

## N Latex IgD Kit

### ANNEX to IFU: *BN™ II System* - Proposal of Application

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

*BN™* and *Atellica®* are registered trademarks of *Siemens Healthcare Diagnostics Products GmbH, Marburg, Deutschland*

#### Reagent Definition

**Antiserum Reagent** ( **REF TD-42645-RA** - **REAG** **Ab** **IgD** )

Reagent	
<input type="text" value="6668"/>	
Identification	
<input type="text" value="REAG IgD Ab"/>	<input type="text" value="IgD-Ab"/>
Name	Abbreviation
Bottle size	<input type="text" value="5 ml"/>

**Enhancer Reagent 1** ( **REF TD-42645-B1** - **REAG** **Enh-1** **IgD** )

Reagent	
<input type="text" value="6717"/>	
Identification	
<input type="text" value="REAG IgD Enh-1"/>	<input type="text" value="IgD-E1"/>
Name	Abbreviation
Bottle size	<input type="text" value="5 ml"/>

**Enhancer Reagent 2** ( **REF TD-42645-B2** - **REAG** **Enh-2** **IgD** )

Reagent	
<input type="text" value="6718"/>	
Identification	
<input type="text" value="REAG IgD Enh-2"/>	<input type="text" value="IgD-E2"/>
Name	Abbreviation
Bottle size	<input type="text" value="5 ml"/>

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#### Calibrator Definition

Low Calibrator ( REF TD-42658 - CAL L IgD )

IgD CAL L	
Name	
6714	120
Identification	Expiration (min)
<input type="checkbox"/> zero calibrator	
Bottle size	2 ml

Points on curve	5
Start dilution	1:5
<input type="checkbox"/> with zero calibrator	Identification
<input type="checkbox"/> Extrapolation...	0 bits
	Value
	10 %
	permitted deviation

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#### Control Definition

**High Control** ( REF TD-42659-H - CONTROL H IgD )

Name

       
 Identification      Expiration (min)

Bottle size     

IgD Control H  
 Control

---

% permitted deviation      dilution     

**Sequence :**

at the beginning of the sample series  
 every  measurement(s)      first control after       measurement(s)

at the end of the sample series

**Low Control** ( REF TD-42659-L - CONTROL L IgD )

Name

       
 Identification      Expiration (min)

Bottle size     

IgD Control L  
 Control

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% permitted deviation      dilution     

**Sequence :**

at the beginning of the sample series  
 every  measurement(s)      first control after       measurement(s)

at the end of the sample series

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#### Assay Name

Assay name			
<input type="text" value="IgDn"/>	<input type="text" value="IgD TD - 2.0"/>		
Abbreviation	Assay name		
<input type="text" value="9995"/>	<input type="text" value="400"/>	<input type="text" value="2.0"/>	<input type="text" value="0"/>
Identification for host	Position in list	Version	Siemens Assay No.
Derived from assay	<input type="text" value="0"/>		
Sample Type	<input type="text" value="Serum"/> <small>Set the number to 0 in order to delete the connection to the original assay.</small>		
<input checked="" type="checkbox"/> Allow multiple lots			
<input type="checkbox"/> Mini-batch			
<input type="checkbox"/> Do not interrupt preparation			

#### Measurement

Measurement			
Method	<input type="text" value="Fixed-time"/>	<input type="text" value="0.000"/>	mg/dl
		Lower measuring range limit	
<input checked="" type="checkbox"/> Prereaction			
<input type="text" value="7.5"/>	<input type="text" value="180.0"/>	<input type="text" value="1.2"/>	<input type="text" value="50.0"/>
Start prereaction	Stop prereaction [sec]	Factor	Constant to be added
<input type="text" value="30.0"/>	<input type="text" value="600.0"/>	<input type="text" value="4"/>	
Initial measurement [sec]	Last measurement [sec]	Number of averaging points	
VLinIntegral			
<input type="text" value="0.0"/>	<input type="text" value="3"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>
Start evaluation [sec]	Polynomial regress.	Upper preeval. rate	Min. search window
<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>
Stop evaluation [sec]	Preeval. window	Lower preeval. rate	Min. regression time
<input type="text" value="0"/>	<input type="text" value="0.0"/>	<input type="checkbox"/> Variable start of eval.	
Integral area	Upper max. eval. offset		

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#### Remeasurement

**Remeasurement**

Remeasurement in  higher dilution  
 lower dilution

Lower remeasurement limit    Upper remeasurement limit    max. no. of remeas.

If result within limits remeasure in

Take

#### Result

**Result**

Unit

no. of digits after decimal point    Conversion factor from mg/l to IU/l    Conversion factor from mg/l to U/l    Conversion factor from mg/l to mol

#### Sample Dilution / Turbidity Check

**Sample dilution**

Sample dilution

Minimum dilution

**Turbidity check**

Bit     %     Bit  
 Turbidity threshold    Turbidity factor    Upper limit of turbidity check

If you do not wish the turbidity check to be performed, set all values to 0.

#### Washing

**Washing**

Cuvette contamination    Dilution probe contamination

Cuvette washing intensity    Dilution probe rinsing intensity

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#### Technical Parameters

##### Transfer Step no. 1

No. of transfer steps: <table style="display: inline-table; border: none;"> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;">2</td> <td style="text-align: center;">3</td> <td style="text-align: center;">4</td> <td style="text-align: center;">5</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/> <input checked="" type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="checkbox"/> <input type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="checkbox"/> <input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/> <input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/> <input type="checkbox"/></td> </tr> </table>		1	2	3	4	5	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Clean cuvette after preincubation <input type="checkbox"/> Clean cuvette for preparation	
1	2	3	4	5									
<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>									
		1	1										
		Rinsing cycles		Transfer repeats									
Transfer arm	right	1	1000000	10000000									
		Washing program no.	Probe cleaning intensity	Probe rinsing intensity									
System liquid	Diluent	10	10	4									
		Volume [µl]	Dispensing program no.										
Air bubble	Reagent...	10	90	3									
		Volume [µl]	Dispensing program no.										
Reagent	Reagent... IgD-E1	90	90	3									
		Volume [µl]	Dispensing program no.										
Reagent	Reagent... IgD-E2	90	3	2									
		Volume [µl]	Dispensing program no.										
Sample	Reagent...	3	0.600	3									
		Volume [µl]	Mixing time [sec]	Dispensing program no.									
		Dispensing procedure:		6									
		0	0										
		Minimum	Maximum										
<input type="checkbox"/> Preincubation [sec]													
<input type="checkbox"/> Start measurement after this transfer step													

Reagent selection

- RbP
- REAG C1q Ab
- REAG C1q Enh
- REAG C5 Ab
- REAG C5 Enh
- REAG FB Ab
- REAG FB Enh
- REAG IgD Ab
- REAG IgD Enh
- REAG IgD Enh-1

Influences reference curve

Reagent selection

- REAG C1q Ab
- REAG C1q Enh
- REAG C5 Ab
- REAG C5 Enh
- REAG FB Ab
- REAG FB Enh
- REAG IgD Ab
- REAG IgD Enh
- REAG IgD Enh-1
- REAG IgD Enh-2

Influences reference curve

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### ANNEX to IFU: *BN™ II System* - Proposal of Application

#### Technical Parameters

##### Transfer Step no. 2

No. of transfer steps: <table style="display: inline-table; border: none;"> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;">2</td> <td style="text-align: center;">3</td> <td style="text-align: center;">4</td> <td style="text-align: center;">5</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>		1	2	3	4	5	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Clean cuvette after preincubation	
1	2	3	4	5									
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									
		1	1	<input type="checkbox"/> Clean cuvette for preparation									
		Rinsing cycles		Transfer repeats									
Transfer arm	left	1	0	0									
		Washing program no.	Probe cleaning intensity	Probe rinsing intensity									
System liquid	Diluent	10	10	1									
		Volume[ $\mu$ l]	Volume[ $\mu$ l]	Dispensing program no.									
Air bubble	Reagent...	10	10	3									
		Volume[ $\mu$ l]	Volume[ $\mu$ l]	Dispensing program no.									
Reagent	Reagent... IgD-Ab	20	20	3									
		Volume[ $\mu$ l]	Volume[ $\mu$ l]	Dispensing program no.									
...	Reagent...	0	0	1									
		Volume[ $\mu$ l]	Volume[ $\mu$ l]	Dispensing program no.									
...	Reagent...	0	0	1									
		Volume[ $\mu$ l]	Volume[ $\mu$ l]	Dispensing program no.									
Dispensing procedure:		0.600	0.600	3									
		Mixing time [sec]	Mixing time [sec]	Dispensing program no.									
<input checked="" type="checkbox"/> Preincubation [sec]	162	216	216										
		Minimum	Maximum										
<input checked="" type="checkbox"/> Start measurement after this transfer step													

Reagent selection

Myoglobin
Myo Suppl. Reag. "A"
N FLC kappa
N FLC lambda
Plasminogena
Prealbumina
RbP
REAG C1q Ab
REAG C1q Enh
REAG IgD Ab

Influences reference curve

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#### Technical Parameters

##### Transfer Step no. 3

No. of transfer steps: <table style="display: inline-table; border: none;"> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;">2</td> <td style="text-align: center;">3</td> <td style="text-align: center;">4</td> <td style="text-align: center;">5</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>		1	2	3	4	5	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Clean cuvette after preincubation	
1	2	3	4	5									
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>									
		1	1	<input type="checkbox"/> Clean cuvette for preparation									
		Rinsing cycles		Transfer repeats									
Transfer arm	right	1	1000000	10000000									
		Washing program no.	Probe cleaning intensity	Probe rinsing intensity									
System liquid	Diluent	10	4	Dispensing program no.									
		Volume [µl]											
Air bubble	Reagent...	10	3	Dispensing program no.									
		Volume [µl]											
Sample	Reagent...	12	3	Dispensing program no.									
		Volume [µl]											
...	Reagent...	0	1	Dispensing program no.									
		Volume [µl]											
...	Reagent...	0	1	Dispensing program no.									
		Volume [µl]											
Dispensing procedure:		0.600	6	Dispensing program no.									
		Mixing time [sec]											
<input type="checkbox"/> Preincubation [sec]	0	0											
		Minimum	Maximum										
<input type="checkbox"/> Start measurement after this transfer step													