/l = pg/ml	958	766	1150	
	ng/ml = µg/l	1.03	0.824	1.24	Beckman Access - AccuTnI+3
	ng/l = pg/ml	1030	824	1236	
	ng/ml = µg/l	1.59	1.27	1.91	Siemens Centaur CP
	ng/l = pg/ml	1590	1270	1910	
	ng/ml = µg/l	7.84	6.27	9.41	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	7840	6270	9410	
	ng/ml = µg/l	3.26	2.61	3.91	Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH)
	ng/l = pg/ml	3260	2610	3910	

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RANDOX

IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 3 (CRD LIQ CONTROL 3)

CAT. NO. CQ5053 **LOT NO.** 4313CK
SIZE: 3 x 3 ml **EXPIRY:** 2020-06-28

GTIN: 05055273207460

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 3 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Rev. 22 Jul 19 pq

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LIQUID CARDIAC CONTROL - LEVEL 3 (CRD LIQ CONTROL 3)

Cat. No. CQ5053 Lot No. 4313CK Size: 3 x 3 ml Expiry: 2020-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	79.6	55.7	103	Abbott Architect
	ng/ml = µg/l	119	83.3	155	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	130	91.0	169	Siemens Dimension
	ng/ml = µg/l	76.6	53.6	100	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	127	88.9	165	Beckman Coulter Access
	ng/ml = µg/l	114	79.8	148	Siemens Stratus CS
	ng/ml = µg/l	118	82.6	153	BioMerieux Vidas
	ng/ml = µg/l	130	91.0	169	Beckman DxI800
	ng/ml = µg/l	37.3	26.1	48.5	Biosite Triage Meter Plus
	ng/ml = µg/l	39.0	27.3	50.7	Roche h232
	ng/ml = µg/l	152	106	198	Radiometer AQT90 Flex
	ng/ml = µg/l	36.5	25.6	47.5	Roche Cardiac Reader
	ng/ml = µg/l	101	70.7	131	Siemens Centaur CP
D-Dimer	µg/l FEU	2266	1700	2833	Biomerieux Vidas Exclusion II
	µg/l FEU	10882	8162	13603	Mitsubishi Pathfast D-Dimer
	µg/l	1052	789	1315	Roche/ Stago STA-R Evolution
	µg/l	1401	1051	1751	Roche Cobas h232 D-Dimer
	µg/l	1133	850	1416	Roche Integra D-DI 2
	µg/l	1313	985	1641	Alere Biosite Triage D-Dimer
	µg/l	1106	830	1383	Abbott Architect Quantia D-Dimer
	µg/l	2107	1580	2634	Siemens Stratus CS
	µg/l	929	697	1161	Siemens Immulite 2000 D-Dimer
	µg/l	1305	979	1631	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	3234	2426	4043	Siemens Innovance D-Dimer
	µg/l	1221	916	1526	Roche Cobas D-DI 2
	µg/l FEU	3104	2328	3880	HemosIL D-Dimer HS 500
	µg/l	922	692	1153	HemosIL D-Dimer
	µg/l	988	741	1235	HemosIL D-Dimer HS
Digoxin	nmol/l	3.13	2.50	3.76	Chemiluminescence
	ng/ml	2.44	1.95	2.93	
	nmol/l	3.05	2.44	3.66	Enzyme Immunoassay
	ng/ml	2.38	1.91	2.85	
	nmol/l	3.07	2.46	3.68	Turbidimetric
	ng/ml	2.40	1.92	2.88	
	nmol/l	3.10	2.48	3.72	KIMS
	ng/ml	2.42	1.94	2.90	
	nmol/l	3.10	2.48	3.72	Enzyme Linked Flourescent assay
	ng/ml	2.42	1.94	2.90	
hsCRP	mg/l	7.97	6.38	9.56	Nephelometric (IFCC Cal.)
	mg/l	7.99	6.39	9.59	Turbidimetric (IFCC Cal.)
	mg/l	7.72	6.18	9.26	Turbidimetric (Non IFCC Cal.)
	mg/l	8.08	6.46	9.70	Randox Immunoturbidimetric

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LIQUID CARDIAC CONTROL - LEVEL 3 (CRD LIQ CONTROL 3)

Cat. No. CQ5053 Lot No. 4313CK Size: 3 x 3 ml Expiry: 2020-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Myoglobin	ng/ml = µg/l	380	266	494	Abbott Architect
	ng/ml = µg/l	376	263	489	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	387	271	503	Siemens Dimension
	ng/ml = µg/l	264	185	343	Beckman DxI800
	ng/ml = µg/l	277	194	360	Roche Elecsys
	ng/ml = µg/l	274	192	356	Roche Hitachi
	ng/ml = µg/l	247	173	321	Beckman Coulter Access
	ng/ml = µg/l	216	151	281	Siemens Stratus CS
	ng/ml = µg/l	292	204	380	BioMerieux Vidas
	ng/ml = µg/l	344	241	447	Siemens Dimension Vista LOCI
	ng/ml = µg/l	375	263	488	Siemens Centaur CP
	ng/ml = µg/l	449	314	584	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	5.80	4.64	6.96	Abbott Architect
	ng/l = pg/ml	5800	4640	6960	
	ng/ml = µg/l	7.51	6.01	9.01	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	7510	6010	9010	
	ng/ml = µg/l	3.31	2.65	3.97	Siemens Dimension
	ng/l = pg/ml	3310	2650	3970	
	ng/ml = µg/l	3.73	2.98	4.48	Siemens Stratus CS
	ng/l = pg/ml	3730	2980	4480	
	ng/ml = µg/l	27.5	22.0	33.0	Ortho Vitros ECi
	ng/l = pg/ml	27533	22000	33066	
	ng/ml = µg/l	29.7	23.8	35.7	Biomerieux Vidas Ultra
	ng/l = pg/ml	29749	23800	35698	
	ng/ml = µg/l	1.56	1.25	1.87	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	1560	1250	1870	
	ng/ml = µg/l	3.63	2.90	4.36	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	3630	2900	4360	
	ng/ml = µg/l	3.14	2.51	3.77	Siemens/Dade Dimension EXL/Vista
	ng/l = pg/ml	3140	2510	3770	
	ng/ml = µg/l	3.27	2.62	3.92	Siemens Dimension ExI LOCI
	ng/l = pg/ml	3270	2620	3920	
	ng/ml = µg/l	5.61	4.49	6.73	Abbott Architect STAT hs
	ng/l = pg/ml	5610	4490	6730	
	ng/ml = µg/l	3.32	2.66	3.98	Beckman DxI - AccuTnI+3
	ng/l = pg/ml	3320	2660	3980	
	ng/ml = µg/l	3.23	2.58	3.88	Beckman Access - AccuTnI+3
	ng/l = pg/ml	3230	2580	3880	
	ng/ml = µg/l	5.92	4.74	7.10	Siemens Centaur CP
	ng/l = pg/ml	5920	4740	7100	
	ng/ml = µg/l	30.5	24.4	36.6	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	30466	24400	36532	

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RANDOX

IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

CAT. NO. CQ 5052 **LOT NO.** 4315CK
SIZE: 3 x 3 ml **EXPIRY:** 2020-06-28

GTIN: 05055273207453

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 2 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Rev 19 Jul 19 pq

RANDOX

LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot No. 4315CK Size: 3 x 3 ml Expiry: 2020-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	5.07	3.55	6.59	Abbott Architect
	ng/ml = µg/l	9.19	6.43	11.9	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	7.19	5.03	9.35	Siemens Dimension
	ng/ml = µg/l	5.78	4.05	7.51	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	8.33	5.83	10.8	Beckman Coulter Access
	ng/ml = µg/l	7.40	5.18	9.62	Siemens Stratus CS
	ng/ml = µg/l	4.36	3.05	5.67	Ortho Vitros ECi
	ng/ml = µg/l	7.18	5.03	9.33	BioMerieux Vidas
	ng/ml = µg/l	8.60	6.02	11.2	Beckman DxI800
	ng/ml = µg/l	5.83	4.08	7.58	Roche h232
	ng/ml = µg/l	10.2	7.14	13.3	Radiometer AQT90 Flex
	ng/ml = µg/l	7.53	5.27	9.79	Siemens Centaur CP
D-Dimer	µg/l FEU	1700	1275	2125	Biomerieux Vidas Exclusion II
	µg/l FEU	7892	5919	9865	Mitsubishi Pathfast D-Dimer
	µg/l	689	517	861	Roche/ Stago STA-R Evolution
	µg/l	1005	754	1256	Roche Cobas h232 D-Dimer
	µg/l	753	565	941	Roche Integra D-DI 2
	µg/l	879	659	1099	Alere Biosite Triage D-Dimer
	µg/l	862	647	1078	Abbott Architect Quantia D-Dimer
	µg/l	1350	1013	1688	Siemens Stratus CS
	µg/l	615	461	769	Siemens Immulite 2000 D-Dimer
	µg/l	919	689	1149	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	2348	1761	2935	Siemens Innovance D-Dimer
	µg/l	667	500	834	Roche Cobas D-DI 2
	µg/l FEU	2470	1853	3088	HemosIL D-Dimer HS 500
	µg/l	755	566	944	HemosIL D-Dimer
	µg/l	797	598	996	HemosIL D-Dimer HS
Digoxin	nmol/l	1.51	1.21	1.81	Chemiluminescence
	ng/ml	1.18	0.945	1.42	
	nmol/l	1.42	1.14	1.70	Enzyme Immunoassay
	ng/ml	1.11	0.890	1.33	
	nmol/l	1.29	1.03	1.55	Turbidimetric
	ng/ml	1.01	0.804	1.22	
	nmol/l	1.44	1.15	1.73	KIMS
	ng/ml	1.12	0.898	1.34	
	nmol/l	1.37	1.10	1.64	Enzyme Linked Flourescent assay
	ng/ml	1.07	0.859	1.28	
hsCRP	mg/l	1.90	1.52	2.28	Nephelometric (IFCC Cal.)
	mg/l	2.08	1.66	2.50	Turbidimetric (IFCC Cal.)
	mg/l	2.08	1.66	2.50	Turbidimetric (Non IFCC Cal.)
	mg/l	1.89	1.51	2.27	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	85.4	59.8	111	Abbott Architect

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LIQUID CARDIAC CONTROL - LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot No. 4315CK Size: 3 x 3 ml Expiry: 2020-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Myoglobin	ng/ml = µg/l	80.3	56.2	104	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	82.8	58.0	108	Siemens Dimension
	ng/ml = µg/l	61.9	43.3	80.5	Beckman DxI800
	ng/ml = µg/l	64.8	45.4	84.2	Roche Elecsys
	ng/ml = µg/l	69.9	48.9	90.9	Roche Hitachi
	ng/ml = µg/l	59.8	41.9	77.7	Beckman Coulter Access
	ng/ml = µg/l	42.4	29.7	55.1	Siemens Stratus CS
	ng/ml = µg/l	71.0	49.7	92.3	BioMerieux Vidas
	ng/ml = µg/l	64.8	45.4	84.2	Siemens Dimension Vista LOCI
	ng/ml = µg/l	72.1	50.5	93.7	Siemens Centaur CP
	ng/ml = µg/l	96.4	67.5	125	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.048	0.038	0.058	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	48.0	38.0	58.0	
	ng/ml = µg/l	0.208	0.166	0.250	Ortho Vitros ECi
	ng/l = pg/ml	208	166	250	
	ng/ml = µg/l	0.135	0.108	0.162	Biomerieux Vidas Ultra
	ng/l = pg/ml	135	108	162	
	ng/ml = µg/l	0.019	0.015	0.023	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	19.0	15.0	23.0	
	ng/ml = µg/l	0.060	0.048	0.072	Abbott Architect STAT hs
	ng/l = pg/ml	60.0	48.0	72.0	
	ng/ml = µg/l	0.034	0.027	0.041	Beckman DxI - AccuTnI+3
	ng/l = pg/ml	34.0	27.0	41.0	
	ng/ml = µg/l	0.042	0.034	0.050	Siemens Centaur CP
	ng/l = pg/ml	42.0	34.0	50.0	
	ng/ml = µg/l	0.146	0.117	0.175	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	146	117	175	
	ng/ml = µg/l	0.083	0.066	0.100	Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH)
	ng/l = pg/ml	83.0	66.0	100	

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IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 3 (CRD LIQ CONTROL 3)

CAT. NO. CQ5053 **LOT NO.** 4316CK
SIZE: 3 x 3 ml **EXPIRY:** 2020-06-28

GTIN: 05055273207460

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 3 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Rev. 19 Jul 19 pq

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LIQUID CARDIAC CONTROL - LEVEL 3 (CRD LIQ CONTROL 3)

Cat. No. CQ5053 Lot No. 4316CK Size: 3 x 3 ml Expiry: 2020-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	99.0	69.3	129	Abbott Architect
	ng/ml = µg/l	171	120	222	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	179	125	233	Siemens Dimension
	ng/ml = µg/l	102	71.4	133	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	174	122	226	Beckman Coulter Access
	ng/ml = µg/l	146	102	190	Siemens Stratus CS
	ng/ml = µg/l	147	103	191	BioMerieux Vidas
	ng/ml = µg/l	174	122	226	Beckman DxI800
	ng/ml = µg/l	202	141	263	Radiometer AQT90 Flex
	ng/ml = µg/l	162	113	211	Siemens Dimension Vista LOCI
	ng/ml = µg/l	152	106	198	Siemens Centaur CP
D-Dimer	µg/l FEU	3222	2417	4028	Biomerieux Vidas Exclusion II
	µg/l	1491	1118	1864	Roche/ Stago STA-R Evolution
	µg/l	1753	1315	2191	Roche Cobas h232 D-Dimer
	µg/l	1666	1250	2083	Roche Integra D-DI 2
	µg/l	2004	1503	2505	Alere Biosite Triage D-Dimer
	µg/l	1347	1010	1684	Abbott Architect Quantia D-Dimer
	µg/l	3208	2406	4010	Siemens Stratus CS
	µg/l	2088	1566	2610	Siemens Immulite 2000 D-Dimer
	µg/l	1786	1340	2233	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	4840	3630	6050	Siemens Innovance D-Dimer
	µg/l	1956	1467	2445	Roche Cobas D-DI 2
	µg/l FEU	4628	3471	5785	HemosIL D-Dimer HS 500
	µg/l	1452	1089	1815	HemosIL D-Dimer
Digoxin	nmol/l	3.23	2.58	3.88	Chemiluminescence
	ng/ml	2.52	2.01	3.03	
	nmol/l	2.97	2.38	3.56	Enzyme Immunoassay
	ng/ml	2.32	1.86	2.78	
	nmol/l	3.16	2.53	3.79	Turbidimetric
	ng/ml	2.47	1.98	2.96	
	nmol/l	3.09	2.47	3.71	KIMS
	ng/ml	2.41	1.93	2.89	
	nmol/l	3.23	2.58	3.88	Enzyme Linked Flourescent assay
	ng/ml	2.52	2.01	3.03	
hsCRP	mg/l	6.73	5.38	8.08	Nephelometric (IFCC Cal.)
	mg/l	6.72	5.38	8.06	Turbidimetric (IFCC Cal.)
	mg/l	6.50	5.20	7.80	Turbidimetric (Non IFCC Cal.)
	mg/l	6.62	5.30	7.94	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	351	246	456	Abbott Architect
	ng/ml = µg/l	343	240	446	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	360	252	468	Siemens Dimension
	ng/ml = µg/l	224	157	291	Beckman DxI800

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LIQUID CARDIAC CONTROL - LEVEL 3 (CRD LIQ CONTROL 3)

Cat. No. CQ5053 Lot No. 4316CK Size: 3 x 3 ml Expiry: 2020-06-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Myoglobin	ng/ml = µg/l	247	173	321	Roche Elecsys
	ng/ml = µg/l	254	178	330	Roche Hitachi
	ng/ml = µg/l	218	153	283	Beckman Coulter Access
	ng/ml = µg/l	198	139	257	Siemens Stratus CS
	ng/ml = µg/l	260	182	338	BioMerieux Vidas
	ng/ml = µg/l	316	221	411	Siemens Dimension Vista LOCI
	ng/ml = µg/l	339	237	441	Siemens Centaur CP
	ng/ml = µg/l	394	276	512	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	75.3	60.2	90.4	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	75309	60200	90418	
	ng/ml = µg/l	25.9	20.7	31.1	Siemens Dimension
	ng/l = pg/ml	25926	20700	31152	
	ng/ml = µg/l	51.0	40.8	61.2	Beckman DXi800 1st gen
	ng/l = pg/ml	51013	40800	61226	
	ng/ml = µg/l	25.4	20.3	30.5	Siemens Stratus CS
	ng/l = pg/ml	25385	20300	30470	
	ng/ml = µg/l	279	223	335	Tosoh Series
	ng/l = pg/ml	279350	223000	335700	
	ng/ml = µg/l	215	172	258	Ortho Vitros ECi
	ng/l = pg/ml	215352	172000	258704	
	ng/ml = µg/l	13.3	10.7	16.0	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	13332	10700	15964	
	ng/ml = µg/l	46.0	36.8	55.2	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	45983	36800	55166	
	ng/ml = µg/l	24.5	19.6	29.4	Siemens/Dade Dimension EXL/Vista
	ng/l = pg/ml	24486	19600	29372	
	ng/ml = µg/l	25.0	20.0	30.0	Siemens Dimension Exl LOCI
	ng/l = pg/ml	25010	20000	30020	
	ng/ml = µg/l	52.4	41.9	62.9	Abbott Architect STAT hs
	ng/l = pg/ml	52436	41900	62972	
	ng/ml = µg/l	52.7	42.1	63.2	Beckman DxI - AccuTnI+3
	ng/l = pg/ml	52655	42100	63210	
	ng/ml = µg/l	51.5	41.2	61.8	Beckman Access - AccuTnI+3
	ng/l = pg/ml	51474	41200	61748	
	ng/ml = µg/l	57.3	45.8	68.8	Siemens Centaur CP
	ng/l = pg/ml	57299	45800	68798	
	ng/ml = µg/l	235	188	282	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	234603	188000	281206	

RANDOX

IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 1
(CRD LIQ CONTROL 1)

CAT. NO. CQ5051 **LOT NO.** 4317CK
SIZE: 3 x 3 ml **EXPIRY:** 2020-05-28

GTIN: 05055273207446

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 1 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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.

Rev 22 Jul 19 pq

RANDOX

LIQUID CARDIAC CONTROL - LEVEL 1 (CRD LIQ CONTROL 1)

Cat. No. CQ5051 Lot No. 4317CK Size: 3 x 3 ml Expiry: 2020-05-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	2.45	1.72	3.19	Abbott Architect
	ng/ml = µg/l	4.78	3.35	6.21	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	3.24	2.27	4.21	Siemens Dimension
	ng/ml = µg/l	2.97	2.08	3.86	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	4.33	3.03	5.63	Beckman Coulter Access
	ng/ml = µg/l	3.56	2.49	4.63	Siemens Stratus CS
	ng/ml = µg/l	4.73	3.31	6.15	BioMerieux Vidas
	ng/ml = µg/l	4.42	3.09	5.75	Beckman DxI800
	ng/ml = µg/l	3.12	2.18	4.06	Roche h232
	ng/ml = µg/l	5.13	3.59	6.67	Radiometer AQT90 Flex
	ng/ml = µg/l	3.55	2.49	4.62	Siemens Dimension Vista LOCI
	ng/ml = µg/l	3.81	2.67	4.95	Siemens Centaur CP
D - Dimer	µg/l FEU	1248	936	1560	Biomerieux Vidas Exclusion II
	µg/l FEU	4672	3504	5840	Mitsubishi Pathfast D-Dimer
	µg/l	506	380	633	Roche/ Stago STA-R Evolution
	µg/l	682	512	853	Roche Cobas h232 D-Dimer
	µg/l	366	275	458	Roche Integra D-DI 2
	µg/l	745	559	931	Alere Biosite Triage D-Dimer
	µg/l	692	519	865	Abbott Architect Quantia D-Dimer
	µg/l	683	512	854	Siemens Stratus CS
	µg/l	174	131	218	Siemens Immulite 2000 D-Dimer
	µg/l	685	514	856	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1844	1383	2305	Siemens Innovance D-Dimer
	µg/l	216	162	270	Roche Cobas D-DI 2
	µg/l FEU	1872	1404	2340	HemosIL D-Dimer HS 500
	µg/l	560	420	700	HemosIL D-Dimer
	µg/l	651	488	814	HemosIL D-Dimer HS
Digoxin	nmol/l	1.20	0.960	1.44	Chemiluminescence
	ng/ml	0.937	0.750	1.12	
	nmol/l	1.09	0.872	1.31	Enzyme Immunoassay
	ng/ml	0.851	0.681	1.02	
	nmol/l	1.02	0.816	1.22	Turbidimetric
	ng/ml	0.797	0.637	0.957	
	nmol/l	1.04	0.832	1.25	KIMS
	ng/ml	0.812	0.650	0.974	
	nmol/l	1.09	0.872	1.31	Enzyme Linked Flourescent assay
	ng/ml	0.851	0.681	1.02	
hsCRP	mg/l	1.06	0.848	1.27	Nephelometric (IFCC Cal.)
	mg/l	1.16	0.928	1.39	Turbidimetric (IFCC Cal.)
	mg/l	1.15	0.920	1.38	Turbidimetric (Non IFCC Cal.)
	mg/l	1.04	0.830	1.25	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	57.6	40.3	74.9	Abbott Architect

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LIQUID CARDIAC CONTROL - LEVEL 1 (CRD LIQ CONTROL 1)

Cat. No. CQ5051 Lot No. 4317CK Size: 3 x 3 ml Expiry: 2020-05-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Myoglobin	ng/ml = µg/l	48.6	34.0	63.2	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	48.1	33.7	62.5	Siemens Dimension
	ng/ml = µg/l	40.9	28.6	53.2	Beckman DxI800
	ng/ml = µg/l	42.2	29.5	54.9	Roche Elecsys
	ng/ml = µg/l	50.6	35.4	65.8	Roche Hitachi
	ng/ml = µg/l	38.6	27.0	50.2	Beckman Coulter Access
	ng/ml = µg/l	26.6	18.6	34.6	Siemens Stratus CS
	ng/ml = µg/l	43.8	30.7	56.9	BioMerieux Vidas
	ng/ml = µg/l	42.4	29.7	55.1	Siemens Dimension Vista LOCI
	ng/ml = µg/l	45.4	31.8	59.0	Siemens Centaur CP
	ng/ml = µg/l	65.4	45.8	85.0	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.197	0.158	0.236	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	197	158	236	
	ng/ml = µg/l	0.096	0.077	0.115	Siemens Dimension
	ng/l = pg/ml	96.0	77.0	115	
	ng/ml = µg/l	0.123	0.098	0.148	Siemens Stratus CS
	ng/l = pg/ml	123	98.0	148	
	ng/ml = µg/l	1.30	1.04	1.56	Tosoh Series
	ng/l = pg/ml	1300	1040	1560	
	ng/ml = µg/l	0.930	0.744	1.12	Ortho Vitros ECi
	ng/l = pg/ml	930	744	1116	
	ng/ml = µg/l	0.607	0.486	0.728	Biomerieux Vidas Ultra
	ng/l = pg/ml	607	486	728	
	ng/ml = µg/l	0.088	0.070	0.106	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	88.0	70.0	106	
	ng/ml = µg/l	0.099	0.079	0.119	Siemens/Dade Dimension EXL/Vista
	ng/l = pg/ml	99.0	79.0	119	
	ng/ml = µg/l	0.111	0.089	0.133	Siemens Dimension Exl LOCI
	ng/l = pg/ml	111	89.0	133	
	ng/ml = µg/l	0.192	0.154	0.230	Abbott Architect STAT hs
	ng/l = pg/ml	192	154	230	
	ng/ml = µg/l	0.103	0.082	0.124	Beckman DxI - AccuTnI+3
	ng/l = pg/ml	103	82.0	124	
	ng/ml = µg/l	0.105	0.084	0.126	Beckman Access - AccuTnI+3
	ng/l = pg/ml	105	84.0	126	
	ng/ml = µg/l	0.170	0.136	0.204	Siemens Centaur CP
	ng/l = pg/ml	170	136	204	
	ng/ml = µg/l	0.566	0.453	0.679	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	566	453	679	
	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	

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IMPORTANT NOTICE

Catalogue No. CQ5051, CQ5052, CQ5053

Randox no longer make stability claims or quote target values and ranges for N-Terminal Pro-Brain Natriuretic Peptide (NT-pro BNP) assay for quality control materials listed above.

Authorised by:	Stephen Anderson Technical support Team Leader	Ref:	REC414 OCC8210
Date:	6th Sep 19		

LIQUID CARDIAC CONTROL - LEVEL 1
(CRD LIQ CONTROL 1)

CAT. NO. CQ5051 **LOT NO.** 4314CK
SIZE: 3 x 3 ml **EXPIRY:** 2020-05-28

GTIN: 05055273207446

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 analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS
For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

This Cardiac Control contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes, or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of this control, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

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
UNOPENED: Store at +2°C to +8°C. Stable to expiration date printed on individual vials. Myoglobin and CK-MB may show a gradual decrease in values over the shelf life of the product.

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°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.

PREPARATION FOR USE
The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED
Liquid Cardiac Control - Level 1 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED
Not applicable.

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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LIQUID CARDIAC CONTROL - LEVEL 1 (CRD LIQ CONTROL 1)

Cat. No. CQ5051 Lot No. 4314CK Size: 3 x 3 ml Expiry: 2020-05-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK-MB Mass	ng/ml = µg/l	3.64	2.55	4.73	Abbott Architect
	ng/ml = µg/l	7.11	4.98	9.24	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	4.96	3.47	6.45	Siemens Dimension
	ng/ml = µg/l	4.49	3.14	5.84	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	6.31	4.42	8.20	Beckman Coulter Access
	ng/ml = µg/l	5.61	3.93	7.29	Siemens Stratus CS
	ng/ml = µg/l	5.16	3.61	6.71	BioMerieux Vidas
	ng/ml = µg/l	6.44	4.51	8.37	Beckman DxI800
	ng/ml = µg/l	4.34	3.04	5.64	Roche h232
	ng/ml = µg/l	7.90	5.53	10.3	Radiometer AQT90 Flex
	ng/ml = µg/l	5.56	3.89	7.23	Siemens Dimension Vista LOCI
	ng/ml = µg/l	4.17	2.92	5.42	Roche Cardiac Reader
	ng/ml = µg/l	5.93	4.15	7.71	Siemens Centaur CP
D-Dimer	µg/l FEU	1192	894	1490	Biomerieux Vidas Exclusion II
	µg/l FEU	4352	3264	5440	Mitsubishi Pathfast D-Dimer
	µg/l	459	344	574	Roche/ Stago STA-R Evolution
	µg/l	717	538	896	Roche Cobas h232 D-Dimer
	µg/l	354	266	443	Roche Integra D-DI 2
	µg/l	641	481	801	Alere Biosite Triage D-Dimer
	µg/l	656	492	820	Abbott Architect Quantia D-Dimer
	µg/l	645	484	806	Siemens Stratus CS
	µg/l	156	117	195	Siemens Immulite 2000 D-Dimer
	µg/l	716	537	895	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1662	1247	2078	Siemens Innovance D-Dimer
	µg/l	210	158	263	Roche Cobas D-DI 2
	µg/l FEU	1850	1388	2313	HemosIL D-Dimer HS 500
	µg/l	595	446	744	HemosIL D-Dimer
	µg/l	589	442	736	HemosIL D-Dimer HS
	µg/l	725	544	906	Diazyme D-Dimer
Digoxin	nmol/l	1.45	1.16	1.74	Chemiluminescence
	ng/ml	1.13	0.906	1.35	
	nmol/l	1.51	1.21	1.81	Enzyme Immunoassay
	ng/ml	1.18	0.945	1.42	
	nmol/l	1.26	1.01	1.51	Turbidimetric
	ng/ml	0.984	0.789	1.18	
	nmol/l	1.36	1.09	1.63	KIMS
	ng/ml	1.06	0.851	1.27	
	nmol/l	1.38	1.10	1.66	Enzyme Linked Flourescent assay
	ng/ml	1.08	0.859	1.30	
hsCRP	mg/l	1.14	0.912	1.37	Nephelometric (IFCC Cal.)
	mg/l	1.30	1.04	1.56	Turbidimetric (IFCC Cal.)
	mg/l	1.32	1.06	1.58	Turbidimetric (Non IFCC Cal.)

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Cat. No. CQ5051 Lot No. 4314CK Size: 3 x 3 ml Expiry: 2020-05-28

			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
hsCRP	mg/l	1.36	1.09	1.63	Chemiluminescence (IFCC Cal.)
	mg/l	1.17	0.936	1.40	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	65.0	45.5	84.5	Abbott Architect
	ng/ml = µg/l	55.1	38.6	71.6	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	63.3	44.3	82.3	Siemens Dimension
	ng/ml = µg/l	48.2	33.7	62.7	Beckman DxI800
	ng/ml = µg/l	51.2	35.8	66.6	Roche Elecsys
	ng/ml = µg/l	57.3	40.1	74.5	Roche Hitachi
	ng/ml = µg/l	46.5	32.6	60.5	Beckman Coulter Access
	ng/ml = µg/l	30.3	21.2	39.4	Siemens Stratus CS
	ng/ml = µg/l	58.1	40.7	75.5	BioMerieux Vidas
	ng/ml = µg/l	46.1	32.3	59.9	Siemens Dimension Vista LOCI
	ng/ml = µg/l	51.1	35.8	66.4	Siemens Centaur CP
	ng/ml = µg/l	75.1	52.6	97.6	Randox Immunoturbidimetric
Troponin I	ng/ml = µg/l	0.006	0.005	0.008	Abbott Architect STAT hs
	ng/l = pg/ml	6.29	5.00	7.58	
	ng/ml = µg/l	0.010	0.008	0.012	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	10.0	8.00	12.0	
	ng/ml = µg/l	0.009	0.007	0.010	Siemens Centaur XP/XPT High Sensitivity Troponin I (TNIH)
	ng/l = pg/ml	8.72	7.00	10.4	

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