

# MAS<sup>®</sup> CardioImmune<sup>®</sup> - XL

## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

### INTENDED USE

**MAS<sup>®</sup> CardioImmune<sup>®</sup> - XL** is intended for use in the clinical laboratory as an assayed control serum for monitoring assay conditions in specific cardiac marker determinations.

### PRODUCT DESCRIPTION

**CardioImmune - XL** is a liquid stable control material prepared from human serum. Analyte levels are adjusted with various pure chemicals and preparations from recombinant proteins, human tissue or body fluids. Preservatives and stabilizers are added to maintain product integrity.

**CAUTION: CardioImmune - XL** is prepared from human source material. Components of the control which are derived from human source material have been tested using FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), Hepatitis C (HCV), HIV-1 and HIV-2. However, no test method can offer complete assurance that products derived from human source material are free of infectious agents. This control must be handled in accordance with recommendations from Centers for Disease Control/National Institutes of Health manual, "Biosafety in Microbiological and Biomedical Laboratories", 2009. The packaging of this product contains dry natural rubber.

**DANGER: CardioImmune - XL** control contains ≤20.1% porcine gel, ≤5.0% human serum albumin (HSA), and ≤0.02% Proclin 300.

H317 - May cause allergic skin reaction.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H412 - Harmful to aquatic life with long lasting effects.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. Avoid release to the environment. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

### STORAGE AND STABILITY

Once opened, vials of **CardioImmune - XL** are stable for 15 days when stored tightly capped at 2-8°C, except for Digitoxin, Homocysteine, hsCRP and Troponin I, which are stable for 30 days at 2-8°C. Myoglobin 15-day open vial stability is based on the use of dropper tips; open vial stability without dropper tips is 5 days. **CardioImmune-XL** maintained at -25 to -15°C by the manufacturer is stable until the expiration on the box. **SELF-DEFROSTING FREEZERS ARE NOT SUITABLE.**

Bacterial contamination produces an increase in turbidity and/or a characteristic odor. Discard vial if evidence of microbial contamination is observed.

### CONTROL RANGES

The published control ranges are based upon a combination of replicate assays of representative samples by participating laboratories, instrument/reagent manufacturers and direct correlation with other analytical systems in accordance with established protocol. Instrument values provided are specific to this lot of control only and are intended to assist the laboratory in establishing its own means and ranges. All values have been assigned with instruments and reagents available at the time of assay and expected values may vary with different reagents and/or methodologies. Laboratory established means should fall within the assigned ranges although subsequent instrument, reagent or calibration modifications may invalidate assigned values.

Peer comparison data and latest QC lot specific updates are available online through LabLink<sup>®</sup> xL Quality Assurance Program at [www.maslablink.com](http://www.maslablink.com). Refer to the Technical Assistance section for contact information.

### INSTRUCTIONS FOR USE

Thaw control at room temperature (18-25°C) on a rocker or with periodic gentle inversion until liquid and then immediately store at 2-8°C. Thoroughly mix the contents of the vial before each use by gently inverting for several minutes. Open the vial and transfer the required quantity of control into a clean sample cup. Replace cap immediately and store the opened vial at 2-8°C. Assay controls in accordance with the reagent manufacturer's instructions for unknown specimens.

### ONCE THAWED, DO NOT REFREEZE THE CONTROL.

Dropper tips are available to help minimize exposure of control samples to air. DO NOT use a syringe needle to withdraw sample through the control bottle cap.

### QUALITY CONTROL

All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

### LIMITATIONS OF PROCEDURE

Compatibility of **CardioImmune - XL** has been demonstrated only with methods shown in this insert. Caution should be employed when using these controls with methods for which values have not been printed.

If any constituent recovery falls below published ranges, contact MAS Technical Assistance for current peer group data. Peer comparison data and latest QC lot specific updates are available online through LabLink<sup>®</sup> xL Quality Assurance Program at [www.maslablink.com](http://www.maslablink.com).

Accurate and reproducible results are dependent upon properly functioning instruments, reagents, and good laboratory technique. This product is intended for use as an assayed control for quantitative assays of listed constituents in human serum. This product is not intended for use as a calibrator. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. For professional use only.

### TECHNICAL ASSISTANCE

**In the USA**, for technical assistance, call 800-232-3342 or 510-979-5417. For insert updates and information, if your laboratory subscribes to LabLink xL, visit [www.maslablink.com](http://www.maslablink.com) and select LabLink Extra. Alternatively, to subscribe to LabLink xL call 800-232-3342 or 510-979-5451.

**Outside of the USA**, if your laboratory subscribes to LabLink xL, visit [www.maslablink.com](http://www.maslablink.com) select LabLink Extra. Alternatively, please contact your local sales office or authorized distributor.

Cat. No.	Description	Size
CAI-XLL	MAS <sup>®</sup> CardioImmune <sup>®</sup> - XL, Level L	6 x 3 mL
CAI-XL1	MAS <sup>®</sup> CardioImmune <sup>®</sup> - XL, Level 1	6 x 3 mL
CAI-XL2	MAS <sup>®</sup> CardioImmune <sup>®</sup> - XL, Level 2	6 x 3 mL
CAI-XL3	MAS <sup>®</sup> CardioImmune <sup>®</sup> - XL, Level 3	6 x 3 mL
CAI-XL4	MAS <sup>®</sup> CardioImmune <sup>®</sup> - XL, Multi-Pack	6 x 3 mL
286-606	Dropper Tips	Pkg. 100

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## LIQUID ASSAYED CARDIAC MARKER CONTROL

IVD

U	CON										U
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A				
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>			
<b>ABBOTT AEROSSET / ARCHITECT SYSTEMS</b>											
B-Type Natriuretic Peptide (BNP)											
CMIA (Routine) (8K28)	N/A		**		**		**				pg/mL
B-Type Natriuretic Peptide (BNP)											
CMIA (STAT) (8K28)	N/A		51.1	40.8 - 61.3	447	357 - 536	1558	1246 - 1870			pg/mL
C-Reactive Protein (CRP)											
Immunoturbidimetric (CRP32) (6K26)	0.040	<0.020 - 0.061	0.16	0.09 - 0.22	0.42	0.34 - 0.50	0.97	0.78 - 1.16			mg/dL
C-Reactive Protein, High Sensitivity (hsCRP)											
Immunoturbidimetric (CRP16) (6K26)	0.042	0.025 - 0.059	0.15	0.09 - 0.21	0.43	0.34 - 0.52	1.01	0.81 - 1.21			mg/dL
Creatine Kinase-MB (CK-MB)											
CMIA (STAT) (2K42)	2.84	2.18 - 3.50	6.83	5.46 - 8.20	27.2	21.7 - 32.7	74.1	59.3 - 88.9			ng/mL
Creatine Kinase-MB (CK-MB)											
Immunoinhibition (6K25)	<3.00		6.68	<3.00 - 10.4	32.9	26.0 - 39.7	94.6	75.7 - 114			U/L
Digitoxin											
CEDIA	N/A		**		**		**				ng/mL
Digitoxin											
Latex Particle Immunoturbidimetric (6K40)	N/A		17.5	14.0 - 21.0	31.4	24.9 - 38.0	63.6	50.9 - 76.4			ng/mL
Homocysteine											
CMIA (1L71)	N/A		6.04	4.83 - 7.25	11.4	9.14 - 13.7	23.9	19.1 - 28.6			µmol/L
Myoglobin											
CMIA (STAT) (2K43)	20.0	16.0 - 24.0	36.4	29.1 - 43.7	147	118 - 177	363	290 - 435			ng/mL
Myoglobin											
Latex Particle Immunoturbidimetric (6L32)	14.4	<13.0 - 17.3	27.4	21.9 - 32.9	138	111 - 166	357	286 - 429			ng/mL
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>											
CMIA (Alera) (2R10)	97.2	77.8 - 117	369	281 - 457	1854	1483 - 2224	8943	7154 - 10731			pg/mL
Troponin I											
CMIA (STAT) (2K41)	0.044	0.026 - 0.062	0.32	0.19 - 0.45	1.11	0.89 - 1.33	15.8	12.6 - 18.9			ng/mL
Troponin I, High Sensitivity (hsTnI)											
CMIA (STAT) (3P25)	19.8	11.9 - 27.7	163	97.7 - 228	587	441 - 733	12047	9638 - 14456			pg/mL

U	SI										U
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A				
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>			
<b>ABBOTT AEROSSET / ARCHITECT SYSTEMS</b>											
B-Type Natriuretic Peptide (BNP)											
CMIA (Routine) (8K28)	N/A		**		**		**				pmol/L
B-Type Natriuretic Peptide (BNP)											
CMIA (STAT) (8K28)	N/A		14.7	11.8 - 17.7	129	103 - 155	450	360 - 540			pmol/L
C-Reactive Protein (CRP)											
Immunoturbidimetric (CRP32) (6K26)	0.40	<0.20 - 0.61	1.55	0.93 - 2.17	4.20	3.40 - 5.00	9.70	7.80 - 11.6			mg/L
C-Reactive Protein, High Sensitivity (hsCRP)											
Immunoturbidimetric (CRP16) (6K26)	0.42	0.25 - 0.59	1.52	0.91 - 2.13	4.30	3.40 - 5.20	10.1	8.10 - 12.1			mg/L
Creatine Kinase-MB (CK-MB)											
CMIA (STAT) (2K42)	2.84	2.18 - 3.50	6.83	5.46 - 8.20	27.2	21.7 - 32.7	74.1	59.3 - 88.9			µg/L
Creatine Kinase-MB (CK-MB)											
Immunoinhibition (6K25)	<0.05		0.11	<0.05 - 0.17	0.55	0.43 - 0.66	1.58	1.26 - 1.90			µkat/L
Digitoxin											
CEDIA	N/A		**		**		**				nmol/L
Digitoxin											
Latex Particle Immunoturbidimetric (6K40)	N/A		22.9	18.3 - 27.5	41.2	32.6 - 49.7	83.4	66.7 - 100			nmol/L
Homocysteine											
CMIA (1L71)	N/A		6.04	4.83 - 7.25	11.4	9.14 - 13.7	23.9	19.1 - 28.6			µmol/L
Myoglobin											
CMIA (STAT) (2K43)	20.0	16.0 - 24.0	36.4	29.1 - 43.7	147	118 - 177	363	290 - 435			µg/L
Myoglobin											
Latex Particle Immunoturbidimetric (6L32)	14.4	<13.0 - 17.3	27.4	21.9 - 32.9	138	111 - 166	357	286 - 429			µg/L
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>											
CMIA (Alera) (2R10)	11.5	9.18 - 13.8	43.5	33.1 - 53.9	219	175 - 262	1055	844 - 1266			pmol/L
Troponin I											
CMIA (STAT) (2K41)	0.044	0.026 - 0.062	0.32	0.19 - 0.45	1.11	0.89 - 1.33	15.8	12.6 - 18.9			µg/L
Troponin I, High Sensitivity (hsTnI)											
CMIA (STAT) (3P25)	19.8	11.9 - 27.7	163	97.7 - 228	587	441 - 733	12047	9638 - 14456			ng/L

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**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		U	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>ABBOTT ALINITY SYSTEMS</b>										
B-Type Natriuretic Peptide (BNP)										
CMIA (08P24)	N/A		56.3	45.0 - 67.6	464	371 - 557	1605	1284 - 1926	pg/mL	
C-Reactive Protein, High Sensitivity (hsCRP)										
Immunoturbidimetric (CRP16) (07P56)	**		**		**		**		mg/dL	
C-Reactive Protein (wrCRP)										
Immunoturbidimetric (CRP48) (07P56)	<0.100		0.16	0.10 - 0.23	0.43	0.34 - 0.52	0.96	0.77 - 1.15	mg/dL	
Creatine Kinase-MB (CK-MB)										
CMIA (STAT) (04V38)	2.89	2.31 - 3.47	7.11	5.69 - 8.53	28.9	23.1 - 34.7	79.4	63.5 - 95.3	ng/mL	
Creatine Kinase-MB (CK-MB)										
Immuno-inhibition / IFCC (09P95)	<6.00		6.70	<6.00 - 8.73	32.0	25.6 - 38.4	91.3	73.0 - 110	U/L	
Digitoxin										
CEDIA	N/A		9.95	7.56 - 12.3	20.4	16.3 - 24.4	42.8	34.2 - >50.0	ng/mL	
Homocysteine										
CMIA (09P28)	N/A		5.69	4.55 - 6.83	10.6	8.50 - 12.8	22.2	17.8 - 26.6	μmol/L	
Myoglobin										
Latex Particle Immunoturbidimetric (01R15)	13.9	<13.0 - 16.7	28.0	22.4 - 33.6	133	106 - 160	345	276 - 414	ng/mL	
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
CMIA (04S79)	108	86.6 - 130	420	336 - 504	2097	1678 - 2516	9556	7645 - 11467	pg/mL	
Troponin I, High Sensitivity (hsTnI)										
CMIA (STAT) (08P13)	18.3	11.0 - 25.6	146	87.6 - 204	551	441 - 661	11504	9203 - 13805	pg/mL	

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		U	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>ABBOTT ALINITY SYSTEMS</b>										
B-Type Natriuretic Peptide (BNP)										
CMIA (08P24)	N/A		56.3	45.0 - 67.6	464	371 - 557	1605	1284 - 1926	pg/mL	
C-Reactive Protein, High Sensitivity (hsCRP)										
Immunoturbidimetric (CRP16) (07P56)	**		**		**		**		mg/dL	
C-Reactive Protein (wrCRP)										
Immunoturbidimetric (CRP48) (07P56)	<0.100		0.16	0.10 - 0.23	0.43	0.34 - 0.52	0.96	0.77 - 1.15	mg/dL	
Creatine Kinase-MB (CK-MB)										
CMIA (STAT) (04V38)	2.89	2.31 - 3.47	7.11	5.69 - 8.53	28.9	23.1 - 34.7	79.4	63.5 - 95.3	ng/mL	
Creatine Kinase-MB (CK-MB)										
Immuno-inhibition / IFCC (09P95)	<6.00		6.70	<6.00 - 8.73	32.0	25.6 - 38.4	91.3	73.0 - 110	U/L	
Digitoxin										
CEDIA	N/A		9.95	7.56 - 12.3	20.4	16.3 - 24.4	42.8	34.2 - >50.0	ng/mL	
Homocysteine										
CMIA (09P28)	N/A		5.69	4.55 - 6.83	10.6	8.50 - 12.8	22.2	17.8 - 26.6	μmol/L	
Myoglobin										
Latex Particle Immunoturbidimetric (01R15)	13.9	<13.0 - 16.7	28.0	22.4 - 33.6	133	106 - 160	345	276 - 414	ng/mL	
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
CMIA (04S79)	108	86.6 - 130	420	336 - 504	2097	1678 - 2516	9556	7645 - 11467	pg/mL	
Troponin I, High Sensitivity (hsTnI)										
CMIA (STAT) (08P13)	18.3	11.0 - 25.6	146	87.6 - 204	551	441 - 661	11504	9203 - 13805	pg/mL	

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	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>BECKMAN COULTER ACCESS SYSTEMS</b>										
B-Type Natriuretic Peptide (BNP)										
Chemiluminescence (Quidel/Alere)	N/A		**		**		**		pg/mL	
Creatine Kinase-MB (CK-MB)										
Chemiluminescence (CKMB)	**		**		**		**		ng/mL	
Myoglobin	19.2	15.4 - 23.0	37.4	29.9 - 44.9	156	125 - 187	373	298 - 448	ng/mL	
Troponin I	0.039	0.023 - 0.055	0.27	0.16 - 0.37	0.87	0.70 - 1.04	9.52	6.61 - 12.4	ng/mL	
Troponin I, High Sensitivity (hsTnI)										
Chemiluminescence (hsTnI)	**		**		**		**		pg/mL	

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>BECKMAN COULTER ACCESS SYSTEMS</b>										
B-Type Natriuretic Peptide (BNP)										
Chemiluminescence (Quidel/Alere)	N/A		**		**		**		pmol/L	
Creatine Kinase-MB (CK-MB)										
Chemiluminescence (CKMB)	**		**		**		**		µg/L	
Myoglobin	19.2	15.4 - 23.0	37.4	29.9 - 44.9	156	125 - 187	373	298 - 448	µg/L	
Troponin I	0.039	0.023 - 0.055	0.27	0.16 - 0.37	0.87	0.70 - 1.04	9.52	6.61 - 12.4	µg/L	
Troponin I, High Sensitivity (hsTnI)										
Chemiluminescence (hsTnI)	**		**		**		**		ng/L	

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	<b>CXL2306LA</b>		<b>CXL23061A</b>		<b>CXL23062A</b>		<b>CXL23063A</b>		<b>U</b>	
	$\bar{x}$	<b>&lt;R&gt;</b>	$\bar{x}$	<b>&lt;R&gt;</b>	$\bar{x}$	<b>&lt;R&gt;</b>	$\bar{x}$	<b>&lt;R&gt;</b>		
<b>BECKMAN COULTER AU SERIES</b>										
C-Reactive Protein (CRP)										
Latex Particle Immunoturbidimetric (OSR6199)	**		**		**		**		mg/dL	
C-Reactive Protein, High Sensitivity (hsCRP)										
Latex Particle Immunoturbidimetric (OSR6199)	0.040	0.024 - 0.056	0.15	0.09 - 0.21	0.41	0.33 - 0.49	0.99	0.79 - 1.19	mg/dL	
C-Reactive Protein, High Sensitivity (hsCRP)										
Latex Particle Immunoturbidimetric (OSR6199 Non U.S.)	0.051	0.027 - 0.075	0.18	0.11 - 0.25	0.47	0.38 - 0.56	0.99	0.79 - 1.19	mg/dL	
Creatine Kinase-MB (CK-MB)										
Immunoturbidimetric	**		**		**		**		U/L	
Creatine Kinase-MB (CK-MB)										
Immunoturbidimetric (Non U.S.)	<10.0		<10.0		19.7	15.8 - 23.6	56.7	45.4 - 68.0	U/L	
Digitoxin										
CEDIA	N/A		11.0	8.82 - 13.2	21.9	17.5 - 26.3	44.7	35.7 - >50.0	ng/mL	
Digitoxin										
Microparticles (OSR6403)	N/A		**		**		**		ng/mL	
Digitoxin										
Microparticles (OSR6403 Germany)	N/A		**		**		**		ng/mL	
Homocysteine										
Immunoturbidimetric (Axis-Shield B08176)	N/A		6.66	5.33 - 7.99	13.1	10.5 - 15.7	28.0	22.4 - 33.6	µmol/L	
Myoglobin										
Immunoturbidimetric (OSR6168 Non U.S.)	**		**		**		**		ng/mL	

	<b>SI</b>									
	<b>CXL2306LA</b>		<b>CXL23061A</b>		<b>CXL23062A</b>		<b>CXL23063A</b>		<b>U</b>	
	$\bar{x}$	<b>&lt;R&gt;</b>	$\bar{x}$	<b>&lt;R&gt;</b>	$\bar{x}$	<b>&lt;R&gt;</b>	$\bar{x}$	<b>&lt;R&gt;</b>		
<b>BECKMAN COULTER AU SERIES</b>										
C-Reactive Protein (CRP)										
Latex Particle Immunoturbidimetric (OSR6199)	**		**		**		**		mg/L	
C-Reactive Protein, High Sensitivity (hsCRP)										
Latex Particle Immunoturbidimetric (OSR6199)	0.40	0.24 - 0.56	1.53	0.92 - 2.14	4.10	3.30 - 4.90	9.90	7.90 - 11.9	mg/L	
C-Reactive Protein, High Sensitivity (hsCRP)										
Latex Particle Immunoturbidimetric (OSR6199 Non U.S.)	0.51	0.27 - 0.75	1.77	1.06 - 2.48	4.70	3.76 - 5.64	9.90	7.90 - 11.9	mg/L	
Creatine Kinase-MB (CK-MB)										
Immunoturbidimetric	**		**		**		**		µkat/L	
Creatine Kinase-MB (CK-MB)										
Immunoturbidimetric (Non U.S.)	<0.17		<0.17		0.33	0.26 - 0.39	0.95	0.76 - 1.14	µkat/L	
Digitoxin										
CEDIA	N/A		14.4	11.6 - 17.3	28.7	23.0 - 34.4	58.5	46.8 - >65.5	nmol/L	
Digitoxin										
Microparticles (OSR6403)	N/A		**		**		**		nmol/L	
Digitoxin										
Microparticles (OSR6403 Germany)	N/A		**		**		**		nmol/L	
Homocysteine										
Immunoturbidimetric (Axis-Shield B08176)	N/A		6.66	5.33 - 7.99	13.1	10.5 - 15.7	28.0	22.4 - 33.6	µmol/L	
Myoglobin										
Immunoturbidimetric (OSR6168 Non U.S.)	**		**		**		**		µg/L	

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## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>BECKMAN COULTER DXC / SYNCHRON SYSTEMS</b>										
C-Reactive Protein, High Sensitivity (hsCRP)										
Immunoturbidimetric (CRPH)	0.033	0.020 - 0.046	0.15	0.09 - 0.20	0.42	0.34 - 0.50	0.96	0.77 - 1.15	mg/dL	
Creatine Kinase-MB (CK-MB)										
Enzymatic Activity (CMBX)	**		**		**		**		U/L	
Creatine Kinase-MB (CK-MB)										
Sentinel (UDR)	**		**		**		**		U/L	
Digitoxin										
Latex Particle Immunoturbidimetric	N/A		16.7	13.3 - 20.0	28.6	22.9 - 34.3	58.8	47.0 - 70.5	ng/mL	

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>BECKMAN COULTER DXC / SYNCHRON SYSTEMS</b>										
C-Reactive Protein, High Sensitivity (hsCRP)										
Immunoturbidimetric (CRPH)	0.33	0.20 - 0.46	1.46	0.88 - 2.04	4.20	3.40 - 5.00	9.60	7.70 - 11.5	mg/L	
Creatine Kinase-MB (CK-MB)										
Enzymatic Activity (CMBX)	**		**		**		**		μkat/L	
Creatine Kinase-MB (CK-MB)										
Sentinel (UDR)	**		**		**		**		μkat/L	
Digitoxin										
Latex Particle Immunoturbidimetric	N/A		21.8	17.5 - 26.2	37.4	30.0 - 44.9	77.0	61.6 - 92.4	nmol/L	

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## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>BECKMAN COULTER DXI SYSTEMS</b>										
B-Type Natriuretic Peptide (BNP)										
Chemiluminescence (Quidel/Alere)	N/A		70.3	56.2 - 84.4	453	362 - 544	1225	980 - 1470	pg/mL	
Creatine Kinase-MB (CK-MB)										
Chemiluminescence	2.82	2.01 - 3.63	6.99	5.59 - 8.39	29.8	23.7 - 35.9	80.7	64.6 - 96.8	ng/mL	
Myoglobin Chemiluminescence (MYO)	17.1	13.5 - 20.7	32.5	26.0 - 39.0	145	115 - 175	372	293 - 451	ng/mL	
Troponin I Chemiluminescence (AccuTnl+3) (TnlDx)	**		**		**		**		ng/mL	
Troponin I, High Sensitivity (hsTnl) Chemiluminescence	119	71.4 - 167	880	528 - 1232	3101	2481 - 3721	>27027		pg/mL	

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>BECKMAN COULTER DXI SYSTEMS</b>										
B-Type Natriuretic Peptide (BNP)										
Chemiluminescence (Quidel/Alere)	N/A		20.3	16.2 - 24.4	131	105 - 157	354	283 - 424	pmol/L	
Creatine Kinase-MB (CK-MB)										
Chemiluminescence	2.82	2.01 - 3.63	6.99	5.59 - 8.39	29.8	23.7 - 35.9	80.7	64.6 - 96.8	µg/L	
Myoglobin Chemiluminescence (MYO)	17.1	13.5 - 20.7	32.5	26.0 - 39.0	145	115 - 175	372	293 - 451	µg/L	
Troponin I Chemiluminescence (AccuTnl+3) (TnlDx)	**		**		**		**		µg/L	
Troponin I, High Sensitivity (hsTnl) Chemiluminescence	119	71.4 - 167	880	528 - 1232	3101	2481 - 3721	>27027		ng/L	

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## LIQUID ASSAYED CARDIAC MARKER CONTROL


**IVD**

		<b>CON</b>									
		CXL2306LA		CXL23061A		CXL23062A		CXL23063A		U	
		$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>BIOMERIEUX VIDAS SYSTEMS</b>											
Myoglobin	ELFA	**		**		**		**		ng/mL	
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>	ELFA (PBN2)	**		**		**		**		pg/mL	
Troponin I	ELFA, Ultra (TNIU)	**		**		**		**		ng/mL	
Troponin I, High Sensitivity (hsTnI)	ELFA (TNHS)	**		**		**		**		pg/mL	

		<b>SI</b>									
		CXL2306LA		CXL23061A		CXL23062A		CXL23063A		U	
		$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>BIOMERIEUX VIDAS SYSTEMS</b>											
Myoglobin	ELFA	**		**		**		**		µg/L	
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>	ELFA (PBN2)	**		**		**		**		pmol/L	
Troponin I	ELFA, Ultra (TNIU)	**		**		**		**		µg/L	
Troponin I, High Sensitivity (hsTnI)	ELFA (TNHS)	**		**		**		**		ng/L	



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## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>MINDRAY CL-SERIES (Non U.S.)</b>										
B-Type Natriuretic Peptide (BNP)	N/A		**	**	**	**	**	**	pg/mL	
Creatine Kinase-MB (CK-MB)	N/A		**	**	**	**	**	**	ng/mL	
Myoglobin	**	**	**	**	**	**	**	**	ng/mL	
Troponin I	**	**	**	**	**	**	**	**	ng/mL	

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>MINDRAY CL-SERIES (Non U.S.)</b>										
B-Type Natriuretic Peptide (BNP)	N/A		**	**	**	**	**	**	pmol/L	
Creatine Kinase-MB (CK-MB)	N/A		**	**	**	**	**	**	µg/L	
Myoglobin	**	**	**	**	**	**	**	**	µg/L	
Troponin I	**	**	**	**	**	**	**	**	µg/L	

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## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>ORTHO-CLINICAL VITROS SYSTEMS</b>										
C-Reactive Protein, High Sensitivity (hsCRP)										
Immunoturbidimetric	0.052	0.031 - 0.073	0.17	0.10 - 0.24	0.42	0.34 - 0.50	0.97	0.78 - 1.16	mg/dL	
Creatine Kinase-MB (CK-MB)										
Chemiluminescence	2.14	1.71 - 2.57	5.22	4.18 - 6.26	20.5	16.4 - 24.6	55.4	44.3 - 66.5	ng/mL	
Myoglobin	**		**		**		**		ng/mL	
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
Chemiluminescence (NTBNP)	179	143 - 215	697	558 - 836	3141	2513 - 3769	10975	8780 - 13170	pg/mL	
Troponin I										
Chemiluminescence	0.076	0.043 - 0.109	0.64	0.39 - 0.90	2.32	1.86 - 2.78	32.8	26.2 - 39.4	ng/mL	

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>ORTHO-CLINICAL VITROS SYSTEMS</b>										
C-Reactive Protein, High Sensitivity (hsCRP)										
Immunoturbidimetric	0.52	0.31 - 0.73	1.71	1.03 - 2.39	4.20	3.40 - 5.00	9.70	7.80 - 11.6	mg/L	
Creatine Kinase-MB (CK-MB)										
Chemiluminescence	2.14	1.71 - 2.57	5.22	4.18 - 6.26	20.5	16.4 - 24.6	55.4	44.3 - 66.5	µg/L	
Myoglobin	**		**		**		**		µg/L	
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
Chemiluminescence (NTBNP)	21.1	16.9 - 25.4	82.3	65.8 - 98.7	371	297 - 445	1295	1036 - 1554	pmol/L	
Troponin I										
Chemiluminescence	0.076	0.043 - 0.109	0.64	0.39 - 0.90	2.32	1.86 - 2.78	32.8	26.2 - 39.4	µg/L	

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## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>ROCHE COBAS C / HITACHI / MODULAR SYSTEMS</b>										
C-Reactive Protein, High Sensitivity (hsCRP)										
Latex Particle Immunoturbidimetric (CRPHS)	0.036	<0.015 - 0.081	0.17	0.10 - 0.23	0.43	0.34 - 0.52	1.03	0.82 - 1.24		mg/dL
Creatine Kinase-MB (CK-MB)										
Immunological UV (CKMB/ CKMB2 Non U.S.)	<3.00		6.00	3.75 - 8.25	25.5	20.4 - 30.6	71.5	57.2 - 85.8		U/L
Creatine Kinase-MB (CK-MB)										
Immunological UV (CKMBL)	**		**		**		**			U/L
Digitoxin										ng/mL
Microparticles	N/A		**		**		**			ng/mL
Digitoxin										ng/mL
CEDIA	N/A		**		**		**			ng/mL
Myoglobin										ng/mL
Immunoturbidimetric (MYO2)	**		**		**		**			ng/mL

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>ROCHE COBAS C / HITACHI / MODULAR SYSTEMS</b>										
C-Reactive Protein, High Sensitivity (hsCRP)										
Latex Particle Immunoturbidimetric (CRPHS)	0.36	<0.15 - 0.81	1.66	1.00 - 2.32	4.30	3.40 - 5.20	10.3	8.20 - 12.4		mg/L
Creatine Kinase-MB (CK-MB)										
Immunological UV (CKMB/ CKMB2 Non U.S.)	<0.05		0.10	0.06 - 0.14	0.43	0.34 - 0.51	1.19	0.96 - 1.43		μkat/L
Creatine Kinase-MB (CK-MB)										
Immunological UV (CKMBL)	**		**		**		**			μkat/L
Digitoxin										nmol/L
Microparticles	N/A		**		**		**			nmol/L
Digitoxin										nmol/L
CEDIA	N/A		**		**		**			nmol/L
Myoglobin										μg/L
Immunoturbidimetric (MYO2)	**		**		**		**			μg/L

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## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>ROCHE COBAS E / MODULAR SYSTEMS</b>										
Creatine Kinase-MB (CK-MB)										
ECLIA	3.89	3.11 - 4.67	8.40	6.72 - 10.1	30.7	24.6 - 36.8	88.8	71.0 - 107		ng/mL
Creatine Kinase-MB (CK-MB)										
ECLIA (STAT)	3.40	2.72 - 4.08	7.38	5.90 - 8.86	26.4	21.1 - 31.7	73.3	58.6 - 88.0		ng/mL
Digitoxin	N/A		14.5	11.6 - 17.4	27.1	21.7 - 32.5	60.4	48.3 - 72.5		ng/mL
Myoglobin	26.1	<21.0 - 31.4	37.8	30.3 - 45.4	130	104 - 156	316	253 - 379		ng/mL
Myoglobin	25.1	<21.0 - 30.1	36.2	29.0 - 43.4	130	104 - 156	314	251 - 377		ng/mL
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
ECLIA	106	84.8 - 127	399	319 - 479	1803	1442 - 2164	8112	6490 - 9734		pg/mL
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
ECLIA (STAT)	102	81.6 - 122	350	280 - 420	1489	1191 - 1787	6641	5313 - 7969		pg/mL
Troponin I	**		**		**		**			ng/mL
Troponin I	**		**		**		**			ng/mL
Troponin T	N/A		**		**		**			ng/mL
Troponin T	N/A		**		**		**			ng/mL
Troponin T	N/A		0.043	0.034 - 0.052	**		**			ng/mL
Troponin T	N/A		0.081	0.060 - 0.102	0.43	0.31 - 0.55	7.76	5.63 - 9.89		ng/mL
Troponin T	N/A		396	317 - 475	954	763 - 1145	>10000			pg/mL
Troponin T, High Sensitivity (hsTnT)										
ECLIA	N/A		487	390 - 584	1110	888 - 1332	>10000			pg/mL
Troponin T, High Sensitivity (hsTnT)										
ECLIA (STAT)	N/A		256	205 - 307	600	480 - 720	7308	5846 - 8770		pg/mL

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>ROCHE COBAS E / MODULAR SYSTEMS</b>										
Creatine Kinase-MB (CK-MB)										
ECLIA	3.89	3.11 - 4.67	8.40	6.72 - 10.1	30.7	24.6 - 36.8	88.8	71.0 - 107		µg/L
Creatine Kinase-MB (CK-MB)										
ECLIA (STAT)	3.40	2.72 - 4.08	7.38	5.90 - 8.86	26.4	21.1 - 31.7	73.3	58.6 - 88.0		µg/L
Digitoxin	N/A		19.0	15.2 - 22.8	35.5	28.4 - 42.6	79.1	63.3 - 95.0		nmol/L
Myoglobin	26.1	<21.0 - 31.4	37.8	30.3 - 45.4	130	104 - 156	316	253 - 379		µg/L
Myoglobin	25.1	<21.0 - 30.1	36.2	29.0 - 43.4	130	104 - 156	314	251 - 377		µg/L
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
ECLIA	12.5	10.0 - 15.0	47.1	37.7 - 56.5	213	170 - 255	957	766 - 1149		pmol/L
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
ECLIA (STAT)	12.0	9.63 - 14.4	41.3	33.0 - 49.6	176	141 - 211	784	627 - 940		pmol/L
Troponin I	**		**		**		**			µg/L
Troponin I	**		**		**		**			µg/L
Troponin T	N/A		**		**		**			µg/L
Troponin T	N/A		**		**		**			µg/L
Troponin T	N/A		0.043	0.034 - 0.052	**		**			µg/L
Troponin T	N/A		0.081	0.060 - 0.102	0.43	0.31 - 0.55	7.76	5.63 - 9.89		µg/L
Troponin T	N/A		396	317 - 475	954	763 - 1145	>10000			ng/L
Troponin T, High Sensitivity (hsTnT)										
ECLIA	N/A		487	390 - 584	1110	888 - 1332	>10000			ng/L
Troponin T, High Sensitivity (hsTnT)										
ECLIA (STAT)	N/A		256	205 - 307	600	480 - 720	7308	5846 - 8770		ng/L

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## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

	<b>CON</b>										
	<b>U</b>		CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	<b>U</b>
<b>ROCHE INTEGRA SYSTEMS</b>											
C-Reactive Protein (CRP)											
Latex Particle Immunoturbidimetric (CRPLX/ CRPL2)			**		**		**		**		mg/dL
Creatine Kinase-MB (CK-MB)											
Immunological UV (CKMB/ CKMB2 Non U.S.)	**		**		**		**		**		U/L
Creatine Kinase-MB (CK-MB)											
Immunological UV (CKMBL)	**		**		**		**		**		U/L
Myoglobin			**		**		**		**		ng/mL
Latex Enhanced Immunoturbidimetric (MY02)	**		**		**		**		**		

	<b>SI</b>										
	<b>U</b>		CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	<b>U</b>
<b>ROCHE INTEGRA SYSTEMS</b>											
C-Reactive Protein (CRP)											
Latex Particle Immunoturbidimetric (CRPLX/ CRPL2)	**		**		**		**		**		mg/L
Creatine Kinase-MB (CK-MB)											
Immunological UV (CKMB/ CKMB2 Non U.S.)	**		**		**		**		**		µkat/L
Creatine Kinase-MB (CK-MB)											
Immunological UV (CKMBL)	**		**		**		**		**		µkat/L
Myoglobin			**		**		**		**		µg/L
Latex Enhanced Immunoturbidimetric (MY02)	**		**		**		**		**		

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## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>SIEMENS ADVIA CHEMISTRY / CENTAUR SYSTEMS</b>										
B-Type Natriuretic Peptide (BNP)										
Chemiluminescence	N/A		37.6	30.1 - 45.1	273	218 - 328	855	684 - 1026	pg/mL	
C-Reactive Protein (wrCRP)										
Immunoturbidimetric (Wide Range) (1200)	**		**		**		**		mg/dL	
Immunoturbidimetric (Wide Range) (1650/1800)	**		**		**		**		mg/dL	
C-Reactive Protein (wrCRP)										
Immunoturbidimetric (Wide Range) (XPT/2400)	0.010	0.004 - 0.016	0.10	0.06 - 0.14	0.45	0.35 - 0.55	1.09	0.87 - 1.31	mg/dL	
C-Reactive Protein, High Sensitivity (hsCRP)										
Latex Particle Immunoturbidimetric	0.036	0.022 - 0.050	0.15	0.09 - 0.21	0.43	0.34 - 0.52	0.98	0.78 - >1.00	mg/dL	
Creatine Kinase-MB (CK-MB)										
Optimized UV, IFCC (Diasys)	2.01	<2.00 - 2.41	5.90	<2.00 - 10.4	25.0	19.4 - 30.5	70.5	56.4 - 84.6	U/L	
Creatine Kinase-MB (CK-MB)										
Chemiluminescence (Centaur CP)	**		**		**		**		ng/mL	
Creatine Kinase-MB (CK-MB)										
Chemiluminescence (Centaur XP)	**		**		**		**		ng/mL	
Digitoxin										
Chemiluminescence	N/A		10.7	7.95 - 13.5	21.6	17.2 - 26.0	51.3	41.0 - 61.6	ng/mL	
Homocysteine										
Chemiluminescence	N/A		**		**		**		µmol/L	
Myoglobin										
Chemiluminescence	**		**		**		**		ng/mL	
N-Terminal Pro-Brain Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
Chemiluminescence (PBNP)	**		**		**		**		pg/mL	
Troponin I										
Chemiluminescence (TnI-Ultra)	**		**		**		**		ng/mL	
Troponin I, High Sensitivity (hsTnI)										
Chemiluminescence (TNIH)	26.5	15.9 - 37.1	211	127 - 295	708	517 - 899	8088	6104 - 10072	pg/mL	

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>SIEMENS ADVIA CHEMISTRY / CENTAUR SYSTEMS</b>										
B-Type Natriuretic Peptide (BNP)										
Chemiluminescence	N/A		10.9	8.68 - 13.0	78.8	63.1 - 94.6	247	197 - 296	pmol/L	
C-Reactive Protein (wrCRP)										
Immunoturbidimetric (Wide Range) (1200)	**		**		**		**		mg/L	
Immunoturbidimetric (Wide Range) (1650/1800)	**		**		**		**		mg/L	
C-Reactive Protein (wrCRP)										
Immunoturbidimetric (Wide Range) (XPT/2400)	0.10	0.04 - 0.16	1.00	0.60 - 1.40	4.50	3.51 - 5.49	10.9	8.70 - 13.1	mg/L	
C-Reactive Protein, High Sensitivity (hsCRP)										
Latex Particle Immunoturbidimetric	0.36	0.22 - 0.50	1.49	0.89 - 2.09	4.30	3.44 - 5.16	9.80	7.80 - >10.0	mg/L	
Creatine Kinase-MB (CK-MB)										
Optimized UV, IFCC (Diasys)	0.03	<0.03 - 0.04	0.10	<0.03 - 0.17	0.42	0.32 - 0.51	1.18	0.94 - 1.41	µkat/L	
Creatine Kinase-MB (CK-MB)										
Chemiluminescence (Centaur CP)	**		**		**		**		µg/L	
Creatine Kinase-MB (CK-MB)										
Chemiluminescence (Centaur XP)	**		**		**		**		µg/L	
Digitoxin										
Chemiluminescence	N/A		14.0	10.4 - 17.7	28.3	22.6 - 34.0	67.2	53.7 - 80.7	nmol/L	
Homocysteine										
Chemiluminescence	N/A		**		**		**		µmol/L	
Myoglobin										
Chemiluminescence	**		**		**		**		µg/L	
N-Terminal Pro-Brain Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
Chemiluminescence (PBNP)	**		**		**		**		pmol/L	
Troponin I										
Chemiluminescence (TnI-Ultra)	**		**		**		**		µg/L	
Troponin I, High Sensitivity (hsTnI)										
Chemiluminescence (TNIH)	26.5	15.9 - 37.1	211	127 - 295	708	517 - 899	8088	6104 - 10072	ng/L	

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# MAS® CardiolImmune® - XL


## LIQUID ASSAYED CARDIAC MARKER CONTROL

IVD

	<b>CON</b>								
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	U
<b>SIEMENS ATELICA SYSTEMS</b>									
B-Type Natriuretic Peptide (BNP)									
Chemiluminescence	NA		32.9	26.3 - 39.5	243	194 - 292	738	590 - 886	pg/mL
C-Reactive Protein, High Sensitivity (hsCRP)									
Latex Particle Immunoturbidimetric	0.036	0.022 - 0.050	0.14	0.08 - 0.19	0.37	0.30 - 0.44	0.87	0.70 - >1.00	mg/dL
Creatine Kinase-MB (CK-MB)									
Chemiluminescence (CKMB)	3.24	1.98 - 4.50	6.83	5.42 - 8.24	24.8	19.9 - 29.8	65.6	52.5 - 78.7	ng/mL
Creatine Kinase-MB (CK-MB)									
IFCC (DiaSys)	2.63	<2.00 - 4.25	6.11	3.50 - 8.72	26.8	21.4 - 32.1	74.7	59.8 - 89.7	U/L
Digitoxin									
Chemiluminescence (Dgtn)	NA		11.6	9.25 - 13.9	22.7	18.2 - 27.2	50.2	40.2 - 60.2	ng/mL
Homocysteine									
Chemiluminescence (HCY)	NA		2.80	2.14 - 3.46	6.39	5.11 - 7.67	14.0	11.2 - 16.8	μmol/L
Myoglobin									
Chemiluminescence (MYO)	22.7	18.2 - 27.2	42.4	33.9 - 50.9	197	158 - 236	529	423 - 635	ng/mL
N-Terminal Pro-Brain Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>									
Chemiluminescence (PBNP)	171	137 - 205	729	583 - 875	3516	2813 - 4219	13981	11185 - 16777	pg/mL
Troponin I									
Chemiluminescence (TnI-Ultra®/ TnI_UL)	**		**		**		**		ng/mL
Troponin I, High Sensitivity (hsTnI)									
Chemiluminescence (TnIH)	27.7	16.6 - 38.8	207	124 - 290	699	555 - 843	8037	6416 - 9658	pg/mL

	<b>SI</b>								
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	U
<b>SIEMENS ATELICA SYSTEMS</b>									
B-Type Natriuretic Peptide (BNP)									
Chemiluminescence	NA		9.50	7.60 - 11.4	70.2	56.1 - 84.2	213	170 - 256	pmol/L
C-Reactive Protein, High Sensitivity (hsCRP)									
Latex Particle Immunoturbidimetric	0.36	0.22 - 0.50	1.35	0.81 - 1.89	3.70	3.00 - 4.40	8.70	7.00 - >10.0	mg/L
Creatine Kinase-MB (CK-MB)									
Chemiluminescence (CKMB)	3.24	1.98 - 4.50	6.83	5.42 - 8.24	24.8	19.9 - 29.8	65.6	52.5 - 78.7	μg/L
Creatine Kinase-MB (CK-MB)									
IFCC (DiaSys)	0.04	<0.03 - 0.07	0.10	0.06 - 0.15	0.45	0.36 - 0.54	1.25	1.00 - 1.50	μkat/L
Digitoxin									
Chemiluminescence (Dgtn)	NA		15.1	12.1 - 18.2	29.7	23.8 - 35.7	65.8	52.6 - 78.9	nmol/L
Homocysteine									
Chemiluminescence (HCY)	NA		2.80	2.14 - 3.46	6.39	5.11 - 7.67	14.0	11.2 - 16.8	μmol/L
Myoglobin									
Chemiluminescence (MYO)	22.7	18.2 - 27.2	42.4	33.9 - 50.9	197	158 - 236	529	423 - 635	μg/L
N-Terminal Pro-Brain Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>									
Chemiluminescence (PBNP)	20.2	16.1 - 24.2	86.0	68.8 - 103	415	332 - 498	1650	1320 - 1980	pmol/L
Troponin I									
Chemiluminescence (TnI-Ultra®/ TnI_UL)	**		**		**		**		μg/L
Troponin I, High Sensitivity (hsTnI)									
Chemiluminescence (TnIH)	27.7	16.6 - 38.8	207	124 - 290	699	555 - 843	8037	6416 - 9658	ng/L

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**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		U	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>SIEMENS BNII / PROSPEC</b> C-Reactive Protein, High Sensitivity (hsCRP) Immunonephelometry	**		**		**		**			mg/dL

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		U	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>SIEMENS BNII / PROSPEC</b> C-Reactive Protein, High Sensitivity (hsCRP) Immunonephelometry	**		**		**		**			mg/L



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## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		U	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>SIEMENS DIMENSION SYSTEMS</b>										
C-Reactive Protein, High Sensitivity (hsCRP) Colorimetric Immunoassay (CCRP)	**		**		**		**			mg/dL
C-Reactive Protein (CRP) PETIA (Extended Range) (RCRP)	N/A		N/A		0.40	0.28 - 0.52	1.02	0.82 - 1.22		mg/dL
Creatine Kinase-MB (CK-MB) EIA (MMB/ LMMB)	2.01	1.47 - 2.55	4.93	3.70 - 6.16	24.3	19.4 - 29.2	79.9	63.9 - 95.9		ng/mL
Creatine Kinase-MB (CK-MB) IFCC (MBI)	3.40	<3.00 - 5.50	6.63	3.87 - 9.39	27.9	22.3 - 33.5	78.2	62.6 - 93.8		U/L
Digitoxin CMIA (DGTX)	N/A		11.2	8.48 - 13.9	21.7	17.4 - 26.0	46.6	33.9 - 59.3		ng/mL
Myoglobin EIA (MYO)	18.4	14.7 - 22.1	38.4	30.7 - 46.1	204	163 - 245	554	443 - 665		ng/mL
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup> EIA (PBNP/ LBNP)	37.6	28.2 - 47.0	184	138 - 230	1087	815 - 1359	5716	4036 - 7396		pg/mL
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup> LOCI <sup>™</sup> (NTP/ LNTP)	40.0	32.0 - 48.0	183	146 - 220	1129	903 - 1355	6184	4947 - 7421		pg/mL
Troponin I EIA (CTNI/ LTNI)	**		**		**		**			ng/mL
Troponin I LOCI <sup>™</sup> (TNI)	0.115	0.069 - 0.161	0.70	0.42 - 0.97	2.19	1.71 - 2.67	22.4	17.9 - 26.9		ng/mL
Troponin I, High Sensitivity (hsTnI) LOCI <sup>™</sup> (TNIH)	34.8	20.9 - 48.8	213	128 - 299	710	568 - 851	7936	6349 - 9523		pg/mL

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		U	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>SIEMENS DIMENSION SYSTEMS</b>										
C-Reactive Protein, High Sensitivity (hsCRP) Colorimetric Immunoassay (CCRP)	**		**		**		**			mg/L
C-Reactive Protein (CRP) PETIA (Extended Range) (RCRP)	N/A		N/A		4.00	2.80 - 5.20	10.2	8.20 - 12.2		mg/L
Creatine Kinase-MB (CK-MB) EIA (MMB/ LMMB)	2.01	1.47 - 2.55	4.93	3.70 - 6.16	24.3	19.4 - 29.2	79.9	63.9 - 95.9		µg/L
Creatine Kinase-MB (CK-MB) IFCC (MBI)	0.06	<0.05 - 0.09	0.11	0.06 - 0.16	0.47	0.37 - 0.56	1.31	1.04 - 1.57		µkat/L
Digitoxin CMIA (DGTX)	N/A		14.7	11.1 - 18.2	28.4	22.7 - 34.1	61.1	44.5 - 77.6		nmol/L
Myoglobin EIA (MYO)	18.4	14.7 - 22.1	38.4	30.7 - 46.1	204	163 - 245	554	443 - 665		µg/L
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup> EIA (PBNP/ LBNP)	4.44	3.33 - 5.55	21.7	16.3 - 27.1	128	96.2 - 160	674	476 - 873		pmol/L
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup> LOCI <sup>™</sup> (NTP/ LNTP)	4.72	3.78 - 5.66	21.6	17.3 - 25.9	133	107 - 160	730	584 - 876		pmol/L
Troponin I EIA (CTNI/ LTNI)	**		**		**		**			µg/L
Troponin I LOCI <sup>™</sup> (TNI)	0.115	0.069 - 0.161	0.70	0.42 - 0.97	2.19	1.71 - 2.67	22.4	17.9 - 26.9		µg/L
Troponin I, High Sensitivity (hsTnI) LOCI <sup>™</sup> (TNIH)	34.8	20.9 - 48.8	213	128 - 299	710	568 - 851	7936	6349 - 9523		ng/L

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**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>SIEMENS DIMENSION VISTA</b>										
B-Type Natriuretic Peptide (BNP) LOCI <sup>™</sup> (BNP)	N/A		**		**		**		pg/mL	
C-Reactive Protein, High Sensitivity (hsCRP) Nephelometric	0.040	0.024 - 0.056	0.15	0.09 - 0.21	0.43	0.34 - 0.52	0.92	0.74 - >0.95	mg/dL	
Creatine Kinase-MB (CK-MB) IFCC (MBI)	**		**		**		**		U/L	
Creatine Kinase-MB (CK-MB) LOCI <sup>™</sup> (MMB)	3.39	2.71 - 4.07	7.54	6.03 - 9.05	29.5	23.6 - 35.4	81.0	64.8 - 97.2	ng/mL	
Digitoxin CMIA (DGTX)	N/A		**		**		**		ng/mL	
Homocysteine Nephelometric (HCYS)	N/A		4.69	3.75 - 5.63	8.12	6.50 - 9.74	16.3	13.1 - 19.6	μmol/L	
Myoglobin LOCI <sup>™</sup> (MYO)	**		**		**		**		ng/mL	
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup> LOCI <sup>™</sup> (PBNP)	67.9	54.3 - 81.5	300	240 - 360	1574	1259 - 1889	7262	5810 - 8714	pg/mL	
Troponin I LOCI <sup>™</sup> (CTNI)	0.126	0.076 - 0.176	0.84	0.51 - 1.18	2.64	2.11 - 3.17	26.6	21.0 - 32.2	ng/mL	
Troponin I, High Sensitivity (hsTnI) LOCI <sup>™</sup> (TNIH)	**		**		**		**		pg/mL	

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>SIEMENS DIMENSION VISTA</b>										
B-Type Natriuretic Peptide (BNP) LOCI <sup>™</sup> (BNP)	N/A		**		**		**		pmol/L	
C-Reactive Protein, High Sensitivity (hsCRP) Nephelometric	0.40	0.24 - 0.56	1.48	0.89 - 2.07	4.30	3.40 - 5.20	9.20	7.40 - >9.50	mg/L	
Creatine Kinase-MB (CK-MB) IFCC (MBI)	**		**		**		**		μkat/L	
Creatine Kinase-MB (CK-MB) LOCI <sup>™</sup> (MMB)	3.39	2.71 - 4.07	7.54	6.03 - 9.05	29.5	23.6 - 35.4	81.0	64.8 - 97.2	μg/L	
Digitoxin CMIA (DGTX)	N/A		**		**		**		nmol/L	
Homocysteine Nephelometric (HCYS)	N/A		4.69	3.75 - 5.63	8.12	6.50 - 9.74	16.3	13.1 - 19.6	μmol/L	
Myoglobin LOCI <sup>™</sup> (MYO)	**		**		**		**		μg/L	
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup> LOCI <sup>™</sup> (PBNP)	8.01	6.41 - 9.61	35.4	28.3 - 42.5	186	149 - 223	857	686 - 1028	pmol/L	
Troponin I LOCI <sup>™</sup> (CTNI)	0.126	0.076 - 0.176	0.84	0.51 - 1.18	2.64	2.11 - 3.17	26.6	21.0 - 32.2	μg/L	
Troponin I, High Sensitivity (hsTnI) LOCI <sup>™</sup> (TNIH)	**		**		**		**		ng/L	

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**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>SIEMENS IMMULITE SERIES</b>										
C-Reactive Protein, High Sensitivity (hsCRP)										
Chemiluminescence	**		**		**		**			mg/dL
Creatine Kinase-MB (CK-MB)										
Chemiluminescence	**		**		**		**			ng/mL
Creatine Kinase-MB (CK-MB)										
Chemiluminescence (STAT/Turbo)	**		**		**		**			ng/mL
Digitoxin										
Chemiluminescence	N/A		**		**		**			ng/mL
Homocysteine										
Chemiluminescence	N/A		**		**		**			µmol/L
Myoglobin										
Chemiluminescence	**		**		**		**			ng/mL
Myoglobin										
Chemiluminescence (STAT/Turbo)	**		**		**		**			ng/mL
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
Chemiluminescence	**		**		**		**			pg/mL
Troponin I										
Chemiluminescence	**		**		**		**			ng/mL
Troponin I										
Chemiluminescence (STAT/Turbo)	**		**		**		**			ng/mL

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>SIEMENS IMMULITE SERIES</b>										
C-Reactive Protein, High Sensitivity (hsCRP)										
Chemiluminescence	**		**		**		**			mg/L
Creatine Kinase-MB (CK-MB)										
Chemiluminescence	**		**		**		**			µg/L
Creatine Kinase-MB (CK-MB)										
Chemiluminescence (STAT/Turbo)	**		**		**		**			µg/L
Digitoxin										
Chemiluminescence	N/A		**		**		**			nmol/L
Homocysteine										
Chemiluminescence	N/A		**		**		**			µmol/L
Myoglobin										
Chemiluminescence	**		**		**		**			µg/L
Myoglobin										
Chemiluminescence (STAT/Turbo)	**		**		**		**			µg/L
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
Chemiluminescence	**		**		**		**			pmol/L
Troponin I										
Chemiluminescence	**		**		**		**			µg/L
Troponin I										
Chemiluminescence (STAT/Turbo)	**		**		**		**			µg/L

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**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		U	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>SIEMENS STRATUS CS</b>										
C-Reactive Protein, High Sensitivity (hsCRP)										
RPIA	**		**		**		**		**	mg/dL
Creatine Kinase-MB (CK-MB)										
RPIA	**		**		**		**		**	ng/mL
Myoglobin										
RPIA	**		**		**		**		**	ng/mL
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
RPIA	**		**		**		**		**	pg/mL
Troponin I										
RPIA	**		**		**		**		**	ng/mL

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		U	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>SIEMENS STRATUS CS</b>										
C-Reactive Protein, High Sensitivity (hsCRP)										
RPIA	**		**		**		**		**	mg/L
Creatine Kinase-MB (CK-MB)										
RPIA	**		**		**		**		**	µg/L
Myoglobin										
RPIA	**		**		**		**		**	µg/L
N-Terminal Pro B-type Natriuretic Peptide (NT-proBNP) <sup>(a)</sup>										
RPIA	**		**		**		**		**	pmol/L
Troponin I										
RPIA	**		**		**		**		**	µg/L

**LOT** CXL2306L  
 CXL23061  
 CXL23062  
 CXL23063

 2023-06-30

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# MAS<sup>®</sup> CardioImmune<sup>®</sup> - XL


## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

		<b>CON</b>									
		CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
		$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>THERMO FISHER SCIENTIFIC CDx90 SYSTEMS</b>											
Digitoxin	Microparticles	N/A		**		**		**		ng/mL	

		<b>SI</b>									
		CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>	
		$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>THERMO FISHER SCIENTIFIC CDx90 SYSTEMS</b>											
Digitoxin	Microparticles	N/A		**		**		**		nmol/L	

**LOT** CXL2306L  
 CXL23061  
 CXL23062  
 CXL23063

 2023-06-30

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# MAS<sup>®</sup> CardioImmune<sup>®</sup> - XL


## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

		<b>CON</b>									
		CXL2306LA		CXL23061A		CXL23062A		CXL23063A			
		$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	<b>U</b>	
<b>THERMO FISHER SCIENTIFIC INDIKO PLUS</b>											
Digitoxin	CEDIA	N/A		8.98	6.94 - 11.0	20.7	15.9 - 25.5	43.9	35.2 - >50.0	ng/mL	

		<b>SI</b>									
		CXL2306LA		CXL23061A		CXL23062A		CXL23063A			
		$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	<b>U</b>	
<b>THERMO FISHER SCIENTIFIC INDIKO PLUS</b>											
Digitoxin	CEDIA	N/A		11.8	9.09 - 14.4	27.1	20.8 - 33.4	57.6	46.1 - >65.5	nmol/L	

**LOT** CXL2306L  
 CXL23061  
 CXL23062  
 CXL23063

 2023-06-30

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For insert updates go to:  
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# MAS<sup>®</sup> CardioImmune<sup>®</sup> - XL


## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

	<b>CON</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		U	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>THERMO FISHER SCIENTIFIC KONELAB SYSTEMS</b>										
C-Reactive Protein, High Sensitivity (hsCRP)										
Immunoprecipitation	**		**		**		**		**	mg/dL
Creatine Kinase-MB (CK-MB)										
Immunoinhibition (981834/ 981837)	**		**		**		**		**	U/L
Myoglobin										ng/mL
Immunoprecipitation	**		**		**		**		**	

	<b>SI</b>									
	CXL2306LA		CXL23061A		CXL23062A		CXL23063A		U	
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>		
<b>THERMO FISHER SCIENTIFIC KONELAB SYSTEMS</b>										
C-Reactive Protein, High Sensitivity (hsCRP)										
Immunoprecipitation	**		**		**		**		**	mg/L
Creatine Kinase-MB (CK-MB)										
Immunoinhibition (981834/ 981837)	**		**		**		**		**	µkat/L
Myoglobin										µg/L
Immunoprecipitation	**		**		**		**		**	

**LOT** CXL2306L  
CXL23061  
CXL23062  
CXL23063

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For insert updates go to:  
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# MAS<sup>®</sup> CardioImmune<sup>®</sup> - XL

## LIQUID ASSAYED CARDIAC MARKER CONTROL

**IVD**

	<b>CON</b>										
	<b>U</b>		CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	
<b>TOSOH AIA SYSTEMS</b>											
B-Type Natriuretic Peptide (BNP)											
EIA (BNP2 Non U.S.)	N/A		**		**		**				pg/mL
Creatine Kinase-MB (CK-MB)											
EIA	3.20	2.20 - 4.20	7.40	5.20 - 9.60	30.3	21.2 - 39.4	84.8	59.4 - 110			ng/mL
Myoglobin	13.1	9.20 - 17.0	26.9	18.2 - 35.6	109	76.5 - 142	277	194 - 360			ng/mL
Troponin I	0.120	0.080 - 0.160	0.89	0.62 - 1.16	3.09	2.16 - 4.02	34.4	24.1 - 44.7			ng/mL
Troponin I	**		**		**		**				ng/mL

	<b>SI</b>										
	<b>U</b>		CXL2306LA		CXL23061A		CXL23062A		CXL23063A		<b>U</b>
	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	$\bar{x}$	<R>	
<b>TOSOH AIA SYSTEMS</b>											
B-Type Natriuretic Peptide (BNP)											
EIA (BNP2 Non U.S.)	N/A		**		**		**				pmol/L
Creatine Kinase-MB (CK-MB)											
EIA	3.20	2.20 - 4.20	7.40	5.20 - 9.60	30.3	21.2 - 39.4	84.8	59.4 - 110			µg/L
Myoglobin	13.1	9.20 - 17.0	26.9	18.2 - 35.6	109	76.5 - 142	277	194 - 360			µg/L
Troponin I	0.120	0.080 - 0.160	0.89	0.62 - 1.16	3.09	2.16 - 4.02	34.4	24.1 - 44.7			µg/L
Troponin I	**		**		**		**				µg/L



**Aerose®**, **Architect®**, **Axsym®**, Reg. TM: Abbott Laboratories Inc., Abbott Park, IL  
**AIA® Systems**, Reg. TM: Tosoh Medics, South San Francisco, CA  
**ACS-180®**, **Centaur®**, Reg. TM: Siemens Healthcare Diagnostics, Tarrytown, NY  
**Access®**, **Synchron® Series**, **AU Series**, Reg. TM: Beckman-Coulter Inc., Brea, CA  
**Dimension Systems®**, **Immulate®**, **Stratus CS®**, Reg. TM: Siemens Healthcare Diagnostics, Glasgow, DE  
**Konelab Systems®**, Reg. TM: Thermo Fisher Scientific, Vantaa, Finland  
**Vitros Systems**, Reg. TM: Ortho-Clinical Diagnostics, Rochester, NY  
**Cobas 6000®**, **Elecsys®**, **Hitachi®**, **Integra®**, Reg. TM: Roche Diagnostics, Indianapolis, IN

- \*\* Data not available. If interested in participating in our value assignment process, please fax or email your contact information to our Value Assignment group at 510-771-1539, or mgc-va@thermofisher.com.**
- \*\* Keine Daten verfügbar. Falls Sie interessiert sind, an unserem Wertzuweisungsverfahren teilzunehmen, senden Sie bitte ein Fax oder eine E-Mail mit Ihren Kontaktdaten an unsere Abteilung „Value Assignment“ unter 510-771-1539 bzw. mgc-va@thermofisher.com.**
- \*\* Données non disponibles. Si vous souhaitez participer à notre processus d'affectation des valeurs, veuillez nous faire parvenir vos coordonnées par fax ou par e-mail au groupe Value Assignment au 510-771-1539 ou à l'adresse mgc-va@thermofisher.com.**
- \*\* Dati non disponibili. Per partecipare al processo di assegnazione dei valori, inviare tramite fax o e-mail le proprie informazioni di contatto al gruppo di assegnazione dei valori al numero 510-771-1539 o all'indirizzo mgc-va@thermofisher.com.**
- \*\* Datos no disponibles. Si está interesado en participar en nuestro proceso de asignación de valores, envíe un fax o un correo electrónico con su información de contacto a nuestro grupo de asignación de valores al +1 510-771-1539 o a mgc-va@thermofisher.com.**
- \*\* Data er ikke tilgjengelige. Hvis du er interessert i at delta i vores værditildelingsproces, kan du sende en fax eller en e-mail med dine kontaktoplysninger til vores værditildelingsgruppe på 510-771-1539 eller mgc-va@thermofisher.com.**
- \*\* Geen gegevens beschikbaar. Als u geïnteresseerd bent in deelname aan ons waardetoekenningsproces, kunt u uw contactgegevens per fax of e-mail naar onze Value Assignment-groep sturen. Tel.: 510-771-1539. E-mail: mgc-va@thermofisher.com.**
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- \*\* Informações não disponíveis. Caso esteja interessado em participar no nosso processo de atribuição de valores, por favor envie por fax ou por e-mail as suas informações de contacto para o nosso grupo de atribuição de valores pelo número 510-771-1539, ou mgc-va@thermofisher.com.**
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- \*\* 資料無法取得。如果有興趣參與我們的賦值過程，請將您的聯絡方式以傳真或電子郵件寄至我們的賦值小組。傳真號碼 510-771-1539。電子郵件信箱 mgc-va@thermofisher.com。**

- (a) NT-ProBNP Level L (Lot CXL2306L) - for users outside the USA only.**
- (a) NT-ProBNP Level L (Chargennummer CXL2306L) - Nur Für Benutzer außerhalb der Vereinigten Staaten.**
- (a) NT-ProBNP Livello L (numero di lotto CXL2306L) - Soltanto per l'utilizzatori fuori degli Stati Uniti.**
- (a) NT-ProBNP Niveau L (numéro de lot CXL2306L) - Seulement pour les utilisateurs hors Etats Unis.**
- (a) NT-ProBNP Nivel L (número de lote CXL2306L) - Solamente Para los usuarios fuera de los Estados Unidos.**
- (a) NT-ProBNP niveau L (Parti CXL2306L) - kun for brugere uden for USA.**
- (a) NT-ProBNP Niveau L (partij CXL2306L) - Alleen voor gebruikers buiten de VS.**
- (a) NT-ProBNP-taso L (erä CXL2306L) – vain Yhdysvaltojen ulkopuolisille käyttäjille.**
- (a) NT-ProBNP Επίπεδο L (Παρτίδα CXL2306L) – μόνο για χρήστες εκτός Η.Π.Α.**
- (a) NT-ProBNP уровень L (серия CXL2306L) – bare for brukere utenfor USA.**
- (a) NT-ProBNP, poziom L (partia CXL2306L) — wyłącznie dla użytkowników spoza obszaru Stanów Zjednoczonych.**
- (a) NT-ProBNP nivel L (Lote CXL2306L) - apenas para utilizadores fora dos EUA.**
- (a) NT-ProBNP, уровень L (лот CXL2306L) — только для пользователей за пределами США.**
- (a) NT-ProBNP nivå L (parti CXL2306L) – endast för användare utanför USA.**
- (a) NT-ProBNP Seviye L (Lot CXL2306L) - yalnızca ABD dışındaki kullanıcılar için.**
- (a) NT-ProBNP 浓度 L (批次: CXL2306L) — 仅供美国境外的用户使用。**
- (a) NT-ProBNP レベル L (ロット CXL2306L) - 米国外のユーザーのみ。**
- (a) NT-ProBNP razina L (partija CXL2306L) – samo za korisnike izvan SAD-a.**
- (a) NT-ProBNP 濃度 L (批號 CXL2306L) - 僅適用於美國境外的使用者。**

**LOT**

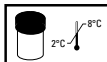
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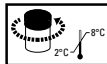
“Use By” date / Verwendbar bis / Date limite d'utilisation optimale / “Utilizzare entro” / Fecha límite de uso / “Anvendes før”-dato / Houdbaarheidsdatum / “Käyt. viim.”-päivämäärä / Ημερομηνία λήξης / Utløpsdato / Termin przydatności / Data de validade / Дата «Использовать до» / Utgångsdatum / “Son Kullanim” tarihi / 此日期前使用 / 使用期限 / Rok trajanja / 使用期限



Shelf life: Frozen Temperature / Date limite d'utilisation optimale / Durée de conservation : température de congélation / Data di scadenza: se conservato a temperatura di congelamento / Vida útil: temperatura de congelación / Holdbarhed: Frysetemperatur / Houdbaarheidsperiode: in bevroren toestand / Käyttöikä: pakastuslämpötilassa / Διάκριση ζωής: θερμοκρασία κατάψυξης / Holdbarhet: Frysetemperatur / Okres trwałości: temperatura zamrażania / Prazo de validade: Temperatura congelada / Срок хранения: температура замораживания / Hållbarhetstid: Fryst temperatur / Raf ömrir: Donna Sicaklığı / 保质期: 冻结温度 / 有効期間: 凍結時温度 / Rok skladištenja: Temperatura zamrzavanja / 儲架壽命: 冷凍溫度



Unopened Vial Stability: Refrigerated Temperature / Haltbarkeit des ungeöffneten Fläschchens: Kühltemperatur / Stabilité du flacon non ouvert : température de réfrigération / Stabilità provetta non aperta: a temperatura refrigerata / Estabilidad del vial sin abrir: temperatura refrigerada / Stabilitet i uåbnet hætteglas: Nedkølet / Stabilitet van ongeopend flesje: in gekoelde toestand / Avaamattoman ampullin stabiilius: jääkaappilämpötilassa / Σταθερότητα σφραγισμένου φιαλιδίου: θερμοκρασία ψύξης / Stabilitet i uåbnet tilstand: Kjøletemperatur / Stabilność odczynników w nieotwartej fiolce: temperatura chłodzenia / Estabilidade de no frasco fechado: Temperatura refrigerada / Стабильность не вскрытого флакона: температура охлаждения / Hållbarhet vid öppnad flaska: kyld temperatur / Açılmamış Flakon Stabilitesi: Soğutulmuş Sicaklık / 未开封药瓶稳定性: 冷藏温度 / 未开封のバイアル安定性: 冷蔵温度 / Stabilitet neotvorene epruvete: temperatura za čuvanje u hladnjaku / 未开封瓶穩定性: 冷藏溫度



Opened Vial Stability: Refrigerated Temperature / Haltbarkeit des geöffneten Fläschchens: Kühltemperatur / Stabilité du flacon ouvert : température de réfrigération / Stabilità provetta aperta: a temperatura refrigerata / Estabilidad del vial abierto: temperatura refrigerada / Stabilitet i åbnet hætteglas: Nedkølet / Stabilitet van geopend flesje: in gekoelde toestand / Avatun ampullin stabiilius: jääkaappilämpötilassa / Σταθερότητα ανοιγμένου φιαλιδίου: θερμοκρασία ψύξης / Stabilitet i åpnet tilstand: Kjøletemperatur / Stabilność odczynników w otwartej fiolce: temperatura chłodzenia / Estabilidade de no frasco aberto: Temperatura refrigerada / Стабильность вскрытого флакона: температура охлаждения / Hållbarhet vid öppnad flaska: kyld temperatur / Açılmış Flakon Stabilitesi: Soğutulmuş Sicaklık / 已开封药瓶稳定性: 冷藏温度 / 已开封的バイアル安定性: 冷蔵温度 / Stabilitet otvorene epruvete: temperatura za čuvanje u hladnjaku / 已开封瓶穩定性: 冷藏溫度

**REF**

Catalog Number / Katalognummer / Catalogue N° / Numero di catalogo / Número de catálogo / Katalognummer / Catalogusnummer / Tuotenumero / Αριθμός καταλόγου / Katalognummer / Numer katalogowy / Referência / Номер по каталогу / Katalognummer / Katalog Numarası / 目录编号 / Каталог番号 / Kataloški broj / 料號



Manufacturer / Hersteller / Fabricant / Produttore / Fabricante / Producent / Fabrikant / Valmistaja / Κατασκευαστής / Produsent / Producent / Fabricante / Производител / Tillverkare / Üretici / 制造商 / 製造元 / Proizvođač / 製造商



Caution / Vorsicht / Attention / Attenzione / Atención / Forsigtig / Let op / Varoitus / Προσοχή / Advarsel / Przewaga / Cuidado / Осторожно / Viktigt / Dikkat / 注意 / 注意 / Opzre / 注意



Consult instructions for use / Gebrauchsanweisung beachten / Se référer au mode d'emploi / Consultare le istruzioni per l'uso / Consultar las instrucciones de uso / Se brugsanvisningen / Raadpleeg de gebruiksaanwijzing / Katso käyttöohjeita / Συμβουλευτείτε τις οδηγίες χρήσης / Se i bruksanvisningen / Sprawdzić w instrukcji użytkowania / Consultar instruções de utilização / См. инструкцию по применению / Läs bruksanvisningen / Kullanim talimatlarına danışın / 参阅使用说明 / 取扱説明書を参照 / Pogledajte upute za upotrebu / 查閱使用指示

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**IVD**

For In Vitro Diagnostic Use / In-vitro-Diagnostikum / Diagnostics in vitro / Per uso diagnostico in vitro / Para uso en diagnóstico in vitro / Til in vitro-diagnostisk anvendelse / Voor diagnostisch gebruik in vitro / In Vitro -diagnostiseen käyttöön / Για In Vitro διαγνωστική χρήση / For in vitro-diagnostikk / Do stosowania w diagnostyce in vitro / Para utilização em diagnóstico in vitro / Для использования в диагностике in vitro / För in vitro-diagnostisk användning / In Vitro Diagnostik Kullanim İçin / 体外诊断用 / 体外診断用 / Za in vitro dijagnostičku upotrebu / 供體外診斷使用



Biological risk / Biogefährdung / Matériel à risque biologique potentiel / Rischio biologico / Material potencialmente peligroso a nivel biológico / Biologisk risiko / Biologisch risico / Biologinen riski / Βιολογικός κίνδυνος / Biologisk risiko / Zagrożenie biologiczne / Risco biológico / Биологическая опасность / Biologisk risk / Biyolojik risk / 生物风险 / 生物学的リスク / Biološka opasnost / 生物風險

**CE**

CE Marking of Conformity / CE-Konformitätszeichen / Marquage CE de conformité / Marchio di conformità CE / Marca de conformidad CE / CE-mærkning / CE-conformiteitsmerk / CE-merkintä / Σήμανση συμμόρφωσης CE / CE-samsvarsmærking / Oznakowanie zgodności CE / Marca de Conformidade CE / Маркировка соответствия стандартам CE / CE-försäkran om överensstämmelse / CE Uyumluluk İşareti / CE 合格标志 / 適合の CE マーキング / CE oznaka skladnosti / CE 符合性標示

**X̄**

Mean Value / Mittelwert / Valeur moyenne / Valore medio / Valor medio / Gennemsnitsværdi / Gemiddelde waarde / Keskiarvo / Μέση τιμή / Middelværdi / Wartość średnia / Valor médio / Среднее значение / Medelvärde / Ortalama Değer / 平均值 / 平均值 / Srednja vrijednost / 平均值

**<R>**

Expected Range / Erwarteter Bereich / Valeur attendue / Intervallo previsto / Intervallo previsto / Forventet område / Verwachte bereik / Odotettu vaihteluväli / Αναμενόμενο εύρος / Forventet område / Zakres wartości oczekiwanych / Intervallo esperado / Ожидаемый интервал / Förväntat intervall / Beklenen Aralık / 预期范围 / 予測範囲 / Öteklivani raspon / 預期範圍

**U**

Units / Einheiten / Unités / Unità / Unidades / Enheder / Eenheden / Yksiköt / Μονάδες / Enheter / Jednostki / Unidades / Единицы / Enheter / Birimler / 單位 / 單位 / Jedince / 單位

**CON**

Conventional Units / Konventionelle Einheiten / Unités conventionnelles / Unità convenzionali / Unidades convencionales / Konventionelle enheder / Conventionele eenheden / Perinteiset yksiköt / Συμβατικές μονάδες / Konvensjonelle enheter / Jednostki konwencjonalne / Unidades convencionais / Условные единицы / Konventionella enheter / Konvansiyonel Birimler / 常用單位 / 慣用單位 / Konvensionalne jedinice / 常規單位

**SI**

System International Units / SI-Einheiten / Système international d'unités / Unità sistema internazionale / Unidades del sistema internacional / SI-enheder / System International-eeenheden / Kansainväliset yksiköt / Μονάδες διεθνούς συστήματος / SI-enheter / Jednostki w układzie SI / Unidades do Sistema Internacional / Единицы СИ / SI-enheter / Sistem Uluslararası Birimleri / 国际单位 / 國際單位系 / Sustav međunarodnih jedinica / 系統國際單位

**U**

Constituent and Method / Bestandteil und Methode / Composant et méthode / Componente e metodo / Componente y método / Bestanddel og metode / Bestanddeel en methode / Aineosa ja menetelmä / Συστατικό και μέθοδος / Konstituent og metode / Składnik i metoda / Componentes e método / Компонент и метод / Innehåll och metod / Bileşen ve Yöntem / 成分和方法 / 成分および測定法 / Sastojak i metoda / 成分與方法

**If you have any questions concerning this notification, in the USA please contact the Technical Support Department at 800-232-3342 or 510-979-5417. Outside the USA, please contact your local Subsidiary or Distributor.**

Falls Sie Fragen zu dieser Benachrichtigung haben, wenden Sie sich in den USA an den technischen Kundendienst unter 800-232-3342 oder 510-979-5417. Außerhalb der USA wenden Sie sich bitte an die Vertriebsniederlassung in Ihrer Nähe oder an einen autorisierten Vertriebspartner.

Aux États-Unis, pour toute question concernant cet avis, contacter le Service d'assistance technique au 800-232-3342 ou au 510-979-5417. En dehors des États-Unis, contacter la filiale locale ou le distributeur local.

Per domande relative a questa notifica e vi trovate negli Stati Uniti, rivolgersi al servizio di assistenza tecnica al numero verde 800-232-3342 o al numero 510-979-5417. Al di fuori degli Stati Uniti, rivolgersi alla filiale locale o al distributore.

Para cualquier consulta acerca de esta notificación, en EE.UU. póngase en contacto con el Departamento de Asistencia técnica en los números 800-232-3342 or 510-979-5417. Fuera de EE.UU., póngase en contacto con la subsidiaria o el distribuidor local.

Hvis du har nogle spørgsmål til denne meddelelse, kan du kontakte den tekniske supportafdeling på 800-232-3342 eller 510-979-5417, hvis du befinder dig i USA. Uden for USA kan du kontakte det lokale datterselskab eller distributøren.

Als u vragen hebt over deze kennisgeving, kunt u contact opnemen met de afdeling Technische ondersteuning op 800-232-3342 of 510-979-5417. Buiten de VS kunt u contact opnemen met de vestiging of distributeur in uw land.

Jos sinulla on kysyttävää tästä ilmoituksesta, ota Yhdysvalloissa yhteyttä tekniseen tukeen numeroon 800 232 3342 tai 510 979 5417. Ota Yhdysvaltojen ulkopuolella yhteyttä paikalliseen tytäryhtiöön tai jälleenmyyjään.

Για οποιοδήποτε ερωτήσες αναφορικά με την παρούσα ειδοποίηση, εντός Η.Π.Α., επικοινωνήστε με το Τμήμα τεχνικής υποστήριξης στον αριθμό 800-232-3342 ή 510-979-5417. Εκτός Η.Π.Α., επικοινωνήστε με την τοπική σας θυγατρική ή τον τοπικό διανομέα.

Dersom du befinner deg i USA og har spørsmål knyttet til denne orienteringen, kontakt avdelingen for teknisk støtte på 800-232-3342 eller 510-979-5417. Dersom du befinner deg utenfor USA, kontakte din lokale forhandler eller distributør.

W razie jakichkolwiek pytań dotyczących tego powiadomienia, należy skontaktować się z działem wsparcia technicznego pod numerem 800-232-3342 lub 510-979-5417 (na obszarze Stanów Zjednoczonych). Poza obszarem Stanów Zjednoczonych należy skontaktować się z lokalnym oddziałem firmy lub dystrybutorem.

Se tiver quaisquer questões relativas a esta notificação, nos EUA por favor contacte o departamento de assistência técnica através do número 800-232-3342 ou 510-979-5417. Fora dos EUA, por favor contacte a filial da sua área ou o distribuidor local.

Если у вас есть вопросы относительно этого уведомления, в США обращайтесь в департамент технической поддержки по телефону 800-232-3342 или 510-979-5417. За пределами США обращайтесь в местную дочернюю компанию или к дистрибьютору.

Om du har några frågor om den här informationen och befinner dig i USA kan du kontakta vår avdelning för teknisk support på telefonnummer +1 800-232-3342 eller +1 510-979-5417. Utanför USA kan du kontakta ditt lokala avdelningskontor eller en distributör.

Bu bildirimle dair herhangi bir sorunuz varsa, ABD'de lütfen 800-232-3342 veya 510-979-5417 numaralı Teknik Destek Departmanı ile iletişim kurun. ABD'nin dışında, lütfen yerel Bayi veya Dağıtıcı ile iletişim kurun.

如果您有任何关于此通知的问题，在美国国内，请联系 800-232-3342 或 510-979-5417 技术支持部门。在美国以外地区，请联系您当地的分公司或经销商。

本通知に関するお問い合わせについては、米国内からはお電話にて (800-232-3342 または 510-979-5417) テクニカルサポート部門までお問い合わせください。米国外の場合は、地域の子会社または代理店までお問い合わせください。

Ako imate pitanja o ovoj obavijesti, u SAD-u nazovite odjel za tehničku podršku na broj 800-232-3342 ili 510-979-5417. Ako ste izvan SAD-a, obratite se lokalnoj podružnici ili distributeru.

若您對於此通知書有任何疑問，請致電 800-232-3342 或 510-979-5417 聯繫技術支援部門 (美國)。在美國以外地區，請聯繫您當地的子公司或是經銷商。

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