

## Technical Bulletin

### Nexus Dx Value Assigned Controls Matrix

This document contains the list of controls that have been value assigned for the IB10 sphingotest® products manufactured by Nexus Dx to be used in conjunction with the Nexus IB10 analyzer.

Control lots and/or control manufacturers not listed below should not be used to QC control any of the Nexus Dx products. 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/>

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

<https://www.invicon.de/>



### Nexus Dx QC Controls Matrix & Value Assignment

Control Manufacturer	Catalog Number	Description	Lot Number	Exp (YYYY/MM/DD)	Biomarker								
					Tnl (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	D-Dimer (ng/mL)	NT-proBNP (pg/mL)	TSH (uIU/mL)	beta-hCG (IU/L)	PCT (ug/L)	
Randox	HS2611	Assayed Chemistry Premium Plus Level 2	1388UN	Batch 506829	2023/03/28						Value: 1.09 Lower Limit: 0.60 Upper Limit: 1.58	Value: 11.31 Lower Limit: 6.22 Upper Limit: 16.40	
	HS2611	Assayed Chemistry Premium Plus Level 3	1087UE	Batch 506829	2023/04/28						Value: 1.08 Lower Limit: 0.59 Upper Limit: 1.56	Value: 71.05 Lower Limit: 39.08 Upper Limit: 103.02	
	HS2611	Assayed Chemistry Premium Plus Level 2	1397UN	Batch 550619	2023/04/28						*Value: 1.49 Lower Limit: 0.82 Upper Limit: 2.17		
	HS2611	Assayed Chemistry Premium Plus Level 3	1103UE	Batch 550619	2023/07/28						*Value: 1.62 Lower Limit: 0.89 Upper Limit: 2.35		
	HS2611	Assayed Chemistry Premium Plus Level 2	1490UN	Batch 578618	2024/06/28						Value: 1.59 Lower Limit: 1.37 Upper Limit: 1.80		
	HS2611	Assayed Chemistry Premium Plus Level 3	1195UE	Batch 578618	2025/04/28						Value: 1.50 Lower Limit: 1.29 Upper Limit: 1.70		
	HS2611	Assayed Chemistry Premium Plus Level 2	1543UN	Batch 590845	2025/03/28						Value: 1.59 Lower Limit: 0.87 Upper Limit: 2.30		
	HS2611	Assayed Chemistry Premium Plus Level 3	1195UE	Batch 590845	2025/03/28						Value: 1.45 Lower Limit: 0.80 Upper Limit: 2.10		
	HS2611	Assayed Chemistry Premium Plus Level 2	1561UN	Batch TBD	2025/11/28						Value: 1.48 Lower Limit: 0.82 Upper Limit: 2.15		
	HS2611	Assayed Chemistry Premium Plus Level 3	1228UN	Batch TBD	2025/11/28						Value: 1.71 Lower Limit: 0.94 Upper Limit: 2.48		
	IAS3113	Immunoassay Specialty I Level 1	2012EC		2022/11/28								Value: 2.99 Lower Limit: 1.64 Upper Limit: 4.34
	IAS3114	Immunoassay Specialty I Level 2	2013EC		2022/11/28								Value: 7.05 Lower Limit: 3.88 Upper Limit: >10
	IAS3113	Immunoassay Specialty I Level 1	2064EC		2023/03/28								Value: 3.92 Lower Limit: 2.16 Upper Limit: 5.68
	IAS3114	Immunoassay Specialty I Level 2	2065EC		2023/03/28								Value: 7.22 Lower Limit: 4.48 Upper Limit: 9.97
	IAS3114	Immunoassay Specialty I Level 2	2096EC		2023/10/28								Value: 9.07 Lower Limit: 4.99 Upper Limit: >10
Cliniq	IVR-IB66 (83068)	Liquid QC Cardiac Marker Controls for Nexus IB10	Set: 2008053 (L1: 2005102) (L2: 2005103)		2022/07/31	Please refer to the 'LOT-specific VA for Cliniqa Liquid QC Cardiac Marker Control for the Nexus IB10' on the Nexus website <a href="https://www.nexus-dx.com/customer-downloads/">https://www.nexus-dx.com/customer-downloads/</a>							

\* Important Information: Re-assigned values, valid from 2021/09/16

## Nexus Dx QC Controls Matrix & Value Assignment – According to Rili-BÄK

(According to the decision of the Board of Directors of the German Medical Association at its meeting on 18.10.2019)

Control Manufacturer	Catalog Number	Description	Lot Number	Exp (YYYY/MM/DD)	Biomarker							
					Tnl (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	D-Dimer (ng/mL)	NT-proBNP (pg/mL)	TSH (mIU/L)	beta-hCG (IU/L)	PCT (ug/L)
Invicon	110321	Seronorm™ Immunoassay Lyo L-1	2010908	2025/02/28						Value: 4.28 Lower Limit: 3.70 Upper Limit: 4.86		
	110322	Seronorm™ Immunoassay Lyo L-2	2011909	2025/02/28						Value: 11.8 Lower Limit: 10.2 Upper Limit: 13.4		

Control Manufacturer	Catalog Number	Description	Lot Number	Exp (YYYY/MM/DD)	Biomarker								
					Tnl (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	D-Dimer (ng/mL)	NT-proBNP (pg/mL)	TSH (uIU/mL)	beta-hCG (IU/L)	PCT (ug/L)	
Randox	HS2611	Assayed Chemistry Premium Plus Level 2	1388UN	batch 506829	2023/03/28						Value: 1.09 Lower Limit: 0.94 Upper Limit: 1.24	Value: 11.31 Lower Limit: 9.39 Upper Limit: 13.23	
	HS2611	Assayed Chemistry Premium Plus Level 3	1087UE		2023/04/28						Value: 1.08 Lower Limit: 0.93 Upper Limit: 1.23	Value: 71.05 Lower Limit: 58.97 Upper Limit: 83.13	
	HS2611	Assayed Chemistry Premium Plus Level 2	1397UN	batch 550619	2023/04/28						*Value: 1.49 Lower Limit: 1.29 Upper Limit: 1.69		
	HS2611	Assayed Chemistry Premium Plus Level 3	1103UE		2023/07/28						*Value: 1.62 Lower Limit: 1.40 Upper Limit: 1.84		
	HS2611	Assayed Chemistry Premium Plus Level 2	1490UN	batch 578618	2024/06/28						Value: 1.59 Lower Limit: 1.38 Upper Limit: 1.80		
	HS2611	Assayed Chemistry Premium Plus Level 3	1195UE		2025/04/28						Value: 1.50 Lower Limit: 1.30 Upper Limit: 1.70		
	HS2611	Assayed Chemistry Premium Plus Level 2	1543UN	Batch 590845	2025/03/28						Value: 1.59 Lower Limit: 1.38 Upper Limit: 1.80		
	HS2611	Assayed Chemistry Premium Plus Level 3	1195UE		2025/03/28						Value: 1.45 Lower Limit: 1.25 Upper Limit: 1.65		
	HS2611	Assayed Chemistry Premium Plus Level 2	1561UN	Batch TBD	2025/11/28						Value: 1.48 Lower Limit: 1.28 Upper Limit: 1.68		
	HS2611	Assayed Chemistry Premium Plus Level 3	1228UN		2025/11/28						Value: 1.71 Lower Limit: 1.48 Upper Limit: 1.94		



Control Manufacturer	Catalog Number	Description	Lot Number	Exp (YYYY/MM/DD)	Biomarker							
					TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	D-Dimer (ng/mL)	NT-proBNP (pg/mL)	TSH (uIU/mL)	TnI (ng/mL)	PCT (ug/L)
Randox	IAS3113	Immunoassay Specialty I Level 1	2012EC	2022/11/28								Value: 2.99 Lower Limit: 2.45 Upper Limit: 3.53
	IAS3114	Immunoassay Specialty I Level 2	2013EC	2022/11/28								Value: 7.05 Lower Limit: 5.78 Upper Limit: 8.32
	IAS3113	Immunoassay Specialty I Level 1	2064EC	2023/03/28								Value: 3.92 Lower Limit: 3.21 Upper Limit: 4.63
	IAS3114	Immunoassay Specialty I Level 2	2065EC	2023/03/28								Value: 7.22 Lower Limit: 5.92 Upper Limit: 8.52
	IAS3114	Immunoassay Specialty I Level 2	2096EC	2023/10/28								Value: 9.07 Lower Limit: 7.44 Upper Limit: >10

\* Important Information: Re-assigned values. valid from 2021/09/16

Control Manufacturer	Catalog Number	Description	Lot Number	Exp (YYYY/MM/DD)	Biomarker								
					TnI (ng/mL)	CKMB (ng/mL)	MYO (ng/mL)	D-Dimer (ng/mL) Rili-BÄK 2019	NT-proBNP (pg/mL) Rili-BÄK 2019	TSH (uIU/mL)	TnI (ng/mL)	PCT (ug/L) Rili-BÄK 2019	
Cliniqa	IVR-IB66 (83068)	Liquid QC Cardiac Marker Controls for Nexus IB10	Set: 2008053 (L1: 2005102) (L2: 2005103)	2022/07/31	Please refer to the 'LOT-specific VA for Cliniqa Liquid QC Cardiac Marker Control for the Nexus IB10' on the Nexus website <a href="https://www.nexus-dx.com/customer-downloads/">https://www.nexus-dx.com/customer-downloads/</a>								