

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 (YYYY/MM/DD)	Control Level	Biomarker				
			TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7001NCM	2022/06/22	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	2022/07/12	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				
R7001X42	2022/10/01	Level 1	Target value: 0.93 Lower Limit: 0.51 Upper Limit: 1.35				
		Level 2	Target value: 2.34 Lower Limit: 1.29 Upper Limit: 3.40				

IB10 sphingotest® Troponin-99 (IVR-IB50) (cont.)

Disc LOT	Disc Exp. date (YYYY/MM/DD)	Control Level	Biomarker				
			TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7001X6S	2022/06/25	Level 1	Target value: 0.99 Lower Limit: 0.55 Upper Limit: 1.44				
		Level 2	Target value: 2.78 Lower Limit: 1.53 Upper Limit: 4.03				
R7001XB1	2023/05/02	Level 1	Target value: 0.85 Lower Limit: 0.47 Upper Limit: 1.23				
		Level 2	Target value: 2.38 Lower Limit: 1.31 Upper Limit: 3.45				
R7001Y1Q	2023/07/27	Level 1	Target value: 0.97 Lower Limit: 0.54 Upper Limit: 1.41				
		Level 2	Target value: 2.44 Lower Limit: 1.34 Upper Limit: 3.54				

IB10 sphingotest® NT-proBNP (IVR-IB56)

Disc LOT	Disc Exp. date (YYYY/MM/DD)	Control Level	Biomarker				
			TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7601NAU	2022/05/23	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	2022/06/09	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	2022/09/12	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® NT-proBNP (IVR-IB56) (cont.)

Disc LOT	Disc Exp. date (YYYY/MM/DD)	Control Level	Biomarker				
			TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7601X77	2023/01/28	Level 1				Target value: 226.56 Lower Limit: 124.61 Upper Limit: 328.52	
		Level 2				Target value: 1064.73 Lower Limit: 585.60 Upper Limit: 1543.85	
R7601XB8	2023/06/01	Level 1				Target value: 202.91 Lower Limit: 111.60 Upper Limit: 294.22	
		Level 2				Target value: 1117.55 Lower Limit: 614.65 Upper Limit: 1620.45	
R7601Y2H	2023/09/10	Level 1				Target value: 176.73 Lower Limit: 97.20 Upper Limit: 256.25	
		Level 2				Target value: 889.69 Lower Limit: 489.33 Upper Limit: 1290.05	

IB10 sphingotest® D-Dimer (IVR-IB52)

Disc LOT	Disc Exp. date (YYYY/MM/DD)	Control Level	Biomarker				
			TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7201X1J	2022/07/20	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
R7201X5Q	2022/11/24	Level 1					Target value: 329.59 Lower Limit: 181.27 Upper Limit: 477.90
		Level 2					Target value: 1031.30 Lower Limit: 567.21 Upper Limit: 1495.38
R7201X7J	2023/01/17	Level 1					Target Value: 301.36 Lower Limit: 165.75 Upper Limit: 436.97
		Level 2					Total Value: 942.92 Lower Limit: 518.61 Upper Limit: 1367.24

IB10 sphingotest® D-Dimer (IVR-IB52) (cont.)

Disc LOT	Disc Exp. date (YYYY/MM/DD)	Control Level	Biomarker				
			TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7201X9L	2023/03/22	Level 1					Target Value: 313.95 Lower Limit: 172.67 Upper Limit: 455.23
		Level 2					Total Value: 995.07 Lower Limit: 547.29 Upper Limit: 1442.85
R7201XAQ	2023/04/26	Level 1					Target Value: 297.32 Lower Limit: 163.52 Upper Limit: 431.11
		Level 2					Total Value: 949.82 Lower Limit: 522.40 Upper Limit: 1377.23
R7201Y24	2023/08/05	Level 1					Total Value: 268.37 Lower Limit: 147.60 Upper Limit: 389.14
		Level 2					Total Value: 976.29 Lower Limit: 536.96 Upper Limit: 1415.63

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

Disc LOT	Disc Exp. date (YYYY/MM/DD)	Control Level	Biomarker				
			TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7101X3I	2022/04/17	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		
R7101X6E	2022/07/14	Level 1	Target value: 0.89 Lower Limit: 0.49 Upper Limit: 1.29	Target value: 7.33 Lower Limit: 4.03 Upper Limit: 10.63	no values assigned		
		Level 2	Target value: 2.27 Lower Limit: 1.25 Upper Limit: 3.30	Target value: 18.09 Lower Limit: 9.95 Upper Limit: 26.23	no values assigned		
R7101X8I	2022/09/17	Level 1	Target value: 0.94 Lower Limit: 0.51 Upper Limit: 1.36	Target value: 5.98 Lower Limit: 3.29 Upper Limit: 8.68	no values assigned		
		Level 2	Target value: 2.15 Lower Limit: 1.18 Upper Limit: 3.12	Target value: 14.28 Lower Limit: 7.85 Upper Limit: 20.70	no values assigned		

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

Disc LOT	Disc Exp. date (YYYY/MM/DD)	Control Level	Biomarker				
			TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7101X80	2022/09/23	Level 1	Target value: 0.90 Lower Limit: 0.49 Upper Limit: 1.30	Target value: 5.99 Lower Limit: 3.29 Upper Limit: 8.68	no values assigned		
		Level 2	Target value: 2.19 Lower Limit: 1.21 Upper Limit: 3.18	Target value: 15.00 Lower Limit: 8.25 Upper Limit: 21.75	no values assigned		
R7101Y2S	2023/03/30	Level 1	Target value: 0.98 Lower Limit: 0.54 Upper Limit: 1.42	Target value: 5.85 Lower Limit: 3.22 Upper Limit: 8.48	no values assigned		
		Level 2	Target value: 2.63 Lower Limit: 1.45 Upper Limit: 3.82	Target value: 14.06 Lower Limit: 7.73 Upper Limit: 20.38	no values assigned		

IB10 sphingotest® SOB (IVR-IB53)

Disc LOT	Disc Exp. date (YYYY/MM/DD)	Control Level	Biomarker				
			TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7301X4J	2022/10/18	Level 1	Target value: 0.91 Lower Limit: 0.50 Upper Limit: 1.32			Target value: 173.99 Lower Limit: 95.69 Upper Limit: 252.28	Target value: 341.26 Lower Limit: 187.69 Upper Limit: 494.83
		Level 2	Target value: 2.18 Lower Limit: 1.20 Upper Limit: 3.16			Target value: 978.72 Lower Limit: 538.29 Upper Limit: 1419.14	Target value: 1113.20 Lower Limit: 612.26 Upper Limit: 1614.14
R7301X6L	2022/12/20	Level 1	Target value: 0.83 Lower Limit: 0.45 Upper Limit: 1.20			Target value: 205.39 Lower Limit: 112.97 Upper Limit: 297.82	Target value: 332.78 Lower Limit: 183.03 Upper Limit: 482.54
		Level 2	Target value: 2.35 Lower Limit: 1.29 Upper Limit: 3.41			Target value: 1015.81 Lower Limit: 558.69 Upper Limit: 1472.92	Target value: 1047.06 Lower Limit: 575.88 Upper Limit: 1518.24
R7301X7C	2023/01/10	Level 1	Target value: 0.76 Lower Limit: 0.42 Upper Limit: 1.10			Target value: 188.98 Lower Limit: 103.94 Upper Limit: 274.02	Target value: 306.88 Lower Limit: 168.78 Upper Limit: 444.97
		Level 2	Target value: 2.05 Lower Limit: 1.13 Upper Limit: 2.97			Target value: 1023.61 Lower Limit: 562.99 Upper Limit: 1484.24	Target value: 1050.60 Lower Limit: 577.83 Upper Limit: 1523.37

IB10 sphingotest® SOB (IVR-IB53) (cont.)

Disc LOT	Disc Exp. date (YYYY/MM/DD)	Control Level	Biomarker				
			TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	NT-proBNP (pg/mL)	D-Dimer (ng/mL)
R7301XBG	2023/05/17	Level 1	Target value: 0.96 Lower Limit: 0.53 Upper Limit: 1.40			Target value: 171.04 Lower Limit: 94.07 Upper Limit: 248.01	Target value: 351.79 Lower Limit: 193.48 Upper Limit: 510.09
		Level 2	Target value: 2.54 Lower Limit: 1.40 Upper Limit: 3.68			Target value: 1035.91 Lower Limit: 569.75 Upper Limit: 1502.07	Target value: 1050.26 Lower Limit: 577.64 Upper Limit: 1522.88