

Ausstellungsdatum: Donnerstag, 7. März 2019**Betrifft Reklamation:** REC371**Art der Maßnahme:**

Produktmodifikation

Nähere Angaben zu den betroffenen Produkten:

Gemäß unseren Aufzeichnungen hat Ihre Einrichtung möglicherweise das folgende Produkt erhalten.

Produktname	Katalog-Nr.	GTIN	Chargen-Bez.	Ablaufdatum	Herstellungsdatum
Liquid Cardiac Control	CQ5051	05055273207446	4243CK	28 Nov. 2019	5. Feb. 2018
	CQ5052	05055273207453	4244CK		
	CQ5053	05055273207460	4245CK		

Grund für die Maßnahme:

Randox hat eine Veränderung bei der Wiederfindung von NTproBNP in den in obiger Tabelle aufgeführten Chargen von Liquid Cardiac Control auf Siemens Dimension EXL LOCI festgestellt. Kunden können eine geringere wiedergefundene Konzentration im Vergleich zu dem in der Wertetabelle angegebenen Zielwert beobachten. Dies gilt jedoch nur für dieses Analysegerät.

Gefahr für die Gesundheit:

Ergebnisse der Qualitätskontrolle, die außerhalb des Bereichs liegen, können zu einer Verzögerung der Ergebnismeldung führen, jedoch wird NTproBNP in Verbindung mit anderen Ergebnissen und Indikatoren zur Diagnose und Überwachung von Herzinsuffizienz bei Patienten verwendet. Dies sollte daher keine ernsthafte Gefahr für die Gesundheit darstellen.

Zu ergreifende Maßnahmen:

- Überprüfen Sie Ihren Bestand und ziehen Sie alle betroffenen Bestände aus dem Verkehr.
- Ersetzen Sie das Werteblatt im Kit durch das mitgelieferte überarbeitete Werteblatt.
- Randox empfiehlt keine Überprüfung früherer Ergebnisse, da Änderungen der Wiederfindung bei der Qualitätskontrolle zum Zeitpunkt des Auftretens überprüft werden.
- Den Inhalt dieser Benachrichtigung mit Ihrem ärztlichen Direktor besprechen
- Füllen Sie das Antwortformular aus, auch wenn sich das betroffene Produkt nicht mehr in Ihrem Bestand befindet. Senden Sie das Antwortformular innerhalb von fünf Werktagen an technical.services@randox.com.

Weiterleitung der Sicherheitsanweisung im Feld: Senden Sie eine Kopie der Sicherheitsanweisung im Feld an alle betroffenen Kunden und an die Personen in Ihrem Unternehmen, die darüber informiert sein müssen.

Wir möchten uns für die Ihnen entstandenen Unannehmlichkeiten entschuldigen. Vielen Dank für Ihre Geduld und Ihr Verständnis. Wenn Sie Fragen oder Bedenken haben, wenden Sie sich bitte an den Technischen Kundendienst von Radox.

Der Unterzeichner bestätigt, dass die zuständige Regulierungsbehörde über diese Mitteilung informiert wurde.



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Gemäß unseren Aufzeichnungen hat Ihre Einrichtung möglicherweise das folgende Produkt erhalten.

Produktname	Katalog-Nr.	GTIN	Chargen-Bez.	Ablaufdatum	Herstellungsdatum
Liquid Cardiac Control	CQ5051	05055273207446	4243CK	28. Nov. 2019	5. Feb. 2018
	CQ5052	05055273207453	4244CK		
	CQ5053	05055273207460	4245CK		

Bitte ALLE zutreffenden Kästchen ankreuzen.

- Ich habe die Rückrufanweisungen in der Sicherheitsanweisung im Feld gelesen und verstanden.
- Ich habe meinen Bestand überprüft und die betroffenen Kits unter Quarantäne gestellt.
- Ich habe alle Personen im Unternehmen informiert, die von dieser Sicherheitsanweisung Kenntnis haben müssen.

Bitte Angaben zum Verbleib des zurückgerufenen Produkts machen:

- keine betroffenen Bestände
- Zurückgesendet (*Stückzahl, Datum und Versandart angeben*)/wird zur Rücksendung bereitgehalten
- Werteblatt ersetzt (*Stückzahl und Datum angeben*);
- Bis zur Fehlerbereinigung in Quarantäne genommen (*Stückzahl angeben*);

Angaben zum Kunden

Name des Unternehmens	
Adresse	

Gesamtstückzahl

Empfangen	
Vertrieben	

Vertriebsbereich (durch Distributoren und die Büros von Randox auszufüllen)

- Ich habe die Kunden, an die dieses Produkt versandt wurde oder möglicherweise versandt wurde, ausfindig gemacht und per (*Benachrichtigungsdatum und -methode angeben*) informiert. **ODER**
- Nachfolgend finden Sie eine Liste der Kunden, die dieses Produkt erhalten haben bzw. möglicherweise erhalten haben. Bitte benachrichtigen Sie meine Kunden. (Die Kundenliste kann auch in einem separaten Anhang versandt werden.)

Wurden Sie über unerwünschte Ereignisse im Zusammenhang mit dem zurückgerufenen Produkt informiert?

- JA
- NEIN

Wenn ja, bitte erläutern: _____

Empfänger	Land	Stückzahl Empfangen	Analysator/Kit Serien- /Chargennummer	Austausch erforderlich

Ausgeführt durch	Name in Druckbuchstaben:	Datum	
	Unterschrift:		
Kontakttelefonnummer			
Kontakt-E-Mail-Adresse			

Bitte füllen Sie das Antwortformular aus und senden Sie es innerhalb von fünf Werktagen an technical.services@randox.com.

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

CAT. NO. CQ5051

LOT NO. 4243CK

SIZE: 3 x 3 ml

EXPIRY: 2019-11-28

GTIN: 05055273207446

INTENDED USE

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

DEVICE DESCRIPTION

The Cardiac Controls are supplied at 3 levels, 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS

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

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

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

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

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

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°C, if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

PREPARATION FOR USE

The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED

Liquid Cardiac Control - Level 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.

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

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

Analyte	unit	Target	Range		methods
			low	high	
CK-MB Mass	ng/ml = µg/l	2.60	1.82	3.38	Abbott Architect
	ng/ml = µg/l	4.27	2.99	5.55	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	2.56	1.79	3.33	Siemens Dimension
	ng/ml = µg/l	2.80	1.96	3.64	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	3.78	2.65	4.91	Beckman Coulter Access
	ng/ml = µg/l	2.86	2.00	3.72	Siemens Stratus CS
	ng/ml = µg/l	4.53	3.17	5.89	BioMerieux Vidas
	ng/ml = µg/l	3.81	2.67	4.95	Beckman Dxl800
	ng/ml = µg/l	2.81	1.97	3.65	Roche h232
	ng/ml = µg/l	4.73	3.31	6.15	Radiometer AQT90 Flex
D-Dimer	µg/l FEU	944	708	1180	Biomerieux Vidas Exclusion II
	µg/l FEU	3018	2264	3773	Mitsubishi Pathfast D-Dimer
	µg/l	391	293	489	Roche/ Stago STA-R Evolution
	µg/l	538	404	673	Roche Cobas h232 D-Dimer
	µg/l	263	197	329	Roche Integra D-DI 2
	µg/l	611	458	764	Alere Biosite Triage D-Dimer
	µg/l	532	399	665	Abbott Architect Quantia D-Dimer
	µg/l	578	434	723	Siemens Stratus CS
	µg/l	574	431	718	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1294	971	1618	Siemens Innovance D-Dimer
	µg/l	157	118	196	Roche Cobas D-DI 2
	µg/l FEU	1540	1155	1925	HemosIL D-Dimer HS 500
	µg/l	453	340	566	HemosIL D-Dimer
	µg/l	520	390	650	HemosIL D-Dimer HS
Digoxin	nmol/l	0.986	0.789	1.18	Chemiluminescence
	ng/ml	0.770	0.616	0.924	
	nmol/l	0.884	0.707	1.06	Enzyme Immunoassay
	ng/ml	0.690	0.552	0.828	
	nmol/l	0.844	0.675	1.01	Turbidimetric
	ng/ml	0.659	0.527	0.791	
	nmol/l	0.807	0.646	0.968	KIMS
	ng/ml	0.630	0.505	0.755	
hsCRP	nmol/l	0.880	0.704	1.06	Enzyme Linked Fluorescent assay
	ng/ml	0.687	0.550	0.824	
	mg/l	0.760	0.608	0.912	Nephelometric (IFCC Cal.)
	mg/l	0.788	0.630	0.946	Nephelometric (Non IFCC Cal.)
	mg/l	0.868	0.694	1.04	Turbidimetric (IFCC Cal.)
	mg/l	0.876	0.701	1.05	Turbidimetric (Non IFCC Cal.)
Myoglobin	mg/l	0.885	0.708	1.06	Chemiluminescence (IFCC Cal.)
	mg/l	0.831	0.660	1.00	Randox Immunoturbidimetric
	ng/ml = µg/l	66.1	46.3	85.9	Abbott Architect
	ng/ml = µg/l	48.3	33.8	62.8	Siemens/Dade Behring Nephelometer

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

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

Range					
Analyte	unit	Target	low	high	methods
Myoglobin	ng/ml = µg/l	50.9	35.6	66.2	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	50.2	35.1	65.3	Siemens Dimension
	ng/ml = µg/l	37.6	26.3	48.9	Beckman Dxl800
	ng/ml = µg/l	45.7	32.0	59.4	Roche Elecsys
	ng/ml = µg/l	52.7	36.9	68.5	Roche Hitachi
	ng/ml = µg/l	37.7	26.4	49.0	Beckman Coulter Access
	ng/ml = µg/l	28.4	19.9	36.9	Siemens Stratus CS
	ng/ml = µg/l	35.0	24.5	45.5	BioMerieux Vidas
	ng/ml = µg/l	45.1	31.6	58.6	Siemens Dimension Vista LOCI
	ng/ml = µg/l	47.3	33.1	61.5	Siemens Centaur CP
	ng/ml = µg/l	67.6	47.3	87.9	Randox Immunoturbidimetric
NT-ProBNP	pmol/l	42.1	31.6	52.6	Siemens Immulite 2000
	pg/ml	357	268	446	
	pmol/l	12.6	9.45	15.8	Siemens Stratus CS
	pg/ml	107	80.1	134	
	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	39.8	29.9	49.8	Mitsubishi Chemical Pathfast
	pg/ml	337	253	421	
	pmol/l	7.83	5.87	9.79	Roche h232
	pg/ml	66.3	49.7	82.9	
	pmol/l	5.19	3.89	6.49	Siemens Dimension Vista LOCI
	pg/ml	44.0	33.0	55.0	
	pmol/l	1.68	1.26	2.10	Siemens Dimension Exl LOCI
	pg/ml	14.2	10.7	17.7	
pmol/l	11.0	8.25	13.8	Biomerieux Vidas 2	
pg/ml	93.2	69.9	117		
pmol/l	8.28	6.21	10.4	Siemens Centaur CP	
pg/ml	70.1	52.6	87.6		
Troponin I	ng/ml = µg/l	0.036	0.028	0.043	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	35.6	28.0	43.2	
	ng/ml = µg/l	0.022	0.018	0.026	Beckman Coulter Access
	ng/l = pg/ml	21.9	18.0	25.8	
	ng/ml = µg/l	0.024	0.019	0.028	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	23.5	19.0	28.0	
	ng/ml = µg/l	0.042	0.033	0.050	Abbott Architect STAT hs
	ng/l = pg/ml	41.8	33.0	50.6	
	ng/ml = µg/l	0.030	0.024	0.036	Siemens Centaur CP
	ng/l = pg/ml	29.9	24.0	35.8	
	ng/ml = µg/l	0.229	0.183	0.275	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	229	183	275	
ng/ml = µg/l	0.023	0.020	0.030	Beckman Dxl - AccuTnl+3	
ng/l = pg/ml	22.9	20.0	30.0		
ng/ml = µg/l	0.023	0.020	0.030	Beckman Access - AccuTnl+3	
ng/l = pg/ml	22.5	20.0	30.0		



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

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

Analyte	unit	Target	Range		methods
			low	high	
Troponin I	ng/ml = µg/l	0.301	0.240	0.360	Ortho Vitros 3600/5600/ECi
	ng/l = pg/ml	301	240	360	
	ng/ml = µg/l	0.048	0.038	0.057	Siemens Dimension EXL high sensitivity Troponin I
	ng/l = pg/ml	47.5	38.0	57.0	
ng/ml = µg/l	0.054	0.040	0.060	Siemens Dimension Vista high sensitivity Troponin I	
ng/l = pg/ml	54.0	40.0	60.0		

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

CAT NO. CQ5052

LOT NO. 4244CK

SIZE: 3 x 3 ml

EXPIRY: 2019-11-28

GTIN: 05055273207453

INTENDED USE

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

DEVICE DESCRIPTION

The Cardiac Controls are supplied at 3 levels, 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS

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

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

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

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

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

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°C, if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

PREPARATION FOR USE

The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED

Liquid Cardiac Control - Level 2 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Not applicable.

ASSIGNED VALUES

Each batch of Cardiac Control is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories and internal testing conducted at Randox Laboratories Ltd. The expected range of the mean is provided to aid laboratory, until it has established its own mean and SD for its methods.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

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LIQUID CARDIAC CONTROL LEVEL 2 (CRD LIQ CONTROL 2)

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

Analyte	unit	Target	Range		methods
			low	high	
CK-MB Mass	ng/ml = µg/l	13.6	9.52	17.7	Abbott Architect
	ng/ml = µg/l	19.0	13.3	24.7	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	14.9	10.4	19.4	Siemens Dimension
	ng/ml = µg/l	13.1	9.17	17.0	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	19.5	13.7	25.4	Beckman Coulter Access
	ng/ml = µg/l	14.1	9.87	18.3	Siemens Stratus CS
	ng/ml = µg/l	19.9	13.9	25.9	BioMerieux Vidas
	ng/ml = µg/l	19.5	13.7	25.4	Beckman Dxl800
	ng/ml = µg/l	12.1	8.47	15.7	Roche h232
	ng/ml = µg/l	25.3	17.7	32.9	Radiometer AQT90 Flex
	ng/ml = µg/l	14.7	10.3	19.1	Siemens Dimension Vista LOCI
ng/ml = µg/l	16.1	11.3	20.9	Siemens Centaur CP	
D - Dimer	µg/l FEU	1154	866	1443	Biomerieux Vidas Exclusion II
	µg/l FEU	4298	3224	5373	Mitsubishi Pathfast D-Dimer
	µg/l	479	359	599	Roche/ Stago STA-R Evolution
	µg/l	681	511	851	Roche Cobas h232 D-Dimer
	µg/l	399	299	499	Roche Integra D-DI 2
	µg/l	835	626	1044	Alere Biosite Triage D-Dimer
	µg/l	618	464	773	Abbott Architect Quantia D-Dimer
	µg/l	854	641	1068	Siemens Stratus CS
	µg/l	238	179	298	Siemens Immulite 2000 D-Dimer
	µg/l	717	538	896	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	1634	1226	2043	Siemens Innovance D-Dimer
	µg/l	301	226	376	Roche Cobas D-DI 2
	µg/l FEU	1886	1415	2358	HemosIL D-Dimer 500
	µg/l FEU	1884	1413	2355	HemosIL D-Dimer HS 500
µg/l	543	407	679	HemosIL D-Dimer	
Digoxin	nmol/l	2.13	1.70	2.56	Chemiluminescence
	ng/ml	1.66	1.33	1.99	
	nmol/l	2.03	1.62	2.44	Enzyme Immunoassay
	ng/ml	1.59	1.27	1.91	
	nmol/l	2.20	1.76	2.64	Turbidimetric
	ng/ml	1.72	1.37	2.07	
	nmol/l	2.10	1.68	2.52	KIMS
	ng/ml	1.64	1.31	1.97	
nmol/l	2.13	1.70	2.56	Enzyme Linked Fluorescent assay	
ng/ml	1.66	1.33	1.99		
hsCRP	mg/l	2.80	2.24	3.36	Nephelometric (IFCC Cal.)
	mg/l	2.84	2.27	3.41	Nephelometric (Non IFCC Cal.)
	mg/l	2.93	2.34	3.52	Turbidimetric (IFCC Cal.)
	mg/l	2.99	2.39	3.59	Turbidimetric (Non IFCC Cal.)
	mg/l	3.35	2.68	4.02	Chemiluminescence (IFCC Cal.)

LIQUID CARDIAC CONTROL LEVEL 2 (CRD LIQ CONTROL 2)

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

Range					
Analyte	unit	Target	low	high	methods
hsCRP	mg/l	2.81	2.25	3.37	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	171	120	222	Abbott Architect
	ng/ml = µg/l	129	90.3	168	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	140	98.0	182	Siemens Dimension
	ng/ml = µg/l	92.0	64.4	120	Beckman Dxl800
	ng/ml = µg/l	115	80.5	150	Roche Elecsys
	ng/ml = µg/l	106	74.2	138	Roche Hitachi
	ng/ml = µg/l	89.4	62.6	116	Beckman Coulter Access
	ng/ml = µg/l	94.4	66.1	123	Siemens Stratus CS
	ng/ml = µg/l	85.0	59.5	111	BioMerieux Vidas
	ng/ml = µg/l	121	84.7	157	Siemens Dimension Vista LOCI
	ng/ml = µg/l	130	91.0	169	Siemens Centaur CP
ng/ml = µg/l	163	114	212	Randox Immunoturbidimetric	
NT-ProBNP	pmol/l	256	192	320	Siemens Immulite 2000
	pg/ml	2169	1627	2711	
	pmol/l	82.4	61.8	103	Siemens Stratus CS
	pg/ml	698	524	872	
	pmol/l	85.5	64.1	107	BioMerieux Vidas
	pg/ml	724	543	905	
	pmol/l	52.6	39.5	65.8	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	446	335	557	
	pmol/l	207	155	259	Mitsubishi Chemical Pathfast
	pg/ml	1754	1313	2195	
	pmol/l	45.3	34.0	56.6	Roche h232
	pg/ml	384	288	480	
	pmol/l	29.9	22.4	37.4	Siemens Dimension Vista LOCI
	pg/ml	253	190	316	
	pmol/l	9.29	6.97	11.6	Siemens Dimension Exl LOCI
pg/ml	78.7	59.0	98.4		
pmol/l	84.8	63.6	106	Biomerieux Vidas 2	
pg/ml	718	539	897		
Troponin I	ng/ml = µg/l	1.15	0.920	1.38	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	1150	920	1380	
	ng/ml = µg/l	0.284	0.227	0.341	Siemens Dimension
	ng/l = pg/ml	284	227	341	
	ng/ml = µg/l	0.394	0.315	0.473	Beckman DXi800 1st gen
	ng/l = pg/ml	394	315	473	
	ng/ml = µg/l	0.407	0.326	0.488	Beckman Coulter Access
	ng/l = pg/ml	407	326	488	
	ng/ml = µg/l	0.376	0.301	0.451	Siemens Stratus CS
	ng/l = pg/ml	376	301	451	
	ng/ml = µg/l	0.231	0.185	0.277	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	231	185	277	
	ng/ml = µg/l	1.06	0.848	1.27	Mitsubishi Chemical Pathfast
ng/l = pg/ml	1060	848	1272		
ng/ml = µg/l	0.333	0.266	0.400	Siemens/Dade Dimension EXL/Vista	
ng/l = pg/ml	333	266	400		

LIQUID CARDIAC CONTROL LEVEL 2 (CRD LIQ CONTROL 2)

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

Range					
Analyte	unit	Target	low	high	methods
Troponin I	ng/ml = µg/l	0.347	0.278	0.416	Siemens Dimension Exl LOCI
	ng/l = pg/ml	347	278	416	
	ng/ml = µg/l	0.670	0.536	0.804	Abbott Architect STAT hs
	ng/l = pg/ml	670	536	804	
	ng/ml = µg/l	0.363	0.290	0.436	Beckman Dxl - AccuTnl+3
	ng/l = pg/ml	363	290	436	
	ng/ml = µg/l	0.386	0.309	0.463	Beckman Access - AccuTnl+3
	ng/l = pg/ml	386	309	463	
	ng/ml = µg/l	0.925	0.740	1.11	Siemens Centaur CP
	ng/l = pg/ml	925	740	1110	
	ng/ml = µg/l	7.52	6.02	9.02	bioMerieux VIDAS hs Troponin I
	ng/l = pg/ml	7520	6020	9020	

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

CAT. NO. CQ5053

LOT NO. 4245CK

SIZE: 3 x 3 ml

EXPIRY: 2019-11-28

GTIN: 05055273207460

INTENDED USE

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

DEVICE DESCRIPTION

The Cardiac Controls are supplied at 3 levels, 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the table below.

SAFETY PRECAUTIONS AND WARNINGS

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

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

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

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

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

OPENED: Store refrigerated (+2°C to +8°C). Liquid Cardiac Controls are stable for 30 days at +2°C to +8°C, if kept capped in original container and free from contamination. Only the required amount of product should be removed. After use, any residual product should NOT BE RETURNED to the original vial.

PREPARATION FOR USE

The Liquid Cardiac Controls are supplied ready to use.

MATERIALS PROVIDED

Liquid Cardiac Control - Level 3 3 x 3 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Not applicable.

ASSIGNED VALUES

Each batch of Cardiac Control is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories and internal testing conducted at Randox Laboratories Ltd. The expected range of the mean is provided to aid laboratory, until it has established its own mean and SD for its methods.

If a method is unavailable, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

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

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

Analyte	unit	Target	Range		methods
			low	high	
CK-MB Mass	ng/ml = µg/l	85.1	59.6	111	Abbott Architect
	ng/ml = µg/l	112	78.4	146	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	120	84.0	156	Siemens Dimension
	ng/ml = µg/l	73.4	51.4	95.4	Roche Elecsys Modular E170 Cobas 6000/e411
	ng/ml = µg/l	124	86.8	161	Beckman Coulter Access
	ng/ml = µg/l	108	75.6	140	Siemens Stratus CS
	ng/ml = µg/l	122	85.4	159	BioMerieux Vidas
	ng/ml = µg/l	124	86.8	161	Beckman Dxl800
	ng/ml = µg/l	49.6	34.7	64.5	Biosite Triage Meter Plus
	ng/ml = µg/l	34.8	24.4	45.2	Roche h232
	ng/ml = µg/l	147	103	191	Radiometer AQT90 Flex
	ng/ml = µg/l	112	78.4	146	Siemens Dimension Vista LOCI
	ng/ml = µg/l	97.5	68.3	127	Siemens Centaur CP
D-Dimer	µg/l FEU	2444	1833	3055	Biomerieux Vidas Exclusion II
	µg/l FEU	10946	8210	13682	Mitsubishi Pathfast D-Dimer
	µg/l	1043	782	1304	Roche/ Stago STA-R Evolution
	µg/l	1539	1154	1924	Roche Cobas h232 D-Dimer
	µg/l	1204	903	1505	Roche Integra D-DI 2
	µg/l	1777	1333	2221	Alere Biosite Triage D-Dimer
	µg/l	1194	896	1493	Abbott Architect Quantia D-Dimer
	µg/l	2119	1589	2649	Siemens Stratus CS
	µg/l	944	708	1180	Siemens Immulite 2000 D-Dimer
	µg/l	1426	1070	1783	Radiometer AQT90 Flex D-Dimer
	µg/l FEU	3836	2877	4795	Siemens Innovance D-Dimer
	µg/l	1302	977	1628	Roche Cobas D-DI 2
	µg/l FEU	3610	2708	4513	HemosIL D-Dimer 500
	µg/l FEU	3890	2918	4863	HemosIL D-Dimer HS 500
µg/l	1159	869	1449	HemosIL D-Dimer HS	
Digoxin	nmol/l	3.48	2.78	4.18	Chemiluminescence
	ng/ml	2.72	2.17	3.27	
	nmol/l	3.41	2.73	4.09	Enzyme Immunoassay
	ng/ml	2.66	2.13	3.19	
	nmol/l	3.61	2.89	4.33	Turbidimetric
	ng/ml	2.82	2.26	3.38	
	nmol/l	3.41	2.73	4.09	KIMS
	ng/ml	2.66	2.13	3.19	
	nmol/l	3.62	2.90	4.34	Enzyme Linked Fluorescent assay
ng/ml	2.83	2.26	3.40		
hsCRP	mg/l	7.45	5.96	8.94	Nephelometric (IFCC Cal.)
	mg/l	7.49	5.99	8.99	Nephelometric (Non IFCC Cal.)
	mg/l	7.48	5.98	8.98	Turbidimetric (IFCC Cal.)
	mg/l	7.61	6.09	9.13	Turbidimetric (Non IFCC Cal.)

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

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

Range					
Analyte	unit	Target	low	high	methods
hsCRP	mg/l	8.37	6.70	10.0	Chemiluminescence (IFCC Cal.)
	mg/l	6.98	5.58	8.38	Randox Immunoturbidimetric
Myoglobin	ng/ml = µg/l	388	272	504	Abbott Architect
	ng/ml = µg/l	323	226	420	Siemens/Dade Behring Nephelometer
	ng/ml = µg/l	346	242	450	Siemens Centaur XP/XPT/Classic
	ng/ml = µg/l	377	264	490	Siemens Dimension
	ng/ml = µg/l	240	168	312	Beckman Dxl800
	ng/ml = µg/l	274	192	356	Roche Elecsys
	ng/ml = µg/l	270	189	351	Roche Hitachi
	ng/ml = µg/l	232	162	302	Beckman Coulter Access
	ng/ml = µg/l	215	151	280	Siemens Stratus CS
	ng/ml = µg/l	251	176	326	BioMerieux Vidas
	ng/ml = µg/l	331	232	430	Biosite Triage Meter Plus
	ng/ml = µg/l	324	227	421	Siemens Dimension Vista LOCI
	ng/ml = µg/l	357	250	464	Siemens Centaur CP
ng/ml = µg/l	421	295	547	Randox Immunoturbidimetric	
NT-ProBNP	pmol/l	521	391	651	Siemens Centaur XP/XPT/Classic
	pg/ml	4414	3313	5515	
	pmol/l	2464	1848	3080	Siemens Immulite 2000
	pg/ml	20875	15656	26094	
	pmol/l	643	482	804	Siemens Stratus CS
	pg/ml	5447	4084	6810	
	pmol/l	836	627	1045	BioMerieux Vidas
	pg/ml	7083	5312	8854	
	pmol/l	518	389	648	Roche Elecsys Modular E170 Cobas 6000/e411
	pg/ml	4388	3296	5480	
	pmol/l	1930	1448	2413	Mitsubishi Chemical Pathfast
	pg/ml	16351	12267	20435	
	pmol/l	889	667	1111	Ortho Vitros 3600/5600/ECi
	pg/ml	7532	5651	9413	
	pmol/l	322	242	403	Roche h232
	pg/ml	2728	2050	3406	
	pmol/l	321	241	401	Siemens Dimension Vista LOCI
	pg/ml	2720	2042	3398	
pmol/l	190	143	237	Siemens Dimension Exl LOCI	
pg/ml	1609	1207	2011		
pmol/l	852	639	1065	Biomerieux Vidas 2	
pg/ml	7218	5414	9022		
Troponin I	ng/ml = µg/l	6.79	5.43	8.15	Siemens Centaur XP/XPT/Classic
	ng/l = pg/ml	6790	5430	8150	
	ng/ml = µg/l	1.41	1.13	1.69	Siemens Dimension
	ng/l = pg/ml	1410	1130	1690	
	ng/ml = µg/l	1.93	1.54	2.32	Beckman DXi800 1st gen
	ng/l = pg/ml	1930	1540	2320	
ng/ml = µg/l	1.77	1.42	2.12	Beckman Coulter Access	
ng/l = pg/ml	1770	1420	2120		

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

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

Analyte	unit	Target	Range		methods
			low	high	
Troponin I	ng/ml = µg/l	1.77	1.42	2.12	Siemens Stratus CS
	ng/l = pg/ml	1770	1420	2120	
	ng/ml = µg/l	31.3	25.0	37.6	Ortho Vitros ECI
	ng/l = pg/ml	31300	25000	37600	
	ng/ml = µg/l	15.7	12.6	18.8	Biomerieux Vidas Ultra
	ng/l = pg/ml	15700	12600	18800	
	ng/ml = µg/l	0.773	0.618	0.928	Roche Elecsys/E170/c6000/e411
	ng/l = pg/ml	773	618	928	
	ng/ml = µg/l	6.30	5.04	7.56	Mitsubishi Chemical Pathfast
	ng/l = pg/ml	6300	5040	7560	
	ng/ml = µg/l	1.66	1.33	1.99	Siemens/Dade Dimension EXL/Vista
	ng/l = pg/ml	1660	1330	1990	
	ng/ml = µg/l	1.69	1.35	2.03	Siemens Dimension Exl LOCI
	ng/l = pg/ml	1690	1350	2030	
	ng/ml = µg/l	2.73	2.18	3.28	Abbott Architect STAT hs
	ng/l = pg/ml	2730	2180	3280	
	ng/ml = µg/l	1.82	1.46	2.18	Beckman Dxl - AccuTnl+3
	ng/l = pg/ml	1820	1460	2180	
ng/ml = µg/l	1.81	1.45	2.17	Beckman Access - AccuTnl+3	
ng/l = pg/ml	1810	1450	2170		
ng/ml = µg/l	5.86	4.69	7.03	Siemens Centaur CP	
ng/l = pg/ml	5860	4690	7030		