

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.thermofisher.com/us/en/home.html>

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



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	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	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	2023/04/28						**Value: 1.49 Lower Limit: 0.82 Upper Limit: 2.17				
	HS2611	Assayed Chemistry Premium Plus Level 3	1103UE	2023/07/28						**Value: 1.62 Lower Limit: 0.89 Upper Limit: 2.35				
	HS2611	Assayed Chemistry Premium Plus Level 2	1490UN	2024/06/28						Value: 1.59 Lower Limit: 1.37 Upper Limit: 1.80				
	HS2611	Assayed Chemistry Premium Plus Level 3	1195UE	2025/04/28						Value: 1.50 Lower Limit: 1.29 Upper Limit: 1.70				
	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	1943EC	2021/11/28								*Value: 2.99 Lower Limit: 1.64 Upper Limit: 4.33		
	IAS3114	Immunoassay Specialty I Level 2	1944EC	2021/11/28								*Value: 7.40 Lower Limit: 4.07 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: 5.92 Upper Limit: 8.52		
Cliniq	IVR-IB66 (83068)	Liquid QC Cardiac Marker Controls for Nexus IB10	Set: 2008053 (L1: 2005102) (L1: 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 https://www.nexus-dx.com/customer-downloads/									

* Important Information: Re-assigned values, valid from 2021/05/04
 ** 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)	NT-proBNP (pg/mL)	TSH (uIU/mL)	beta-hCG (IU/L)	PCT (ug/L)
Thermo Fisher	ORCD-101	TMO Omni MAS (Level 1)	OCRD22011A	2022/01/31	Value: 3.14 Lower Limit: 1.73 Upper Limit: 4.55			Value: 1941.90 Lower Limit: 1068.05 Upper Limit: 2815.76	Value: 1275.59 Lower Limit: 701.57 Upper Limit: 1849.60			Value: 1.51 Lower Limit: 0.83 Upper Limit: 2.18
	ORCD-202	TMO Omni MAS (Level 2)	OCRD22012A	2022/01/31	Value: 5.26 Lower Limit: 2.89 Upper Limit: 7.63							Value: 12.26 Lower Limit: 6.74 Upper Limit: 17.78
	ORCD-UL	TMO Omni MAS (Level UL)	OCRD2201UA	2022/01/31								Value: 1.00 Lower Limit: 0.55 Upper Limit: 1.44
	ORCD-L	TMO Omni MAS (Level L)	OCRD2201LA	2022/01/31								Value: 0.91 Lower Limit: 0.50 Upper Limit: 1.32