



Urgent Notice de Sécurité

Contrôle Liquide Cardiaque Niveau 2 & Niveau 3

CQ5052 – 3834CK, 3836CK

CQ5053 – 3835CK, 3837CK

GTIN: 05055273207453, 05055273207460

Référence de Plainte: 261

Type d'Action: Modification de matériel

Date: 12 Septembre 2016

Cher client,

Nous observons actuellement la nécessité de réassigner les produits indiqués ci-dessous et nous tenons à vous transmettre cet avis de sécurité pour vous en informer.

Détail des produits affectés:

Liquide Cardiaque Contrôle Niveau 2, Référence Catalogue CQ5052, lots 3834CK & 3836CK

Liquide Cardiaque Contrôle Niveau 3, Référence Catalogue CQ5053, lots 3835CK & 3837CK

Description

Les taux de myoglobine des lots 3834CK, 3835CK, 3836CK et 3837CK ont diminué pour les Randox immunoturbidimétrique et Siemens Centaur.

Les taux de CKMB des lots 3834CK, 3835CK, 3836CK et 3837CK ont diminué pour les automates Roche e411, BioMerieux Vidas et Siemens Centaur classiques.

Nous avons réaffecté les valeurs cibles et les intervalles de confiance

Risque pour la Santé: Les contenus de cette lettre doivent être discutés avec votre Directeur Médical.



Urgent Notice de Sécurité

Action à prendre: Actualiser vos produits avec cette notice importante.

Merci de compléter, signer et retourner **impérativement** la section réponse (page 3/3) à technical.services@randox.com au plus tard dans les cinq jours.

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

Point de Contact:

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.



Urgent Notice de Sécurité

Contrôle Liquide Cardiaque Niveau 2 & Niveau 3

CQ5052 – 3834CK, 3836CK

CQ5053 – 3835CK, 3837CK

GTIN: 05055273207453, 05055273207460

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 Kits Received

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 2 (CRD LIQ CONTROL 2)

CAT. NO. CQ 5052 **LOT NO.** 3834CK

SIZE: 3 x 3 ml **EXPIRY:** 2017-04

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 10 Aug '16 pl

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

Cat. No. CQ5052 Lot No. 3834CK Size: 3 x 3 ml Expiry: 2017-04

Analyte	unit	Target	Range		methods
			low	high	
CK-MB Mass	ng/ml = µg/l	17.4	13.9	20.9	Abbott Architect
	ng/ml = µg/l	17.5	14.0	21.0	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	17.1	13.7	20.5	Siemens Dimension
	ng/ml = µg/l	12.8	10.2	15.4	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	21.7	17.4	26.0	Beckman Coulter Access
	ng/ml = µg/l	17.7	14.2	21.2	Siemens Stratus CS
	ng/ml = µg/l	13.9	11.1	16.7	Ortho Vitros ECI
	ng/ml = µg/l	23.5	18.8	28.2	BioMerieux Vidas
	ng/ml = µg/l	21.9	17.5	26.3	Beckman DxI800
	ng/ml = µg/l	13.7	11.0	16.4	Roche h232
	ng/ml = µg/l	26.9	21.5	32.3	Radiometer AQT90 Flex
	ng/ml = µg/l	16.7	13.4	20.0	Siemens Dimension Vista LOCI
	ng/ml = µg/l	17.2	13.8	20.6	Siemens Centaur CP
D - Dimer	µg/l FEU	1366	1025	1708	Biomerieux Vidas Exclusion II
	µg/l FEU	5064	3798	6330	Mitsubishi Pathfast D-Dimer
	µg/l	472	354	590	Roche/ Stago STA-R Evolution
	µg/l	804	603	1005	Roche Cobas h232 D-Dimer
	µg/l	496	372	620	Roche Integra D-DI 2
	µg/l	822	617	1028	Alere Biosite Triage D-Dimer
	µg/l	717	538	896	Abbott Architect Quantia D-Dimer
	µg/l	851	638	1064	Siemens Stratus CS
	µg/l	340	255	425	Siemens Immulite 2000 D-Dimer
	µg/l	787	590	984	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1916	1437	2395	Siemens Innovance D-Dimer
	µg/l	373	280	466	Roche Cobas D-DI 2
	µg/l FEU	2134	1601	2668	HemosIL D-Dimer HS 500
	µg/l	596	447	745	HemosIL D-Dimer
µg/l	644	483	805	HemosIL D-Dimer HS	
Digoxin	nmol/l	2.44	1.95	2.93	Chemiluminescence
	ng/ml	1.91	1.52	2.30	
	nmol/l	2.16	1.73	2.59	Enzyme Immunoassay
	ng/ml	1.69	1.35	2.03	
	nmol/l	2.29	1.83	2.75	Turbidimetric
	ng/ml	1.79	1.43	2.15	
	nmol/l	2.11	1.69	2.53	KIMS
ng/ml	1.65	1.32	1.98		
hsCRP	mg/l	2.95	2.36	3.54	Nephelometric (IFCC Cal.)
	mg/l	2.95	2.36	3.54	Nephelometric (Non IFCC Cal.)
	mg/l	3.18	2.54	3.82	Turbidimetric (IFCC Cal.)
	mg/l	3.13	2.50	3.76	Turbidimetric (Non IFCC Cal.)
	mg/l	3.15	2.52	3.78	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	146	117	175	Abbott Architect

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

Cat. No. CQ5052 Lot No. 3834CK Size: 3 x 3 ml Expiry: 2017-04

Analyte	unit	Target	Range		methods
			low	high	
Myoglobin	ng/ml = µg/l	122	97.6	146	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	120	96.0	144	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	143	114	172	Siemens Dimension
	ng/ml = µg/l	100	80.0	120	Beckman Dxl800
	ng/ml = µg/l	107	85.6	128	Roche Elecsys
	ng/ml = µg/l	114	91.2	137	Roche Hitachi
	ng/ml = µg/l	133	106	160	Roche Integra
	ng/ml = µg/l	94.3	75.4	113	Beckman Coulter Access
	ng/ml = µg/l	79.9	63.9	95.9	Siemens Stratus CS
	ng/ml = µg/l	127	102	152	BioMerieux Vidas
	ng/ml = µg/l	28.0	22.4	33.6	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	215	172	258	Ortho Vitros 3600/5600/ECi
	ng/ml = µg/l	117	93.6	140	Siemens Dimension Vista LOCI
	ng/ml = µg/l	122	97.6	146	Siemens Centaur CP
ng/ml = µg/l	109	87.2	131	Randox Immunoturbidimetric	
NT-ProBNP	pmol/l	30.3	22.7	37.9	Siemens Dimension
	pg/ml	257	192	322	
	pmol/l	166	125	208	Siemens Immulite 2000
	pg/ml	1406	1059	1753	
	pmol/l	68.9	51.7	86.1	Siemens Stratus CS
	pg/ml	584	438	730	
	pmol/l	67.1	50.3	83.9	BioMerieux Vidas
	pg/ml	568	426	710	
	pmol/l	46.4	34.8	58.0	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	393	295	491	
	pmol/l	168	126	210	Mitsubishi Chemical Pathfast
	pg/ml	1423	1067	1779	
	pmol/l	85.8	64.4	107	Ortho Vitros 3600/5600/ECi
	pg/ml	727	546	908	
	pmol/l	24.5	18.4	30.6	Roche h232
	pg/ml	208	156	260	
	pmol/l	27.8	20.9	34.8	Siemens Dimension Vista LOCI
	pg/ml	236	177	295	
pmol/l	14.0	10.5	17.5	Siemens Dimension Exl LOCI	
pg/ml	119	89.0	149		
pmol/l	65.9	49.4	82.4	Biomerieux Vidas 2	
pg/ml	558	419	697		
Troponin I	ng/ml = µg/l	12.6	10.1	15.1	Abbott Architect
	ng/ml = µg/l	1.73	1.38	2.08	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.835	0.668	1.00	Siemens Dimension
	ng/ml = µg/l	0.974	0.779	1.17	Beckman DXi800 1st gen
	ng/ml = µg/l	0.972	0.778	1.17	Beckman Coulter Access
	ng/ml = µg/l	1.20	0.960	1.44	Siemens Stratus CS
	ng/ml = µg/l	9.07	7.26	10.9	Tosoh AIA360
	ng/ml = µg/l	8.63	6.90	10.4	Ortho Vitros ECi
ng/ml = µg/l	4.64	3.71	5.57	BioMerieux Vidas	

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

Cat. No. CQ5052 Lot No. 3834CK Size: 3 x 3 ml Expiry: 2017-04

Analyte	unit	Target	Range		methods
			low	high	
Troponin I	ng/ml = µg/l	4.61	3.69	5.53	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.764	0.611	0.917	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	1.48	1.18	1.78	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	1.22	0.976	1.46	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	1.23	0.984	1.48	Siemens Dimension Exl LOCI
	ng/ml = µg/l	1.28	1.02	1.54	Abbott Architect STAT hs
	ng/ml = µg/l	0.984	0.787	1.18	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	0.986	0.789	1.18	Beckman Access - AccuTnl+3
	ng/ml = µg/l	1.34	1.07	1.61	Siemens Centaur CP
Troponin T	µg/l	0.202	0.152	0.253	Roche Cobas TroponinT
	µg/l	0.224	0.168	0.280	Roche Cobas Troponin T HS
	µg/l	0.117	0.088	0.146	Roche h232
	µg/l	0.180	0.135	0.225	Radiometer AQT90 Flex

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

CAT. NO. CQ5053 **LOT NO.** 3835CK
SIZE: 3 x 3 ml **EXPIRY:** 2017-05

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 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 10 Aug '16 pl

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

Cat. No. CQ5053 Lot No. 3835CK Size: 3 x 3 ml Expiry: 2017-05

Analyte	unit	Target	Range		methods
			low	high	
CK-MB Mass	ng/ml = µg/l	84.3	67.4	101	Abbott Architect
	ng/ml = µg/l	81.7	65.4	98.0	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	101	80.8	121	Siemens Dimension
	ng/ml = µg/l	56.7	45.4	68.0	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	111	88.8	133	Beckman Coulter Access
	ng/ml = µg/l	102	81.6	122	Siemens Stratus CS
	ng/ml = µg/l	108	86.4	130	BioMerieux Vidas
	ng/ml = µg/l	117	93.6	140	Beckman Dxl800
	ng/ml = µg/l	33.6	26.9	40.3	Roche h232
	ng/ml = µg/l	121	96.8	145	Radiometer AQT90 Flex
	ng/ml = µg/l	95.5	76.4	115	Siemens Dimension Vista LOCI
ng/ml = µg/l	86.1	68.9	103	Siemens Centaur CP	
D - Dimer	µg/l FEU	2810	2108	3513	Biomerieux Vidas Exclusion II
	µg/l FEU	12232	9174	15290	Mitsubishi Pathfast D-Dimer
	µg/l	1068	801	1335	Roche/ Stago STA-R Evolution
	µg/l	1566	1175	1958	Roche Cobas h232 D-Dimer
	µg/l	1373	1030	1716	Roche Integra D-DI 2
	µg/l	1884	1413	2355	Alere Biosite Triage D-Dimer
	µg/l	1336	1002	1670	Abbott Architect Quantia D-Dimer
	µg/l	2101	1576	2626	Siemens Stratus CS
	µg/l	980	735	1225	Siemens Immulite 2000 D-Dimer
	µg/l	1698	1274	2123	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	3932	2949	4915	Siemens Innovance D-Dimer
	µg/l	1414	1061	1768	Roche Cobas D-DI 2
	µg/l FEU	3818	2864	4773	HemosIL D-Dimer HS 500
µg/l	1002	752	1253	HemosIL D-Dimer	
µg/l	1187	890	1484	HemosIL D-Dimer HS	
Digoxin	nmol/l	3.88	3.10	4.66	Chemiluminescence
	ng/ml	3.03	2.42	3.64	
	nmol/l	3.14	2.51	3.77	Vitros
	ng/ml	2.45	1.96	2.94	
	nmol/l	3.46	2.77	4.15	Enzyme Immunoassay
	ng/ml	2.70	2.16	3.24	
	nmol/l	3.40	2.72	4.08	Turbidimetric
	ng/ml	2.66	2.12	3.20	
nmol/l	3.28	2.62	3.94	KIMS	
ng/ml	2.56	2.05	3.07		
hsCRP	mg/l	8.29	6.63	9.95	Nephelometric (IFCC Cal.)
	mg/l	8.36	6.69	10.0	Nephelometric (Non IFCC Cal.)
	mg/l	8.15	6.52	9.78	Turbidimetric (IFCC Cal.)
	mg/l	7.69	6.15	9.23	Turbidimetric (Non IFCC Cal.)
	mg/l	8.72	6.98	10.5	Randox Immunoturbidimetric

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

Cat. No. CQ5053 Lot No. 3835CK Size: 3 x 3 ml Expiry: 2017-05

Analyte	unit	Target	Range		methods
			low	high	
Myoglobin	ng/ml = µg/l	454	363	545	Abbott Architect
	ng/ml = µg/l	385	308	462	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	376	301	451	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	463	370	556	Siemens Dimension
	ng/ml = µg/l	285	228	342	Beckman Dxl800
	ng/ml = µg/l	310	248	372	Roche Elecsys
	ng/ml = µg/l	312	250	374	Roche Hitachi
	ng/ml = µg/l	382	306	458	Roche Integra
	ng/ml = µg/l	271	217	325	Beckman Coulter Access
	ng/ml = µg/l	266	213	319	Siemens Stratus CS
	ng/ml = µg/l	354	283	425	BioMerieux Vidas
	ng/ml = µg/l	157	126	188	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	577	462	692	Ortho Vitros 3600/5600/ECi
	ng/ml = µg/l	367	294	440	Siemens Dimension Vista LOCI
ng/ml = µg/l	415	332	498	Randox Immunoturbidimetric	
NT-ProBNP	pmol/l	431	323	539	Siemens Dimension
	pg/ml	3651	2736	4566	
	pmol/l	2354	1766	2943	Siemens Immulite 2000
	pg/ml	19943	14962	24924	
	pmol/l	673	505	841	Siemens Stratus CS
	pg/ml	5702	4278	7126	
	pmol/l	698	524	873	BioMerieux Vidas
	pg/ml	5913	4439	7387	
	pmol/l	520	390	650	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	4405	3304	5506	
	pmol/l	1935	1451	2419	Mitsubishi Chemical Pathfast
	pg/ml	16393	12293	20493	
	pmol/l	987	740	1234	Ortho Vitros 3600/5600/ECi
	pg/ml	8362	6269	10455	
	pmol/l	194	146	243	Roche h232
	pg/ml	1644	1237	2051	
	pmol/l	316	237	395	Siemens Dimension Vista LOCI
	pg/ml	2677	2008	3346	
pmol/l	235	176	294	Siemens Dimension Exl LOCI	
pg/ml	1991	1491	2491		
pmol/l	736	552	920	Biomerieux Vidas 2	
pg/ml	6235	4677	7793		
Troponin I	ng/ml = µg/l	51.8	41.4	62.2	Abbott Architect
	ng/ml = µg/l	8.84	7.07	10.6	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	3.83	3.06	4.60	Siemens Dimension
	ng/ml = µg/l	27.6	22.1	33.1	Siemens Immulite 1000
	ng/ml = µg/l	4.64	3.71	5.57	Beckman DXi800 1st gen
	ng/ml = µg/l	4.15	3.32	4.98	Beckman Coulter Access
	ng/ml = µg/l	5.44	4.35	6.53	Siemens Stratus CS
	ng/ml = µg/l	36.7	29.4	44.0	Tosoh AIA360
ng/ml = µg/l	33.5	26.8	40.2	Ortho Vitros ECi	

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

Cat. No. CQ5053 Lot No. 3835CK Size: 3 x 3 ml Expiry: 2017-05

Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	14.7	11.8	17.6	BioMerieux Vidas
	ng/ml = µg/l	14.8	11.8	17.8	Biomerieux Vidas Ultra
	ng/ml = µg/l	2.65	2.12	3.18	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	9.79	7.83	11.7	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	4.61	3.69	5.53	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	4.90	3.92	5.88	Siemens Dimension Exl LOCI
	ng/ml = µg/l	6.53	5.22	7.84	Abbott Architect STAT hs
	ng/ml = µg/l	4.44	3.55	5.33	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	4.44	3.55	5.33	Beckman Access - AccuTnl+3
	ng/ml = µg/l	6.93	5.54	8.32	Siemens Centaur CP
Troponin T	µg/l	3.260	2.450	4.080	Roche Cobas TroponinT
	µg/l	3.130	2.350	3.910	Roche Cobas Troponin T HS
	µg/l	1.140	0.855	1.430	Roche h232
	µg/l	3.930	2.950	4.910	Radiometer AQT90 Flex

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

CAT. NO. CQ 5052 **LOT NO.** 3836CK
SIZE: 3 x 3 ml **EXPIRY:** 2017-05

INTENDED USE

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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, Dioxin, 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 30 Aug '16 pl

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

Cat. No. CQ5052 Lot No. 3836CK Size: 3 x 3 ml Expiry: 2017-05

Analyte	unit	Target	Range		methods
			low	high	
CK-MB Mass	ng/ml = µg/l	5.16	4.13	6.19	Abbott Architect
	ng/ml = µg/l	6.04	4.83	7.25	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	4.89	3.84	5.94	Siemens Dimension
	ng/ml = µg/l	4.60	3.68	5.52	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	6.96	5.57	8.35	Beckman Coulter Access
	ng/ml = µg/l	5.77	4.62	6.92	Siemens Stratus CS
	ng/ml = µg/l	8.29	6.63	9.95	BioMerieux Vidas
	ng/ml = µg/l	6.84	5.47	8.21	Beckman Dxl800
	ng/ml = µg/l	5.18	4.14	6.22	Roche h232
	ng/ml = µg/l	8.31	6.65	9.97	Radiometer AQT90 Flex
	ng/ml = µg/l	5.07	4.06	6.08	Siemens Dimension Vista LOCI
ng/ml = µg/l	5.77	4.62	6.92	Siemens Centaur CP	
D - Dimer	µg/l FEU	1676	1257	2095	Biomerieux Vidas Exclusion II
	µg/l FEU	8020	6015	10025	Mitsubishi Pathfast D-Dimer
	µg/l	672	504	840	Roche/ Stago STA-R Evolution
	µg/l	1032	774	1290	Roche Cobas h232 D-Dimer
	µg/l	837	628	1046	Roche Integra D-DI 2
	µg/l	1098	824	1373	Alere Biosite Triage D-Dimer
	µg/l	936	702	1170	Abbott Architect Quantia D-Dimer
	µg/l	1269	952	1586	Siemens Stratus CS
	µg/l	429	322	536	Siemens Immulite 2000 D-Dimer
	µg/l	1090	818	1363	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	2256	1692	2820	Siemens Innovance D-Dimer
	µg/l	782	587	978	Roche Cobas D-DI 2
	µg/l FEU	2450	1838	3063	HemosIL D-Dimer HS 500
µg/l	679	509	849	HemosIL D-Dimer	
µg/l	754	566	943	HemosIL D-Dimer HS	
Digoxin	nmol/l	1.77	1.42	2.12	Chemiluminescence
	ng/ml	1.38	1.11	1.65	
	nmol/l	1.46	1.17	1.75	Vitros
	ng/ml	1.14	0.914	1.37	
	nmol/l	1.54	1.23	1.85	Enzyme Immunoassay
	ng/ml	1.20	0.961	1.44	
	nmol/l	1.52	1.22	1.82	Turbidimetric
	ng/ml	1.19	0.953	1.43	
nmol/l	1.43	1.14	1.72	KIMS	
ng/ml	1.12	0.890	1.35		
hsCRP	mg/l	1.79	1.43	2.15	Nephelometric (IFCC Cal.)
	mg/l	1.89	1.51	2.27	Nephelometric (Non IFCC Cal.)
	mg/l	1.95	1.56	2.34	Turbidimetric (IFCC Cal.)
	mg/l	1.94	1.55	2.33	Turbidimetric (Non IFCC Cal.)
	mg/l	1.95	1.56	2.34	Radox Immunoturbidimetric

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

Cat. No. CQ5052 Lot No. 3836CK Size: 3 x 3 ml Expiry: 2017-05

Analyte	unit	Target	Range		methods
			low	high	
Myoglobin	ng/ml = µg/l	98.8	79.0	119	Abbott Architect
	ng/ml = µg/l	80.4	64.3	96.5	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	88.3	70.6	106	Siemens Dimension
	ng/ml = µg/l	63.2	50.6	75.8	Beckman Dxl800
	ng/ml = µg/l	72.8	58.2	87.4	Roche Elecsys
	ng/ml = µg/l	77.3	61.8	92.8	Roche Hitachi
	ng/ml = µg/l	60.8	48.6	73.0	Beckman Coulter Access
	ng/ml = µg/l	50.4	40.3	60.5	Siemens Stratus CS
	ng/ml = µg/l	79.6	63.7	95.5	BioMerieux Vidas
	ng/ml = µg/l	22.9	18.3	27.5	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	142	114	170	Ortho Vitros 3600/5600/ECi
	ng/ml = µg/l	69.5	55.6	83.4	Siemens Dimension Vista LOCI
	ng/ml = µg/l	85.2	68.2	102	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	62.0	46.5	77.5	Siemens Immulite 2000
	pg/ml	525	394	656	
	pmol/l	22.7	17.0	28.4	Siemens Stratus CS
	pg/ml	192	144	240	
	pmol/l	20.8	15.6	26.0	BioMerieux Vidas
	pg/ml	176	132	220	
	pmol/l	18.7	14.0	23.4	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	158	119	197	
	pmol/l	58.0	43.5	72.5	Mitsubishi Chemical Pathfast
	pg/ml	491	369	613	
	pmol/l	34.7	26.0	43.4	Ortho Vitros 3600/5600/ECi
	pg/ml	294	220	368	
	pmol/l	9.60	7.20	12.0	Roche h232
	pg/ml	81.3	61.0	102	
	pmol/l	3.97	2.98	4.96	Siemens Dimension Exl LOCI
pg/ml	33.6	25.2	42.0		
pmol/l	20.2	15.2	25.3	Biomerieux Vidas 2	
pg/ml	171	129	213		
Troponin I	ng/ml = µg/l	0.416	0.333	0.499	Abbott Architect
	ng/ml = µg/l	0.043	0.034	0.052	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	0.010	0.008	0.012	Siemens Dimension
	ng/ml = µg/l	0.030	0.024	0.036	Beckman DXi800 1st gen
	ng/ml = µg/l	0.030	0.024	0.036	Beckman Coulter Access
	ng/ml = µg/l	0.290	0.232	0.348	Tosoh AIA360
	ng/ml = µg/l	0.247	0.198	0.296	Ortho Vitros ECi
	ng/ml = µg/l	0.262	0.210	0.314	BioMerieux Vidas
	ng/ml = µg/l	0.255	0.204	0.306	Biomerieux Vidas Ultra
	ng/ml = µg/l	0.102	0.082	0.122	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	0.032	0.026	0.038	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	0.018	0.014	0.022	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	0.043	0.034	0.052	Abbott Architect STAT hs
	ng/ml = µg/l	0.030	0.024	0.036	Beckman Access - AccuTnl+3
	ng/ml = µg/l	0.038	0.030	0.046	Siemens Centaur CP

RANDOX

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

Cat. No. CQ5052 Lot No. 3836CK Size: 3 x 3 ml Expiry: 2017-05

Range

Analyte	unit	Target	low	high	methods
Troponin T	µg/l	0.021	0.016	0.026	Roche Cobas TroponinT
	µg/l	0.020	0.015	0.025	Roche Cobas Troponin T HS
	µg/l	0.050	0.038	0.063	Roche h232



Urgent Notice de Sécurité

Contrôle Liquide Cardiaque Niveau 2 & Niveau 3

CQ5052 – 3834CK, 3836CK

CQ5053 – 3835CK, 3837CK

GTIN: 05055273207453, 05055273207460

Référence de Plainte: 261

Type d'Action: Modification de matériel

Date: 12 Septembre 2016

Cher client,

Nous observons actuellement la nécessité de réassigner les produits indiqués ci-dessous et nous tenons à vous transmettre cet avis de sécurité pour vous en informer.

Détail des produits affectés:

Liquide Cardiaque Contrôle Niveau 2, Référence Catalogue CQ5052, lots 3834CK & 3836CK

Liquide Cardiaque Contrôle Niveau 3, Référence Catalogue CQ5053, lots 3835CK & 3837CK

Description

Les taux de myoglobine des lots 3834CK, 3835CK, 3836CK et 3837CK ont diminué pour les Randox immunoturbidimétrique et Siemens Centaur.

Les taux de CKMB des lots 3834CK, 3835CK, 3836CK et 3837CK ont diminué pour les automates Roche e411, BioMerieux Vidas et Siemens Centaur classiques.

Nous avons réaffecté les valeurs cibles et les intervalles de confiance

Risque pour la Santé: Les contenus de cette lettre doivent être discutés avec votre Directeur Médical.



Urgent Notice de Sécurité

Action à prendre: Actualiser vos produits avec cette notice importante.

Merci de compléter, signer et retourner **impérativement** la section réponse (page 3/3) à technical.services@randox.com au plus tard dans les cinq jours.

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

Point de Contact:

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.



Urgent Notice de Sécurité

Contrôle Liquide Cardiaque Niveau 2 & Niveau 3

CQ5052 – 3834CK, 3836CK

CQ5053 – 3835CK, 3837CK

GTIN: 05055273207453, 05055273207460

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 Kits Received

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 3 (CRD LIQ CONTROL 3)

CAT. NO. CQ5053 **LOT NO.** 3837CK

SIZE: 3 x 3 ml **EXPIRY:** 2017-05

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 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.

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Revised 10 Aug '16 pl

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

Cat. No. CQ5053 Lot No. 3837CK Size: 3 x 3 ml Expiry: 2017-05

Analyte	unit	Target	Range		methods
			low	high	
CK-MB Mass	ng/ml = µg/l	103	81.0	125	Abbott Architect
	ng/ml = µg/l	104	83.2	125	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	125	100	150	Siemens Dimension
	ng/ml = µg/l	73.9	59.1	88.7	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	138	110	166	Beckman Coulter Access
	ng/ml = µg/l	129	103	155	Siemens Stratus CS
	ng/ml = µg/l	79.9	63.9	95.9	Ortho Vitros ECi
	ng/ml = µg/l	126	101	151	BioMerieux Vidas
	ng/ml = µg/l	143	114	172	Beckman DxI800
	ng/ml = µg/l	36.2	29.0	43.4	Roche h232
	ng/ml = µg/l	152	122	182	Radiometer AQT90 Flex
	ng/ml = µg/l	119	95.2	143	Siemens Dimension Vista LOCI
	ng/ml = µg/l	110	84.7	135	Siemens Centaur CP
D - Dimer	µg/l FEU	3334	2501	4168	Biomerieux Vidas Exclusion II
	µg/l FEU	15488	11616	19360	Mitsubishi Pathfast D-Dimer
	µg/l	1438	1079	1798	Roche/ Stago STA-R Evolution
	µg/l	420	315	525	Nycocard D-Dimer
	µg/l	1997	1498	2496	Roche Cobas h232 D-Dimer
	µg/l	1956	1467	2445	Roche Integra D-DI 2
	µg/l	2134	1601	2668	Alere Biosite Triage D-Dimer
	µg/l	1516	1137	1895	Abbott Architect Quantia D-Dimer
	µg/l	2792	2094	3490	Siemens Stratus CS
	µg/l	1167	875	1459	Siemens Immulite 2000 D-Dimer
	µg/l	2076	1557	2595	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	4906	3680	6133	Siemens Innovance D-Dimer
	µg/l	2119	1589	2649	Roche Cobas D-DI 2
	µg/l FEU	5100	3825	6375	HemosIL D-Dimer HS 500
µg/l	1699	1239	2159	HemosIL D-Dimer HS	
Digoxin	nmol/l	3.57	2.86	4.28	Chemiluminescence
	ng/ml	2.79	2.23	3.35	
	nmol/l	3.03	2.42	3.64	Vitros
	ng/ml	2.37	1.89	2.85	
	nmol/l	3.23	2.58	3.88	Enzyme Immunoassay
	ng/ml	2.52	2.01	3.03	
	nmol/l	3.27	2.62	3.92	Turbidimetric
	ng/ml	2.55	2.05	3.05	
nmol/l	3.03	2.42	3.64	KIMS	
ng/ml	2.37	1.89	2.85		
hsCRP	mg/l	7.29	5.83	8.75	Nephelometric (IFCC Cal.)
	mg/l	7.90	6.32	9.48	Nephelometric (Non IFCC Cal.)
	mg/l	7.06	5.50	8.62	Turbidimetric (IFCC Cal.)
	mg/l	6.77	4.96	8.58	Turbidimetric (Non IFCC Cal.)

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

Cat. No. CQ5053 Lot No. 3837CK Size: 3 x 3 ml Expiry: 2017-05

Analyte	unit	Target	Range		methods
			low	high	
hsCRP	mg/l	7.44	5.95	8.93	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	355	284	426	Abbott Architect
	ng/ml = µg/l	330	264	396	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	300	240	360	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	404	323	485	Siemens Dimension
	ng/ml = µg/l	260	208	312	Beckman Dxl800
	ng/ml = µg/l	262	210	314	Roche Elecsys
	ng/ml = µg/l	267	214	320	Roche Hitachi
	ng/ml = µg/l	306	245	367	Roche Integra
	ng/ml = µg/l	241	193	289	Beckman Coulter Access
	ng/ml = µg/l	215	172	258	Siemens Stratus CS
	ng/ml = µg/l	344	275	413	BioMerieux Vidas
	ng/ml = µg/l	68.9	55.1	82.7	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	586	469	703	Ortho Vitros 3600/5600/ECi
	ng/ml = µg/l	318	254	382	Siemens Dimension Vista LOCI
ng/ml = µg/l	327	262	392	Siemens Centaur CP	
ng/ml = µg/l	246	197	295	Randox Immunoturbidimetric	
NT-ProBNP	pmol/l	352	264	440	Siemens Dimension
	pg/ml	2982	2237	3727	
	pmol/l	1871	1403	2339	Siemens Immulite 2000
	pg/ml	15851	11886	19816	
	pmol/l	493	370	616	Siemens Stratus CS
	pg/ml	4177	3135	5219	
	pmol/l	602	452	753	BioMerieux Vidas
	pg/ml	5100	3829	6371	
	pmol/l	420	315	525	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	3558	2669	4447	
	pmol/l	1650	1238	2063	Mitsubishi Chemical Pathfast
	pg/ml	13979	10488	17470	
	pmol/l	789	592	986	Ortho Vitros 3600/5600/ECi
	pg/ml	6684	5015	8353	
	pmol/l	160	120	200	Roche h232
	pg/ml	1356	1017	1695	
	pmol/l	253	190	316	Siemens Dimension Vista LOCI
	pg/ml	2143	1610	2676	
pmol/l	179	134	224	Siemens Dimension Exl LOCI	
pg/ml	1516	1135	1897		
pmol/l	624	468	780	Biomerieux Vidas 2	
pg/ml	5287	3965	6609		
Troponin I	ng/ml = µg/l	326	261	391	Abbott Architect
	ng/ml = µg/l	63.0	50.4	75.6	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	20.1	16.1	24.1	Siemens Dimension
	ng/ml = µg/l	39.3	31.4	47.2	Beckman DXi800 1st gen
	ng/ml = µg/l	42.9	34.3	51.5	Beckman Coulter Access
	ng/ml = µg/l	25.3	20.2	30.4	Siemens Stratus CS
ng/ml = µg/l	231	185	277	Tosoh AIA360	

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

Cat. No. CQ5053 Lot No. 3837CK Size: 3 x 3 ml Expiry: 2017-05

Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	225	180	270	Ortho Vitros ECI
	ng/ml = µg/l	81.4	65.1	97.7	BioMerieux Vidas
	ng/ml = µg/l	85.9	68.7	103	Biomerieux Vidas Ultra
	ng/ml = µg/l	13.9	11.1	16.7	Roche Elecsys/E170/c6000/e411
	ng/ml = µg/l	52.6	41.6	63.6	Mitsubishi Chemical Pathfast
	ng/ml = µg/l	26.1	20.9	31.3	Siemens/Dade Dimension EXL/Vista
	ng/ml = µg/l	26.1	20.9	31.3	Siemens Dimension Exl LOCI
	ng/ml = µg/l	45.2	36.2	54.2	Abbott Architect STAT hs
	ng/ml = µg/l	42.6	34.1	51.1	Beckman Dxl - AccuTnl+3
	ng/ml = µg/l	43.7	35.0	52.4	Beckman Access - AccuTnl+3
Troponin T	µg/l	50.8	40.6	61.0	Siemens Centaur CP
	µg/l	3.140	2.360	3.930	Roche Cobas TroponinT
	µg/l	3.170	2.360	3.980	Roche Cobas Troponin T HS
	µg/l	1.390	1.040	1.740	Roche h232
	µg/l	3.580	2.690	4.480	Radiometer AQT90 Flex