

Technical Bulletin

IB10 sphingotest® LOT-specific Value Assignment for CLINIQA Liquid QC Cardiac Marker Controls for the Nexus IB10

This document contains the IB10 sphingotest® LOT-specific value assignment for the “Liquid QC Cardiac Marker Controls for the Nexus IB10 (REF: IVR-IB66, LOT: 2008053)”, manufactured by Cliniqa Corporation, to be used in conjunction with the Nexus IB10 analyzer.

If your IB10 sphingotest® LOT is not listed below please consult your distributor or you can access the latest revisions of control technical bulletin at <https://www.nexus-dx.com/customer-downloads/>. Any LOTs not specified below should not refer to the values in this document for QC control.

Controls should be stored and used as described in the control manufacturer’s product inserts.
For further inquiries, please directly visit the control manufacturer’s website:

<https://www.cliniqa.com/>

Liquid QC Cardiac Marker Controls for the Nexus IB10

REF: IVR-IB66 LOT: 2008053 Exp.date: 2022-07-31

(LOT Level 1: 2005102, LOT Level 2: 2005103)

Important Information: Please check your sphingotest® LOT number located on the disc pouch and box. The values listed below are Disc Lot-specific. For your analysis, please use the assigned values for the sphingotest® disc LOT you are using!

IB10 sphingotest® Troponin-99 (IVR-IB50)

Disc LOT	Disc Exp. date (mm/dd/yyyy)	Control Level	Biomarker				
			TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7001N34	09/02/2021	Level 1	Target value: 0.72 Lower Limit: 0.40 Upper Limit: 1.04				
		Level 2	Target value: 1.97 Lower Limit: 1.08 Upper Limit: 2.85				
R7001NCM	06/22/2022	Level 1	Target value: 0.90 Lower Limit: 0.50 Upper Limit: 1.31				
		Level 2	Target value: 2.72 Lower Limit: 1.50 Upper Limit: 3.94				
R7001X1B	07/12/2022	Level 1	Target value: 0.76 Lower Limit: 0.42 Upper Limit: 1.11				
		Level 2	Target value: 2.05 Lower Limit: 1.13 Upper Limit: 2.97				



IB10 sphingotest® NT-proBNP (IVR-IB56)

Disc LOT	Disc Exp. date (mm/dd/yyyy)	Control Level	Biomarker				
			Tnl (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7601NAU	05/23/2022	Level 1				Target value: 212.37 Lower Limit: 116.81 Upper Limit: 307.94	
		Level 2				Target value: 1201.40 Lower Limit: 660.77 Upper Limit: 1742.03	
R7601NBG	06/09/2022	Level 1				Target value: 216.14 Lower Limit: 118.88 Upper Limit: 313.41	
		Level 2				Target value: 1096.97 Lower Limit: 603.33 Upper Limit: 1590.60	
R7601X2J	09/12/2022	Level 1				Target value: 186.28 Lower Limit: 102.45 Upper Limit: 270.10	
		Level 2				Target value: 1015.98 Lower Limit: 558.79 Upper Limit: 1473.17	

IB10 sphingotest® D-Dimer (IVR-IB52)

Disc LOT	Disc Exp. date (mm/dd/yyyy)	Control Level	Biomarker				
			TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7201MBI	05/18/2021	Level 1					Target value: 269.18 Lower Limit: 148.05 Upper Limit: 390.31
		Level 2					Target value: 887.18 Lower Limit: 487.95 Upper Limit: 1286.41
R7201N5Q	11/24/2021	Level 1					Target value: 292.10 Lower Limit: 160.66 Upper Limit: 423.55
		Level 2					Target value: 925.94 Lower Limit: 509.27 Upper Limit: 1342.62
R7201N7M	01/20/2022	Level 1					Target value: 349.46 Lower Limit: 192.21 Upper Limit: 506.72
		Level 2					Target value: 1090.42 Lower Limit: 599.73 Upper Limit: 1581.11

IB10 sphingotest® D-Dimer (IVR-IB52)

Disc LOT	Disc Exp. date (mm/dd/yyyy)	Control Level	Biomarker				
			Tnl (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7201X1J	07/20/2022	Level 1					Target value: 313.89 Lower Limit: 172.64 Upper Limit: 455.15
		Level 2					Target value: 1006.37 Lower Limit: 553.50 Upper Limit: 1459.23

IB10 sphingotest® 3-in-1 Cardiac (IVR-IB51)

Disc LOT	Disc Exp. date (mm/dd/yyyy)	Control Level	Biomarker				
			TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7101NA5	11/04/2021	Level 1	Target value: 0.72 Lower Limit: 0.39 Upper Limit: 1.04	Target value: 6.53 Lower Limit: 3.59 Upper Limit: 9.47	no values assigned		
		Level 2	Target value: 2.19 Lower Limit: 1.20 Upper Limit: 3.17	Target value: 15.39 Lower Limit: 8.47 Upper Limit: 22.32	no values assigned		
R7101X3I	04/17/2022	Level 1	Target value: 0.91 Lower Limit: 0.50 Upper Limit: 1.32	Target value: 6.99 Lower Limit: 3.84 Upper Limit: 10.14	no values assigned		
		Level 2	Target value: 2.28 Lower Limit: 1.25 Upper Limit: 3.30	Target value: 16.90 Lower Limit: 9.30 Upper Limit: 24.51	no values assigned		

IB10 sphingotest® SOB (IVR-IB53)

Disc LOT	Disc Exp. date (mm/dd/yyyy)	Control Level	Biomarker				
			Tnl (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7301N20	08/24/2021	Level 1	Target value: 0.79 Lower Limit: 0.43 Upper Limit: 1.14			Target value: 315.46 Lower Limit: 173.50 Upper Limit: 457.42	Target value: 250.07 Lower Limit: 137.54 Upper Limit: 362.60
		Level 2	Target value: 2.29 Lower Limit: 1.26 Upper Limit: 3.32			Target value: 1732.94 Lower Limit: 953.12 Upper Limit: 2512.76	Target value: 943.11 Lower Limit: 518.71 Upper Limit: 1367.51
R7301N40	10/23/2021	Level 1	Target value: 0.75 Lower Limit: 0.41 Upper Limit: 1.09			Target value: 263.03 Lower Limit: 144.67 Upper Limit: 381.39	Target value: 327.20 Lower Limit: 179.96 Upper Limit: 474.43
		Level 2	Target value: 2.23 Lower Limit: 1.23 Upper Limit: 3.24			Target value: 1413.59 Lower Limit: 777.47 Upper Limit: 2049.71	Target value: 977.94 Lower Limit: 537.87 Upper Limit: 1418.02