

RANDOX

Avis de sécurité urgent

Date : 17 février 2017

Référence de la plainte : 284

Type d'action : Modification de dispositif

Détails sur les dispositifs concernés :

Selon les informations dont nous disposons, votre établissement est susceptible d'avoir reçu le produit ci-dessous.

Analyse	Numéro de catalogue	GTIN	Numéro de lot	Date d'expiration	Date de fabrication
Myoglobine	CQ5051	05055273207446	3909CK	28 th Oct 17	10 th Nov 15
			3910CK	28 th Oct 17	10 th Nov 15
			3913CK	28 th Oct 17	10 th Nov 15
	CQ5052	05055273207453	3911CK	28 th Oct 17	30 th Oct 15
			3990CK	28 th Apr 18	13 th May 16
			3991CK	28 th Apr 18	13 th May 16
			3992CK	28 th Apr 18	13 th May 16
	CQ5053	05055273207460	3912CK	28 th Oct 17	9 th Nov 15

Raison du rappel :

Randox confirme un changement dans la récupération pour la myoglobine dans les lots de contrôle cardiaque liquide énumérés ci-dessus pour la méthode immunoturbidimétrique Randox.

Des tests internes sur les lots touchés ont mis en évidence une augmentation du taux de dégradation uniquement pour la myoglobine. De nouvelles cibles et de nouvelles plages de contrôle ont par conséquent été attribuées pour la méthode immunoturbidimétrique Randox.

La récupération de la myoglobine pour les autres méthodes citées dans le mode d'emploi n'a pas été confirmée. Il est conseillé aux clients utilisant d'autres méthodes que la méthode immunoturbidimétrique Randox de revoir leur moyenne de CQI actuelle afin de repérer une éventuelle modification de tendance qui pourrait indiquer la nécessité de revoir la plage de contrôle.

Risque pour la santé :

Un CQI qui ressort comme étant hors limites pourrait conduire à un retard de rendu des résultats de la myoglobine. Étant donné que la myoglobine sérique n'est généralement pas utilisée isolément pour le diagnostic des lésions cardiaques, un retard dans le rendu de ces résultats ne devrait pas poser un risque grave pour la santé.

RANDOX

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Mesures à prendre :

- Pour tout le stock inutilisé, retirer le mode d'emploi et le remplacer par document ci-joint qui est spécifique au lot.
- Examiner les résultats générés avec les lots concernés en relation avec le profil clinique de chaque patient.
- Discuter du contenu du présent avis avec votre Directeur médical.
- Conformément aux exigences des autorités réglementaires de votre pays, vous devez nous renvoyer le formulaire d'action ci-joint. Veuillez remplir la section relative à l'action de vigilance et retourner ce formulaire à technical.services@randox.com **dans un délai de cinq jours ouvrables.**

Transmission de la notice de sécurité (Field Safety Notice): Copies envoyées à tous les clients concernés et ceux qui sont concernés dans votre organisation.

Contact de Référence:

Randox Technical Services
Randox Laboratories Ltd,
55 Diamond Road,
Crumlin,
United Kingdom,
BT29 4QY
Email: technical.services@randox.com
Tel: +44 (0) 28 9445 1070
Fax: +44 (0) 28 9445 2912

Veillez accepter nos excuses pour la gêne occasionnée. Merci pour votre patience et votre compréhension. Si vous avez des questions ou des préoccupations n'hésitez pas à contacter Randox Services techniques.

Cette notice de sécurité a été notifiée à l'Agence des affaires réglementaire.

Dr Pauline Armstrong
Global QA/RA Manager

RANDOX

Avis de sécurité urgent

Section Réponse

Détails

Nom du laboratoire	
Adresse	

Quantité totale de coffrets

Reçu de Randox	
Qt de coffrets distribués	

Zone de Distribution

(Section complétée uniquement par les Distributeurs et Bureaux Randox)

Consignee	Country	Quantity Received	Analyser Serial Number	Replacements Required

Je confirme avoir lu cette Notice de sécurité (Urgent Field Safety Notice) ainsi que les instructions fournies

Complété par				Date	
Coordonnées	Tel		Email		

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

CAT. NO. CQ5051 **LOT NO.** 3909CK

SIZE: 3 x 3 ml **EXPIRY:** 2017-10

INTENDED USE

This product is intended for *in vitro* diagnostic use, in the quality control of Cardiac Markers on clinical chemistry and Immunoassay systems.

DEVICE DESCRIPTION

The Cardiac Controls are supplied at 3 levels, 1, 2 and 3. Target values and ranges are supplied for the following analytes: CK-MB Mass, Digoxin, D-Dimer, hsCRP, Myoglobin, NT-ProBNP, Troponin I and Troponin T.

SAFETY PRECAUTIONS AND WARNINGS

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

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.

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 I 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 08 Feb 17 pl

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

Cat. No. CQ5051 Lot No. 3909CK Size: 3 x 3 ml Expiry: 2017-10

Analyte	unit	Target	Range		methods
			low	high	
CK-MB Mass	ng/ml = µg/l	3.40	2.72	4.08	Abbott Architect
	ng/ml = µg/l	4.19	3.35	5.03	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	2.66	2.13	3.19	Siemens Dimension
	ng/ml = µg/l	3.32	2.66	3.98	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	3.99	3.19	4.79	Beckman Coulter Access
	ng/ml = µg/l	2.99	2.39	3.59	Siemens Stratus CS
	ng/ml = µg/l	6.29	5.03	7.55	BioMerieux Vidas
	ng/ml = µg/l	4.08	3.26	4.90	Beckman Dxl800
	ng/ml = µg/l	3.55	2.84	4.26	Roche h232
	ng/ml = µg/l	2.52	2.02	3.02	Siemens Dimension Vista LOCI
D - Dimer	ng/ml = µg/l	3.35	2.68	4.02	Siemens Centaur CP
	µg/l FEU	1116	837	1395	Biomerieux Vidas Exclusion II
	µg/l FEU	3354	2516	4193	Mitsubishi Pathfast D-Dimer
	µg/l	370	278	463	Roche/ Stago STA-R Evolution
	µg/l	637	478	796	Roche Cobas h232 D-Dimer
	µg/l	368	276	460	Roche Integra D-DI 2
	µg/l	676	507	845	Alere Biosite Triage D-Dimer
	µg/l	660	495	825	Abbott Architect Quantia D-Dimer
	µg/l	555	416	694	Roche Cardiac Reader D-Dimer
	µg/l	545	409	681	Siemens Stratus CS
	µg/l	130	97.5	163	Siemens Immulite 2000 D-Dimer
	µg/l	647	485	809	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1498	1124	1873	Siemens Innovance D-Dimer
	µg/l	241	181	301	Roche Cobas D-DI 2
	µg/l FEU	1642	1232	2053	HemosIL D-Dimer HS 500
Digoxin	µg/l	473	355	591	HemosIL D-Dimer
	µg/l	510	383	638	HemosIL D-Dimer HS
	nmol/l	1.20	0.960	1.44	Chemiluminescence
	ng/ml	0.937	0.750	1.12	
	nmol/l	1.03	0.824	1.24	Enzyme Immunoassay
	ng/ml	0.804	0.644	0.964	
	nmol/l	0.943	0.754	1.13	Turbidimetric
hsCRP	ng/ml	0.736	0.589	0.883	
	nmol/l	0.915	0.732	1.10	KIMS
	ng/ml	0.715	0.572	0.858	
	mg/l	0.793	0.634	0.952	Nephelometric (IFCC Cal.)
	mg/l	0.843	0.674	1.01	Nephelometric (Non IFCC Cal.)
Myoglobin	mg/l	0.902	0.722	1.08	Turbidimetric (IFCC Cal.)
	mg/l	0.890	0.720	1.06	Turbidimetric (Non IFCC Cal.)
	mg/l	0.863	0.690	1.04	Randox Immunoturbidimetric
	ng/ml = µg/l	57.9	46.3	69.5	Abbott Architect
	ng/ml = µg/l	51.6	41.3	61.9	Siemens Centaur XP/XPT/Classic

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

Cat. No. CQ5051 Lot No. 3909CK Size: 3 x 3 ml Expiry: 2017-10

Analyte	unit	Target	Range		methods
			low	high	
Myoglobin	ng/ml = µg/l	45.8	36.6	55.0	Siemens Dimension
	ng/ml = µg/l	35.1	28.1	42.1	Beckman DxI800
	ng/ml = µg/l	41.5	33.2	49.8	Roche Elecsys
	ng/ml = µg/l	47.5	38.0	57.0	Roche Hitachi
	ng/ml = µg/l	59.0	47.2	70.8	Roche Integra
	ng/ml = µg/l	34.8	27.8	41.8	Beckman Coulter Access
	ng/ml = µg/l	24.8	19.8	29.8	Siemens Stratus CS
	ng/ml = µg/l	38.7	31.0	46.4	BioMerieux Vidas
	ng/ml = µg/l	49.5	39.6	59.4	Biosite Triage Meter Plus
	ng/ml = µg/l	37.0	29.6	44.4	Siemens Dimension Vista LOCI
	ng/ml = µg/l	54.0	37.8	70.2	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	38.9	29.2	48.6	Siemens Immulite 2000
	pg/ml	330	247	413	
	pmol/l	13.8	10.4	17.3	Siemens Stratus CS
	pg/ml	117	88.1	146	
	pmol/l	11.4	8.55	14.3	BioMerieux Vidas
	pg/ml	96.6	72.4	121	
	pmol/l	10.9	8.18	13.6	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	92.3	69.3	115	
	pmol/l	37.6	28.2	47.0	Mitsubishi Chemical Pathfast
	pg/ml	319	239	399	
	pmol/l	21.7	16.3	27.1	Ortho Vitros 3600/5600/ECi
	pg/ml	184	138	230	
	pmol/l	7.26	5.45	9.08	Roche h232
	pg/ml	61.5	46.2	76.8	
	pmol/l	5.13	3.85	6.41	Siemens Dimension Vista LOCI
	pg/ml	43.5	32.6	54.4	
pmol/l	2.49	1.87	3.11	Siemens Dimension Exl LOCI	
pg/ml	21.1	15.8	26.4		
pmol/l	10.4	7.80	13.0	Biomerieux Vidas 2	
pg/ml	88.1	66.1	110		
Troponin I	ng/ml = µg/l	0.563	0.450	0.676	Abbott Architect
	ng/ml = µg/l	0.030	0.024	0.036	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.357	0.286	0.428	Tosoh AIA360
	ng/ml = µg/l	0.332	0.266	0.398	Ortho Vitros ECi
	ng/ml = µg/l	0.393	0.314	0.472	BioMerieux Vidas
	ng/ml = µg/l	0.395	0.316	0.474	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.101	0.081	0.121	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	0.029	0.023	0.035	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.016	0.013	0.019	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.043	0.034	0.052	Abbott Architect STAT hs
	ng/ml = µg/l	0.031	0.025	0.037	Siemens Centaur CP
Troponin T	µg/l	0.010	0.008	0.013	Roche Cobas Troponin T HS

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

CAT. NO. CQ505I **LOT NO.** 3910CK

SIZE: 3 x 3 ml **EXPIRY:** 2017-10-28

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 following analytes: CK-MB Mass, D-Dimer, Digoxin, hsCRP, Myoglobin, NT-ProBNP, Troponin I and Troponin T.

SAFETY PRECAUTIONS AND WARNINGS

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

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.

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 I 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. 09 Feb '17 bm

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

Cat. No. CQ5051 Lot No. 3910CK Size: 3 x 3 ml Expiry: 2017-10-28

Analyte	unit	Target	Range		methods
			low	high	
CK-MB Mass	ng/ml = µg/l	3.52	2.82	4.22	Abbott Architect
	ng/ml = µg/l	4.26	3.41	5.11	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	2.57	2.06	3.08	Siemens Dimension
	ng/ml = µg/l	3.49	2.79	4.19	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	4.31	3.45	5.17	Beckman Coulter Access
	ng/ml = µg/l	3.10	2.48	3.72	Siemens Stratus CS
	ng/ml = µg/l	6.37	5.10	7.64	BioMerieux Vidas
	ng/ml = µg/l	4.48	3.58	5.38	Beckman Dxl800
	ng/ml = µg/l	3.52	2.82	4.22	Roche h232
	ng/ml = µg/l	5.74	4.59	6.89	Radiometer AQT90 Flex
	ng/ml = µg/l	2.67	2.14	3.20	Siemens Dimension Vista LOCI
	ng/ml = µg/l	3.74	2.99	4.49	Siemens Centaur CP
D - Dimer	µg/l FEU	1198	899	1498	Biomerieux Vidas Exclusion II
	µg/l FEU	3990	2993	4988	Mitsubishi Pathfast D-Dimer
	µg/l	395	296	494	Roche/ Stago STA-R Evolution
	µg/l	621	466	776	Roche Cobas h232 D-Dimer
	µg/l	410	308	513	Roche Integra D-DI 2
	µg/l	742	557	928	Alere Biosite Triage D-Dimer
	µg/l	671	503	839	Abbott Architect Quantia D-Dimer
	µg/l	648	486	810	Siemens Stratus CS
	µg/l	160	120	200	Siemens Immulite 2000 D-Dimer
	µg/l	680	510	850	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1588	1191	1985	Siemens Innovance D-Dimer
	µg/l	245	184	306	Roche Cobas D-DI 2
	µg/l FEU	1794	1346	2243	HemosIL D-Dimer HS 500
	µg/l	541	406	676	HemosIL D-Dimer
µg/l	548	411	685	HemosIL D-Dimer HS	
Digoxin	nmol/l	1.08	0.864	1.30	Chemiluminescence
	ng/ml	0.843	0.675	1.01	
	nmol/l	1.10	0.880	1.32	Vitros
	ng/ml	0.859	0.687	1.03	
	nmol/l	0.885	0.708	1.06	Enzyme Immunoassay
	ng/ml	0.691	0.553	0.829	
	nmol/l	0.832	0.666	0.998	Turbidimetric
	ng/ml	0.650	0.520	0.780	
nmol/l	0.817	0.654	0.980	KIMS	
ng/ml	0.638	0.511	0.765		
hsCRP	mg/l	1.25	1.00	1.50	Vitros (IFCC Cal.)
	mg/l	0.841	0.673	1.01	Nephelometric (IFCC Cal.)
	mg/l	0.936	0.749	1.12	Nephelometric (Non IFCC Cal.)
	mg/l	0.945	0.756	1.13	Turbidimetric (IFCC Cal.)
	mg/l	0.939	0.751	1.13	Turbidimetric (Non IFCC Cal.)

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

Cat. No. CQ5051 Lot No. 3910CK Size: 3 x 3 ml Expiry: 2017-10-28

Analyte	unit	Target	Range		methods
			low	high	
hsCRP	mg/l	0.923	0.740	1.11	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	65.1	52.1	78.1	Abbott Architect
	ng/ml = µg/l	41.8	33.4	50.2	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	56.0	44.8	67.2	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	49.5	39.6	59.4	Siemens Dimension
	ng/ml = µg/l	38.5	30.8	46.2	Beckman Dxl800
	ng/ml = µg/l	44.8	35.8	53.8	Roche Elecsys
	ng/ml = µg/l	50.7	40.6	60.8	Roche Hitachi
	ng/ml = µg/l	60.5	48.4	72.6	Roche Integra
	ng/ml = µg/l	37.1	29.7	44.5	Beckman Coulter Access
	ng/ml = µg/l	25.9	20.7	31.1	Siemens Stratus CS
	ng/ml = µg/l	45.5	36.4	54.6	BioMerieux Vidas
	ng/ml = µg/l	38.3	30.6	46.0	Siemens Dimension Vista LOCI
	ng/ml = µg/l	46.7	37.4	56.0	Siemens Centaur CP
	ng/ml = µg/l	59.0	41.3	76.7	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	38.7	29.0	48.4	Siemens Immulite 2000
	pg/ml	328	246	410	
	pmol/l	14.2	10.7	17.8	Siemens Stratus CS
	pg/ml	120	90.7	149	
	pmol/l	11.0	8.25	13.8	BioMerieux Vidas
	pg/ml	93.2	69.9	117	
	pmol/l	11.1	8.33	13.9	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	94.0	70.6	117	
	pmol/l	32.6	24.5	40.8	Mitsubishi Chemical Pathfast
	pg/ml	276	208	344	
	pmol/l	21.6	16.2	27.0	Ortho Vitros 3600/5600/ECi
	pg/ml	183	137	229	
	pmol/l	7.96	5.97	9.95	Roche h232
	pg/ml	67.4	50.6	84.2	
	pmol/l	5.62	4.22	7.03	Siemens Dimension Vista LOCI
	pg/ml	47.6	35.8	59.4	
	pmol/l	2.66	2.00	3.33	Siemens Dimension Exl LOCI
	pg/ml	22.5	16.9	28.1	
pmol/l	10.7	8.03	13.4	Biomerieux Vidas 2	
pg/ml	90.7	68.0	113		
Troponin I	ng/ml = µg/l	0.086	0.069	0.103	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.461	0.369	0.553	Siemens Immulite 2000
	ng/ml = µg/l	0.054	0.043	0.065	Beckman DXi800 1st gen
	ng/ml = µg/l	0.049	0.039	0.059	Beckman Coulter Access
	ng/ml = µg/l	0.036	0.025	0.047	Siemens Stratus CS
	ng/ml = µg/l	1.03	0.824	1.24	Tosoh AIA360
	ng/ml = µg/l	0.855	0.684	1.03	Ortho Vitros ECi
	ng/ml = µg/l	0.869	0.695	1.04	BioMerieux Vidas
	ng/ml = µg/l	0.867	0.694	1.04	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.103	0.082	0.124	Roche Elecsys/E170/c6000/e411
ng/ml = µg/l	0.078	0.062	0.094	Mitsubishi Chemical Pathfast	

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

Cat. No. CQ5051 Lot No. 3910CK Size: 3 x 3 ml Expiry: 2017-10-28

Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	0.419	0.335	0.503	Abbott i STAT
	ng/ml = µg/l	0.033	0.026	0.040	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.038	0.030	0.046	Siemens Dimension Exl LOCI
	ng/ml = µg/l	0.099	0.079	0.119	Abbott Architect STAT hs
	ng/ml = µg/l	0.053	0.042	0.064	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	0.050	0.040	0.060	Beckman Access - AccuTnl+3
	ng/ml = µg/l	0.073	0.058	0.088	Siemens Centaur CP
Troponin T	µg/l	0.021	0.016	0.026	Roche Cobas TroponinT
	µg/l	0.024	0.018	0.030	Roche Cobas Troponin T HS
	µg/l	0.045	0.034	0.056	Roche h232

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

CAT. NO. CQ505I **LOT NO.** 3913CK

SIZE: 3 x 3 ml **EXPIRY:** 2017-10

GTIN: 05055273207446

INTENDED USE

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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.

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 I 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 08 Feb '17 pl

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

Cat. No. CQ5051 Lot No. 3913CK Size: 3 x 3 ml Expiry: 2017-10

Range					
Analyte	unit	Target	low	high	methods
CK-MB Mass	ng/ml = µg/l	5.01	4.01	6.01	Abbott Architect
	ng/ml = µg/l	6.05	4.84	7.26	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	3.94	3.15	4.73	Siemens Dimension
	ng/ml = µg/l	4.80	3.84	5.76	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	6.21	4.97	7.45	Beckman Coulter Access
	ng/ml = µg/l	4.47	3.58	5.36	Siemens Stratus CS
	ng/ml = µg/l	8.82	7.06	10.6	BioMerieux Vidas
	ng/ml = µg/l	6.33	5.06	7.60	Beckman Dxl800
	ng/ml = µg/l	5.09	4.07	6.11	Roche h232
	ng/ml = µg/l	7.70	6.16	9.24	Radiometer AQT90 Flex
	ng/ml = µg/l	3.96	3.17	4.75	Siemens Dimension Vista LOCI
ng/ml = µg/l	5.45	4.36	6.54	Siemens Centaur CP	
D - Dimer	µg/l FEU	1154	866	1443	Biomerieux Vidas Exclusion II
	µg/l FEU	3706	2780	4633	Mitsubishi Pathfast D-Dimer
	µg/l	378	284	473	Roche/ Stago STA-R Evolution
	µg/l	614	461	768	Roche Cobas h232 D-Dimer
	µg/l	372	279	465	Roche Integra D-DI 2
	µg/l	651	488	814	Alere Biosite Triage D-Dimer
	µg/l	623	467	779	Abbott Architect Quantia D-Dimer
	µg/l	588	441	735	Siemens Stratus CS
	µg/l	155	116	194	Siemens Immulite 2000 D-Dimer
	µg/l	642	482	803	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1564	1173	1955	Siemens Innovance D-Dimer
	µg/l	226	170	283	Roche Cobas D-DI 2
	µg/l FEU	1718	1289	2148	HemosIL D-Dimer HS 500
	µg/l	493	370	616	HemosIL D-Dimer
µg/l	536	402	670	HemosIL D-Dimer HS	
Digoxin	nmol/l	1.39	1.11	1.67	Chemiluminescence
	ng/ml	1.09	0.867	1.31	
	nmol/l	1.19	0.952	1.43	Vitros
	ng/ml	0.929	0.744	1.11	
	nmol/l	1.19	0.952	1.43	Enzyme Immunoassay
	ng/ml	0.929	0.744	1.11	
	nmol/l	1.08	0.864	1.30	Turbidimetric
	ng/ml	0.843	0.675	1.01	
nmol/l	0.996	0.797	1.20	KIMS	
ng/ml	0.778	0.622	0.934		
hsCRP	mg/l	1.26	1.01	1.51	Nephelometric (IFCC Cal.)
	mg/l	1.20	0.960	1.44	Nephelometric (Non IFCC Cal.)
	mg/l	1.35	1.08	1.62	Turbidimetric (IFCC Cal.)
	mg/l	1.31	1.05	1.57	Turbidimetric (Non IFCC Cal.)
	mg/l	1.35	1.08	1.62	Radox Immunoturbidimetric

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

Cat. No. CQ5051 Lot No. 3913CK Size: 3 x 3 ml Expiry: 2017-10

Range					
Analyte	unit	Target	low	high	methods
Myoglobin	ng/ml = µg/l	73.0	58.4	87.6	Abbott Architect
	ng/ml = µg/l	48.7	39.0	58.4	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	61.7	49.4	74.0	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	59.8	47.8	71.8	Siemens Dimension
	ng/ml = µg/l	45.6	36.5	54.7	Beckman Dxl800
	ng/ml = µg/l	52.0	41.6	62.4	Roche Elecsys
	ng/ml = µg/l	56.3	45.0	67.6	Roche Hitachi
	ng/ml = µg/l	67.4	53.9	80.9	Roche Integra
	ng/ml = µg/l	42.6	34.1	51.1	Beckman Coulter Access
	ng/ml = µg/l	31.5	25.2	37.8	Siemens Stratus CS
	ng/ml = µg/l	53.7	43.0	64.4	BioMerieux Vidas
	ng/ml = µg/l	54.5	43.6	65.4	Biosite Triage Meter Plus
	ng/ml = µg/l	99.0	79.2	119	Ortho Vitros 3600/5600/ECi
	ng/ml = µg/l	46.3	37.0	55.6	Siemens Dimension Vista LOCI
ng/ml = µg/l	58.0	40.6	75.4	Randox Immunoturbidimetric	
NT-ProBNP	pmol/l	7.87	5.90	9.84	Siemens Dimension
	pg/ml	66.7	50.0	83.4	
	pmol/l	48.2	36.2	60.3	Siemens Immulite 2000
	pg/ml	408	307	509	
	pmol/l	17.9	13.4	22.4	Siemens Stratus CS
	pg/ml	152	114	190	
	pmol/l	12.6	9.45	15.8	BioMerieux Vidas
	pg/ml	107	80.1	134	
	pmol/l	12.9	9.68	16.1	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	109	82.0	136	
	pmol/l	40.2	30.2	50.3	Mitsubishi Chemical Pathfast
	pg/ml	341	256	426	
	pmol/l	26.4	19.8	33.0	Ortho Vitros 3600/5600/ECi
	pg/ml	224	168	280	
	pmol/l	8.61	6.46	10.8	Roche h232
	pg/ml	72.9	54.7	91.1	
	pmol/l	6.87	5.15	8.59	Siemens Dimension Vista LOCI
	pg/ml	58.2	43.6	72.8	
pmol/l	3.30	2.48	4.13	Siemens Dimension Exl LOCI	
pg/ml	28.0	21.0	35.0		
pmol/l	12.6	9.45	15.8	Biomerieux Vidas 2	
pg/ml	107	80.1	134		
Troponin I	ng/ml = µg/l	0.013	0.010	0.016	Ortho Vitros ECi
	ng/ml = µg/l	0.002	0.000	0.004	Abbott Architect STAT hs
Troponin T	µg/l	0.011	0.008	0.014	Roche Cobas TroponinT
	µg/l	0.011	0.008	0.014	Roche Cobas Troponin T HS
	µg/l	0.047	0.035	0.059	Roche h232

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

CAT. NO. CQ5052

LOT NO. 3911CK

SIZE: 3 x 3 ml

EXPIRY: 2017-10-28

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 following analytes: CK-MB Mass, D-Dimer, Digoxin, hsCRP, Myoglobin, NT-ProBNP, Troponin I and Troponin T.

SAFETY PRECAUTIONS AND WARNINGS

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

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.

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.

Revised 08 Feb '17 pl

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

Cat. No. CQ5052 Lot No. 3911CK Size: 3 x 3 ml Expiry: 2017-10-28

Analyte	unit	Target	Range		methods
			low	high	
CK-MB Mass	ng/ml = µg/l	19.5	15.6	23.4	Abbott Architect
	ng/ml = µg/l	20.9	16.7	25.1	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	18.9	15.1	22.7	Siemens Dimension
	ng/ml = µg/l	16.4	13.1	19.7	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	24.3	19.4	29.2	Beckman Coulter Access
	ng/ml = µg/l	19.0	15.2	22.8	Siemens Stratus CS
	ng/ml = µg/l	30.3	24.2	36.4	BioMerieux Vidas
	ng/ml = µg/l	24.5	19.6	29.4	Beckman DxI800
	ng/ml = µg/l	12.0	9.60	14.4	Biosite Triage Meter Plus
	ng/ml = µg/l	15.8	12.6	19.0	Roche h232
	ng/ml = µg/l	30.8	24.6	37.0	Radiometer AQT90 Flex
	ng/ml = µg/l	17.6	14.1	21.1	Siemens Dimension Vista LOCI
	ng/ml = µg/l	19.4	15.5	23.3	Siemens Centaur CP
D - Dimer	µg/l FEU	1304	978	1630	Biomerieux Vidas Exclusion II
	µg/l FEU	4538	3404	5673	Mitsubishi Pathfast D-Dimer
	µg/l	437	328	546	Roche/ Stago STA-R Evolution
	µg/l	740	555	925	Roche Cobas h232 D-Dimer
	µg/l	418	314	523	Roche Integra D-DI 2
	µg/l	746	560	933	Alere Biosite Triage D-Dimer
	µg/l	717	538	896	Abbott Architect Quantia D-Dimer
	µg/l	747	560	934	Roche Cardiac Reader D-Dimer
	µg/l	727	545	909	Siemens Stratus CS
	µg/l	224	168	280	Siemens Immulite 2000 D-Dimer
	µg/l	710	533	888	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1778	1334	2223	Siemens Innovance D-Dimer
	µg/l	301	226	376	Roche Cobas D-DI 2
	µg/l FEU	1894	1421	2368	HemosIL D-Dimer HS 500
	µg/l	563	422	704	HemosIL D-Dimer
µg/l	593	445	741	HemosIL D-Dimer HS	
Digoxin	nmol/l	2.23	1.78	2.68	Chemiluminescence
	ng/ml	1.74	1.39	2.09	
	nmol/l	1.88	1.50	2.26	Vitros
	ng/ml	1.47	1.17	1.77	
	nmol/l	2.03	1.62	2.44	Enzyme Immunoassay
	ng/ml	1.59	1.27	1.91	
	nmol/l	1.97	1.58	2.36	Turbidimetric
	ng/ml	1.54	1.23	1.85	
nmol/l	1.88	1.50	2.26	KIMS	
ng/ml	1.47	1.17	1.77		
hsCRP	mg/l	2.88	2.30	3.46	Nephelometric (IFCC Cal.)
	mg/l	2.89	2.31	3.47	Turbidimetric (IFCC Cal.)
	mg/l	2.93	2.34	3.52	Turbidimetric (Non IFCC Cal.)

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

Cat. No. CQ5052 Lot No. 3911CK Size: 3 x 3 ml Expiry: 2017-10-28

Analyte	unit	Target	Range		methods
			low	high	
hsCRP	mg/l	2.89	2.31	3.47	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	152	122	182	Abbott Architect
	ng/ml = µg/l	115	92.0	138	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	133	106	160	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	137	110	164	Siemens Dimension
	ng/ml = µg/l	93.8	75.0	113	Beckman DxI800
	ng/ml = µg/l	105	84.0	126	Roche Elecsys
	ng/ml = µg/l	106	84.8	127	Roche Hitachi
	ng/ml = µg/l	118	94.4	142	Roche Integra
	ng/ml = µg/l	90.8	72.6	109	Beckman Coulter Access
	ng/ml = µg/l	74.6	59.7	89.5	Siemens Stratus CS
	ng/ml = µg/l	114	91.2	137	BioMerieux Vidas
	ng/ml = µg/l	144	115	173	Biosite Triage Meter Plus
	ng/ml = µg/l	50.7	40.6	60.8	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	111	88.8	133	Siemens Dimension Vista LOCI
ng/ml = µg/l	132	106	158	Siemens Centaur CP	
ng/ml = µg/l	128	89.6	166	Randox Immunoturbidimetric	
NT-ProBNP	pmol/l	26.4	19.8	33.0	Siemens Dimension
	pg/ml	224	168	280	
	pmol/l	209	157	261	Siemens Immulite 2000
	pg/ml	1771	1330	2212	
	pmol/l	75.1	56.3	93.9	Siemens Stratus CS
	pg/ml	636	477	795	
	pmol/l	60.4	45.3	75.5	BioMerieux Vidas
	pg/ml	512	384	640	
	pmol/l	47.5	35.6	59.4	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	402	302	502	
	pmol/l	181	136	226	Mitsubishi Chemical Pathfast
	pg/ml	1533	1152	1914	
	pmol/l	100	75.0	125	Ortho Vitros 3600/5600/ECi
	pg/ml	847	635	1059	
	pmol/l	34.9	26.2	43.6	Roche h232
	pg/ml	296	222	370	
	pmol/l	27.6	20.7	34.5	Siemens Dimension Vista LOCI
	pg/ml	234	175	293	
pmol/l	13.7	10.3	17.1	Siemens Dimension Exl LOCI	
pg/ml	116	87.3	145		
pmol/l	60.7	45.5	75.9	Biomerieux Vidas 2	
pg/ml	514	385	643		
Troponin I	ng/ml = µg/l	15.5	12.4	18.6	Abbott Architect
	ng/ml = µg/l	2.23	1.78	2.68	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.499	0.399	0.599	Siemens Dimension
	ng/ml = µg/l	4.07	3.26	4.88	Siemens Immulite 2000
	ng/ml = µg/l	0.679	0.543	0.815	Beckman DXi800 1st gen
	ng/ml = µg/l	0.631	0.505	0.757	Beckman Coulter Access
ng/ml = µg/l	0.746	0.597	0.895	Siemens Stratus CS	

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

Cat. No. CQ5052 Lot No. 3911CK Size: 3 x 3 ml Expiry: 2017-10-28

Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	10.2	8.16	12.2	Tosoh AIA360
	ng/ml = µg/l	8.57	6.86	10.3	Ortho Vitros ECI
	ng/ml = µg/l	4.87	3.90	5.84	BioMerieux Vidas
	ng/ml = µg/l	5.24	4.19	6.29	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.449	0.359	0.539	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	1.14	0.912	1.37	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	6.26	5.01	7.51	Abbott i STAT
	ng/ml = µg/l	0.680	0.544	0.816	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.648	0.518	0.778	Siemens Dimension Exl LOCI
	ng/ml = µg/l	0.975	0.780	1.17	Abbott Architect STAT hs
	ng/ml = µg/l	0.695	0.556	0.834	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	0.648	0.518	0.778	Beckman Access - AccuTnl+3
	ng/ml = µg/l	1.02	0.816	1.22	Siemens Centaur CP
Troponin T	µg/l	0.190	0.143	0.238	Roche Cobas TroponinT
	µg/l	0.193	0.145	0.241	Roche Cobas Troponin T HS
	µg/l	0.074	0.056	0.093	Roche h232
	µg/l	0.156	0.117	0.195	Radiometer AQT90 Flex

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

CAT. NO. CQ 5052 **LOT NO.** 3990CK
SIZE: 3 x 3 ml **EXPIRY:** 2018-04-28
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 following analytes: CK-MB Mass, Digoxin, D-Dimer, hsCRP, Myoglobin, NT-ProBNP, Troponin I and Troponin T.

SAFETY PRECAUTIONS AND WARNINGS

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

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.

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.

Revised 08 Feb 17

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

Cat. No. CQ5052 Lot No. 3990CK Size: 3 x 3 ml Expiry: 2018-04-28

Range					
Analyte	unit	Target	low	high	methods
CK-MB Mass	ng/ml = µg/l	6.03	4.82	7.24	Abbott Architect
	ng/ml = µg/l	6.99	5.59	8.39	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	4.90	3.92	5.88	Siemens Dimension
	ng/ml = µg/l	5.61	4.49	6.73	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	7.56	6.05	9.07	Beckman Coulter Access
	ng/ml = µg/l	5.95	4.76	7.14	Siemens Stratus CS
	ng/ml = µg/l	9.15	7.32	11.0	BioMerieux Vidas
	ng/ml = µg/l	7.93	6.34	9.52	Beckman Dxl800
	ng/ml = µg/l	5.50	4.40	6.60	Roche h232
	ng/ml = µg/l	9.24	7.39	11.1	Radiometer AQT90 Flex
	ng/ml = µg/l	5.32	4.26	6.38	Siemens Dimension Vista LOCI
	ng/ml = µg/l	6.62	5.30	7.94	Siemens Centaur CP
D-Dimer	µg/l FEU	1786	1340	2233	Biomerieux Vidas Exclusion II
	µg/l	669	502	836	Roche/ Stago STA-R Evolution
	µg/l	1068	801	1335	Roche Cobas h232 D-Dimer
	µg/l	789	592	986	Roche Integra D-DI 2
	µg/l	1121	841	1401	Alere Biosite Triage D-Dimer
	µg/l	929	697	1161	Abbott Architect Quantia D-Dimer
	µg/l	1210	908	1513	Siemens Stratus CS
	µg/l	421	316	526	Siemens Immulite 2000 D-Dimer
	µg/l	1074	806	1343	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	2334	1751	2918	Siemens Innovance D-Dimer
	µg/l	704	528	880	Roche Cobas D-DI 2
	µg/l FEU	2526	1895	3158	HemosIL D-Dimer HS 500
µg/l	759	569	949	HemosIL D-Dimer	
Digoxin	nmol/l	1.39	1.11	1.67	Chemiluminescence
	ng/ml	1.09	0.867	1.31	
	nmol/l	1.41	1.13	1.69	Vitros
	ng/ml	1.10	0.883	1.32	
	nmol/l	1.18	0.944	1.42	Enzyme Immunoassay
	ng/ml	0.922	0.737	1.11	
	nmol/l	1.17	0.936	1.40	Turbidimetric
	ng/ml	0.914	0.731	1.10	
hsCRP	nmol/l	1.10	0.880	1.32	KIMS
	ng/ml	0.859	0.687	1.03	
	mg/l	1.81	1.45	2.17	Nephelometric (IFCC Cal.)
	mg/l	1.88	1.50	2.26	Nephelometric (Non IFCC Cal.)
	mg/l	1.98	1.58	2.38	Turbidimetric (IFCC Cal.)
	mg/l	2.05	1.64	2.46	Turbidimetric (Non IFCC Cal.)
	mg/l	1.88	1.50	2.26	Randox Immunoturbidimetric
	mg/l				
Myoglobin	ng/ml = µg/l	75.0	60.0	90.0	Abbott Architect
	ng/ml = µg/l	55.6	44.5	66.7	Siemens/Dade Behring Nephelometer

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

Cat. No. CQ5052 Lot No. 3990CK Size: 3 x 3 ml Expiry: 2018-04-28

Analyte	unit	Target	Range		methods
			low	high	
Myoglobin	ng/ml = µg/l	71.3	57.0	85.6	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	69.7	55.8	83.6	Siemens Dimension
	ng/ml = µg/l	53.5	42.8	64.2	Beckman Dxl800
	ng/ml = µg/l	62.3	49.8	74.8	Roche Elecsys
	ng/ml = µg/l	60.8	48.6	73.0	Roche Hitachi
	ng/ml = µg/l	68.6	54.9	82.3	Roche Integra
	ng/ml = µg/l	49.0	39.2	58.8	Beckman Coulter Access
	ng/ml = µg/l	35.4	28.3	42.5	Siemens Stratus CS
	ng/ml = µg/l	66.0	52.8	79.2	BioMerieux Vidas
	ng/ml = µg/l	72.2	57.8	86.6	Biosite Triage Meter Plus
	ng/ml = µg/l	54.1	43.3	64.9	Siemens Dimension Vista LOCI
	ng/ml = µg/l	65.2	52.2	78.2	Siemens Centaur CP
ng/ml = µg/l	74.7	52.3	97.1	Randox Immunoturbidimetric	
NT-ProBNP	pmol/l	7.92	5.94	9.90	Siemens Dimension
	pg/ml	67.1	50.3	83.9	
	pmol/l	61.2	45.9	76.5	Siemens Immulite 2000
	pg/ml	518	389	647	
	pmol/l	21.5	16.1	26.9	Siemens Stratus CS
	pg/ml	182	136	228	
	pmol/l	16.1	12.1	20.1	BioMerieux Vidas
	pg/ml	136	103	169	
	pmol/l	16.5	12.4	20.6	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	140	105	175	
	pmol/l	52.1	39.1	65.1	Mitsubishi Chemical Pathfast
	pg/ml	441	331	551	
	pmol/l	33.0	24.8	41.3	Ortho Vitros 3600/5600/ECi
	pg/ml	280	210	350	
	pmol/l	9.35	7.01	11.7	Roche h232
	pg/ml	79.2	59.4	99.0	
	pmol/l	8.00	6.00	10.0	Siemens Dimension Vista LOCI
	pg/ml	67.8	50.8	84.8	
pmol/l	3.56	2.67	4.45	Siemens Dimension Exl LOCI	
pg/ml	30.2	22.6	37.8		
pmol/l	16.1	12.1	20.1	Biomerieux Vidas 2	
pg/ml	136	103	169		
Troponin I	ng/ml = µg/l	0.020	0.014	0.026	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.260	0.208	0.312	Tosoh AIA360
	ng/ml = µg/l	0.194	0.155	0.233	Ortho Vitros ECi
	ng/ml = µg/l	0.270	0.216	0.324	BioMerieux Vidas
	ng/ml = µg/l	0.272	0.218	0.326	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.017	0.014	0.020	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.137	0.110	0.164	Abbott i STAT
	ng/ml = µg/l	0.033	0.026	0.040	Abbott Architect STAT hs
	ng/ml = µg/l	0.021	0.015	0.027	Siemens Centaur CP
	ng/ml = µg/l	0.168	0.134	0.202	bioMerieux VIDAS hs Troponin I
Troponin T	µg/l	0.017	0.013	0.021	Roche Cobas TroponinT

RANDOX

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

Cat. No. CQ5052 Lot No. 3990CK Size: 3 x 3 ml Expiry: 2018-04-28

Range					
Analyte	unit	Target	low	high	methods
Troponin T	µg/l	0.020	0.015	0.025	Roche Cobas Troponin T HS
	µg/l	0.017	0.013	0.021	Roche Cobas Troponin T hs STAT

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

CAT. NO. CQ 5052

LOT NO. 3991CK

SIZE: 3 x 3 ml

EXPIRY: 2018-04-28

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 following analytes: CK-MB Mass, Digoxin, D-Dimer, hsCRP, Myoglobin, NT-ProBNP, Troponin I and Troponin T.

SAFETY PRECAUTIONS AND WARNINGS

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

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.

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.

Revised 08 Feb '17 pl

LIQUID CARDIAC CONTROL LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot. No. 3991CK Size 3 x 3 ml Expiry 2018-04

Range					
Analyte	unit	Target	low	high	methods
CK-MB Mass	ng/ml = µg/l	18.5	14.8	22.2	Abbott Architect
	ng/ml = µg/l	20.2	16.2	24.2	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	17.9	14.3	21.5	Siemens Dimension
	ng/ml = µg/l	15.7	12.6	18.8	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	23.4	18.7	28.1	Beckman Coulter Access
	ng/ml = µg/l	17.2	13.8	20.6	Siemens Stratus CS
	ng/ml = µg/l	26.9	21.5	32.3	BioMerieux Vidas
	ng/ml = µg/l	24.0	19.2	28.8	Beckman Dxl800
	ng/ml = µg/l	13.5	10.8	16.2	Roche h232
	ng/ml = µg/l	29.0	23.2	34.8	Radiometer AQT90 Flex
	ng/ml = µg/l	17.5	14.0	21.0	Siemens Dimension Vista LOCI
ng/ml = µg/l	19.1	15.3	22.9	Siemens Centaur CP	
D - Dimer	µg/l FEU	1524	1143	1905	Biomerieux Vidas Exclusion II
	µg/l FEU	6350	4763	7938	Mitsubishi Pathfast D-Dimer
	µg/l	514	386	643	Roche/ Stago STA-R Evolution
	µg/l	803	602	1004	Roche Cobas h232 D-Dimer
	µg/l	510	383	638	Roche Integra D-DI 2
	µg/l	939	704	1174	Alere Biosite Triage D-Dimer
	µg/l	773	580	966	Abbott Architect Quantia D-Dimer
	µg/l	906	680	1133	Siemens Stratus CS
	µg/l	265	199	331	Siemens Immulite 2000 D-Dimer
	µg/l	871	653	1089	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1956	1467	2445	Siemens Innovance D-Dimer
	µg/l	400	300	500	Roche Cobas D-DI 2
	µg/l FEU	2148	1611	2685	HemosIL D-Dimer HS 500
	µg/l	631	473	789	HemosIL D-Dimer
µg/l	631	473	789	HemosIL D-Dimer HS	
Digoxin	nmol/l	2.12	1.70	2.54	Chemiluminescence
	ng/ml	1.66	1.33	1.99	
	nmol/l	1.88	1.50	2.26	Enzyme Immunoassay
	ng/ml	1.47	1.17	1.77	
	nmol/l	1.93	1.54	2.32	Turbidimetric
	ng/ml	1.51	1.20	1.82	
	nmol/l	1.77	1.42	2.12	KIMS
ng/ml	1.38	1.11	1.65		
hsCRP	mg/l	3.78	3.02	4.53	Vitros (IFCC Cal.)
	mg/l	3.01	2.41	3.61	Nephelometric (IFCC Cal.)
	mg/l	2.99	2.39	3.59	Turbidimetric (IFCC Cal.)
	mg/l	3.10	2.48	3.72	Turbidimetric (Non IFCC Cal.)
	mg/l	2.93	2.34	3.52	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	158	126	190	Abbott Architect
	ng/ml = µg/l	113	90.4	136	Siemens/Dade Behring Nephelometer

LIQUID CARDIAC CONTROL LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot. No. 3991CK Size 3 x 3 ml Expiry 2018-04

Analyte	unit	Target	Range		methods
			low	high	
Myoglobin	ng/ml = µg/l	134	107	161	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	133	106	160	Siemens Dimension
	ng/ml = µg/l	90.6	72.5	109	Beckman Dxl800
	ng/ml = µg/l	105	84.0	126	Roche Elecsys
	ng/ml = µg/l	107	85.6	128	Roche Hitachi
	ng/ml = µg/l	124	99.0	149	Roche Integra
	ng/ml = µg/l	90.4	72.3	108	Beckman Coulter Access
	ng/ml = µg/l	70.8	56.6	85.0	Siemens Stratus CS
	ng/ml = µg/l	96.8	77.4	116	BioMerieux Vidas
	ng/ml = µg/l	116	92.8	139	Siemens Dimension Vista LOCI
	ng/ml = µg/l	136	109	163	Siemens Centaur CP
ng/ml = µg/l	149	104	194	Randox Immunoturbidimetric	
NT-ProBNP	pmol/l	26.1	19.6	32.6	Siemens Dimension
	pg/ml	221	166	276	
	pmol/l	228	171	285	Siemens Immulite 2000
	pg/ml	1932	1449	2415	
	pmol/l	299	224	374	Siemens Immulite 1000
	pg/ml	2533	1898	3168	
	pmol/l	75.0	56.3	93.8	Siemens Stratus CS
	pg/ml	635	477	793	
	pmol/l	65.9	49.4	82.4	BioMerieux Vidas
	pg/ml	558	419	697	
	pmol/l	51.1	38.3	63.9	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	433	324	542	
	pmol/l	201	151	251	Mitsubishi Chemical Pathfast
	pg/ml	1703	1279	2127	
	pmol/l	115	86.3	144	Ortho Vitros 3600/5600/ECi
	pg/ml	974	731	1217	
	pmol/l	43.2	32.4	54.0	Roche h232
	pg/ml	366	274	458	
pmol/l	25.2	18.9	31.5	Siemens Dimension Vista LOCI	
pg/ml	213	160	266		
pmol/l	12.2	9.15	15.3	Siemens Dimension Exl LOCI	
pg/ml	103	77.5	129		
pmol/l	67.4	50.6	84.3	Biomerieux Vidas 2	
pg/ml	571	429	713		
Troponin I	ng/ml = µg/l	1.02	0.816	1.22	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.438	0.350	0.526	Siemens Dimension
	ng/ml = µg/l	0.541	0.433	0.649	Beckman DXi800 1st gen
	ng/ml = µg/l	0.585	0.468	0.702	Beckman Coulter Access
	ng/ml = µg/l	0.612	0.490	0.734	Siemens Stratus CS
	ng/ml = µg/l	9.06	7.25	10.9	Tosoh AIA360
	ng/ml = µg/l	7.94	6.35	9.53	Ortho Vitros ECi
	ng/ml = µg/l	4.62	3.70	5.54	BioMerieux Vidas
	ng/ml = µg/l	4.71	3.77	5.65	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.352	0.282	0.422	Roche Elecsys/E170/c6000/e411

LIQUID CARDIAC CONTROL LEVEL 2 (CRD LIQ CONTROL 2)

Cat. No. CQ5052 Lot. No. 3991CK Size 3 x 3 ml Expiry 2018-04

Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	0.946	0.757	1.14	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	5.15	4.12	6.18	Abbott i STAT
	ng/ml = µg/l	0.534	0.427	0.641	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.529	0.423	0.635	Siemens Dimension Exl LOCI
	ng/ml = µg/l	0.891	0.713	1.07	Abbott Architect STAT hs
	ng/ml = µg/l	0.555	0.444	0.666	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	0.591	0.473	0.709	Beckman Access - AccuTnl+3
	ng/ml = µg/l	0.853	0.682	1.02	Siemens Centaur CP
Troponin T	µg/l	0.196	0.147	0.245	Roche Cobas TroponinT
	µg/l	0.207	0.155	0.259	Roche Cobas Troponin T HS
	µg/l	0.081	0.061	0.101	Roche h232
	µg/l	0.161	0.121	0.201	Radiometer AQT90 Flex

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

CAT. NO. CQ5053 **LOT NO.** 3912CK
SIZE: 3 x 3 ml **EXPIRY:** 2017-10-28

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 following analytes: CK-MB Mass, D-Dimer, Digoxin, hsCRP, Myoglobin, NT-ProBNP, Troponin I and Troponin T.

SAFETY PRECAUTIONS AND WARNINGS

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

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.

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.

Revised 08 Feb 17 pl

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

Cat. No. CQ5053 Lot No. 3912CK Size: 3 x 3 ml Expiry: 2017-10-28

Analyte	unit	Target	Range		methods
			low	high	
CK-MB Mass	ng/ml = µg/l	102	81.6	122	Abbott Architect
	ng/ml = µg/l	107	85.6	128	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	115	92.0	138	Siemens Dimension
	ng/ml = µg/l	78.9	63.1	94.7	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	129	103	155	Beckman Coulter Access
	ng/ml = µg/l	105	84.0	126	Siemens Stratus CS
	ng/ml = µg/l	138	110	166	BioMerieux Vidas
	ng/ml = µg/l	130	104	156	Beckman Dxl800
	ng/ml = µg/l	41.0	32.8	49.2	Biosite Triage Meter Plus
	ng/ml = µg/l	35.3	28.2	42.4	Roche h232
	ng/ml = µg/l	148	118	178	Radiometer AQT90 Flex
ng/ml = µg/l	103	82.4	124	Siemens Centaur CP	
D - Dimer	µg/l FEU	2482	1862	3103	Biomerieux Vidas Exclusion II
	µg/l FEU	10952	8214	13690	Mitsubishi Pathfast D-Dimer
	µg/l	974	731	1218	Roche/ Stago STA-R Evolution
	µg/l	1466	1100	1833	Roche Cobas h232 D-Dimer
	µg/l	1179	884	1474	Roche Integra D-DI 2
	µg/l	1482	1112	1853	Alere Biosite Triage D-Dimer
	µg/l	1193	895	1491	Abbott Architect Quantia D-Dimer
	µg/l	1992	1494	2490	Siemens Stratus CS
	µg/l	797	598	996	Siemens Immulite 2000 D-Dimer
	µg/l	1547	1160	1934	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	3594	2696	4493	Siemens Innovance D-Dimer
	µg/l	1176	882	1470	Roche Cobas D-DI 2
	µg/l FEU	3416	2562	4270	HemosIL D-Dimer HS 500
µg/l	975	731	1219	HemosIL D-Dimer	
µg/l	1136	852	1420	HemosIL D-Dimer HS	
Digoxin	nmol/l	3.53	2.79	4.27	Chemiluminescence
	ng/ml	2.76	2.18	3.34	
	nmol/l	2.84	2.27	3.41	Vitros
	ng/ml	2.22	1.77	2.67	
	nmol/l	3.16	2.84	3.48	Enzyme Immunoassay
	ng/ml	2.47	2.22	2.72	
	nmol/l	3.16	2.51	3.81	Turbidimetric
	ng/ml	2.47	1.96	2.98	
nmol/l	3.00	2.70	3.30	KIMS	
ng/ml	2.34	2.11	2.57		
hsCRP	mg/l	8.11	6.49	9.73	Nephelometric (IFCC Cal.)
	mg/l	7.63	6.10	9.16	Nephelometric (Non IFCC Cal.)
	mg/l	7.98	6.38	9.58	Turbidimetric (IFCC Cal.)
	mg/l	7.54	6.03	9.05	Turbidimetric (Non IFCC Cal.)
	mg/l	8.32	6.66	9.98	Radox Immunoturbidimetric

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

Cat. No. CQ5053 Lot No. 3912CK Size: 3 x 3 ml Expiry: 2017-10-28

Analyte	unit	Target	Range		methods
			low	high	
Myoglobin	ng/ml = µg/l	403	322	484	Abbott Architect
	ng/ml = µg/l	352	282	422	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	382	306	458	Siemens Dimension
	ng/ml = µg/l	237	190	284	Beckman Dxl800
	ng/ml = µg/l	266	213	319	Roche Elecsys
	ng/ml = µg/l	262	210	314	Roche Hitachi
	ng/ml = µg/l	310	248	372	Roche Integra
	ng/ml = µg/l	223	178	268	Beckman Coulter Access
	ng/ml = µg/l	207	166	248	Siemens Stratus CS
	ng/ml = µg/l	275	220	330	BioMerieux Vidas
	ng/ml = µg/l	267	214	320	Biosite Triage Meter Plus
	ng/ml = µg/l	488	390	586	Ortho Vitros 3600/5600/ECi
	ng/ml = µg/l	315	252	378	Siemens Dimension Vista LOCI
	ng/ml = µg/l	331	265	397	Siemens Centaur CP
ng/ml = µg/l	341	239	443	Randox Immunoturbidimetric	
NT-ProBNP	pmol/l	409	307	511	Siemens Dimension
	pg/ml	3465	2601	4329	
	pmol/l	2358	1769	2948	Siemens Immulite 2000
	pg/ml	19977	14987	24967	
	pmol/l	637	478	796	Siemens Stratus CS
	pg/ml	5397	4050	6744	
	pmol/l	733	550	916	BioMerieux Vidas
	pg/ml	6210	4660	7760	
	pmol/l	520	390	650	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	4405	3304	5506	
	pmol/l	1768	1326	2210	Mitsubishi Chemical Pathfast
	pg/ml	14978	11234	18722	
	pmol/l	1002	752	1253	Ortho Vitros 3600/5600/ECi
	pg/ml	8489	6371	10607	
	pmol/l	235	176	294	Roche h232
	pg/ml	1991	1491	2491	
	pmol/l	318	239	398	Siemens Dimension Vista LOCI
	pg/ml	2694	2025	3363	
pmol/l	218	164	273	Siemens Dimension Exl LOCI	
pg/ml	1847	1389	2305		
pmol/l	753	565	941	Biomerieux Vidas 2	
pg/ml	6379	4787	7971		
Troponin I	ng/ml = µg/l	7.61	6.09	9.13	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	2.30	1.84	2.76	Siemens Dimension
	ng/ml = µg/l	3.26	2.61	3.91	Beckman DXi800 1st gen
	ng/ml = µg/l	3.06	2.45	3.67	Beckman Coulter Access
	ng/ml = µg/l	3.28	2.62	3.94	Siemens Stratus CS
	ng/ml = µg/l	40.0	32.0	48.0	Tosoh AIA360
	ng/ml = µg/l	35.0	28.0	42.0	Ortho Vitros ECi
	ng/ml = µg/l	17.2	13.8	20.6	BioMerieux Vidas
ng/ml = µg/l	17.5	14.0	21.0	Biomerieux Vidas Ultra	

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

Cat. No. CQ5053 Lot No. 3912CK Size: 3 x 3 ml Expiry: 2017-10-28

Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	1.69	1.35	2.03	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	7.90	6.32	9.48	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	25.5	20.4	30.6	Abbott i STAT
	ng/ml = µg/l	2.74	2.19	3.29	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	2.85	2.28	3.42	Siemens Dimension Exl LOCI
	ng/ml = µg/l	4.73	3.78	5.68	Abbott Architect STAT hs
	ng/ml = µg/l	3.20	2.56	3.84	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	3.10	2.48	3.72	Beckman Access - AccuTnl+3
	ng/ml = µg/l	6.24	4.99	7.49	Siemens Centaur CP
Troponin T	µg/l	3.420	2.570	4.280	Roche Cobas TroponinT
	µg/l	3.700	2.780	4.630	Roche Cobas Troponin T HS
	µg/l	1.150	0.863	1.440	Roche h232
	µg/l	4.430	3.320	5.540	Radiometer AQT90 Flex