

N Latex IgD Kit

ANNEX to IFU: *Atellica® NEPH 630 / BN ProSpec® Systems* - Proposal of Application

REF TD-42650 - IgD Immunoglobulins - for *BN™ Series and Atellica® NEPH 630*

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Reagent-Definition

Reagent-ID:	6668	Name:	IgD Ab	Longname:	REAG IgD Ab
Bottle-Type:	GW 5	Cooltime:	0		
Reagent-ID:	6717	Name:	IgD Enh1	Longname:	REAG IgD Enh 1
Bottle-Type:	GW 5	Cooltime:	0		
Reagent-ID:	6718	Name:	IgD Enh2	Longname:	REAG IgD Enh 2
Bottle-Type:	GW 5	Cooltime:	0		

Calibrator-Definition

Calibrator-ID:	6714	Name:	IGD CAL L
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Control-Definition

Control-ID:	6715	Name:	IgD Control H	Longname:	IgD Control H
Bottle-Type:	GW 2.5	Cooltime:	0		
Control-ID:	6716	Name:	IgD Control L	Longname:	IgD Control L
Bottle-Type:	GW 2.5	Cooltime:	0		

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Assay-Definition

Assay-ID:	210	Name:	IgDn	long name:	IgD TD v2
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Version:	200	Assayclass:	Neph	Assaygroup:	Serum
Result unit:	mg/dl	lower reference range		upper reference range	9999999999
Sample dilution:	1:20	Min. dilution:	1:5		
Max. dilution:	unassigned				
<u>Evaluation:</u>					
Measurement duration [1/10 sec.]:	8160	Measurement transfer:			2
Evaluation method:	9 - Two point (BNP)				
Measurement window [1/10 sec.] from:			300	until:	6000
Blockmode:	0	Overflow:	0		
<u>Calibration:</u>					
Calibration method:	LogitLog	Deviation [%]:	10	Calibration valid until:	0
Calibrator:	6714 - IGD CAL L				
Start dilution:	1:5	Supporting points:	5		
<u>Prereaction:</u>					
Evaluation method:	8 - Two point (BNII)				
Measurement window [1/10 sec.] from:			75	until:	1680
<u>Compare:</u>					
Compare 1:	1,2	Compare 2:	50		
<u>Special parameters:</u>					
Parameter 1:	2	Parameter 2:	0,5	Parameter 3:	-30
				Parameter 4:	80
<u>Controls</u>					
Control-ID	6715	Name	IgD Control H		
Dilution	1:20	Deviation [%]	20	Level	High
Control-ID	6716	Name	IgD Control L		
Dilution	1:20	Deviation [%]	20	Level	Low

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Assay-Definition

Assay-ID: 210 Name: IgDn long name: IgD TD v2

Transfers:

Transfer number: 1

Mixing: normal Start wash: 13 - intensive End wash: 06 - goto waste
 Incubation time [1/10 sec.]: 0 Incubation delta [1/10 sec.]: 0

Medium:

Medium number: 1
 Type: SystemLiquid Medium ID: Diluens
 Syringe profile: 7 Volume [µl]: 10

Medium number: 2
 Type: SystemLiquid Medium ID: Air bubble
 Syringe profile: 2 Volume [µl]: 2

Medium number: 3
 Type: Reagent Medium ID: 6717 - IgD Enh1
 Syringe profile: 5 Volume [µl]: 90

Medium number: 4
 Type: Reagent Medium ID: 6718 - IgD Enh2
 Syringe profile: 3 Volume [µl]: 90

Medium number: 5
 Type: SystemLiquid Medium ID: Air bubble
 Syringe profile: 2 Volume [µl]: 2

Medium number: 6
 Type: Sample
 Syringe profile: 5 Volume [µl]: 3

Medium number: 7
 Type: Destination
 Syringe profile: 5 Volume [µl]: -197

Transfer number: 2

Mixing: normal Start wash: 06 - goto waste End wash: 06 - goto waste
 Incubation time [1/10 sec.]: 1980 Incubation delta [1/10 sec.]: 180

Medium:

Medium number: 1
 Type: SystemLiquid Medium ID: Diluens
 Syringe profile: 7 Volume [µl]: 10

Medium number: 2
 Type: SystemLiquid Medium ID: Air bubble
 Syringe profile: 2 Volume [µl]: 2

Medium number: 3
 Type: Reagent Medium ID: 6668 - IgD Ab
 Syringe profile: 5 Volume [µl]: 20

Medium number: 4
 Type: Destination
 Syringe profile: 5 Volume [µl]: -32

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Assay-Definition

Assay-ID:	210	Name:	IgDn	long name:	IgD TD v2
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Transfer number:	3				
Mixing:	normal	Start wash:	13 - intensive	End wash:	06 - goto waste
Incubation time [1/10 sec.]:	0	Incubation delta [1/10 sec.]:	0		
<u>Medium:</u>					
Medium number:	1	Type:	SystemLiquid	Medium ID:	Diluens
		Syringe profile:	7	Volume [µl]:	10
Medium number:	2	Type:	SystemLiquid	Medium ID:	Air bubble
		Syringe profile:	2	Volume [µl]:	2
Medium number:	3	Type:	Sample		
		Syringe profile:	5	Volume [µl]:	12
Medium number:	4	Type:	Destination		
		Syringe profile:	5	Volume [µl]:	-24