

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) |
| R7001N34 | 2021/09/02 | 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 | 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 | | | | |



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) |
| 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® NT-proBNP (IVR-IB56)

| Disc LOT | Disc Exp. date (YYYY/MM/DD) | Control Level | Biomarker | | | | |
|----------|--------------------------------|------------------|-------------|-----------------|-------------|--|-----------------|
| | | | Tnl (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® D-Dimer (IVR-IB52)

| Disc LOT | Disc Exp. date (YYYY/MM/DD) | Control Level | Biomarker | | | | |
|----------|--------------------------------|------------------|-------------|-----------------|-------------|-------------------|---|
| | | | Tnl (ng/mL) | CKMB (ng/mL) | MYO (ng/mL) | NT-proBNP (pg/mL) | D-Dimer (ng/mL) |
| R7201MBI | 2021/05/18 | 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 | 2021/11/24 | 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 | 2022/01/20 | 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 (YYYY/MM/DD) | Control Level | Biomarker | | | | |
|----------|--------------------------------|------------------|-------------|-----------------|-------------|-------------------|---|
| | | | Tnl (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 |

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) |
| R7101NA5 | 2021/11/04 | 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 | 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 | | |

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) |
| R7301N2O | 2021/08/24 | 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 |
| R7301N4O | 2021/10/23 | 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 |
| 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 |