

N C5 Kit

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

REF TD-42570 - C5 Complement - for *BN™ Series and Atellica® NEPH 630*

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Reagent Definition

Antiserum Reagent (REF TD-42565-RA - REAG Ab C5)

Reagent	
6702	Identification
REAG C5 Ab	C5-AB
Name	Abbreviation
Bottle size	5 ml

Enhancer Reagent (REF TD-42565-B - REAG Enh C5)

Reagent	
6797	Identification
REAG C5 Enh	C5-Enh
Name	Abbreviation
Bottle size	5 ml

Calibrator Definition

Low Calibrator (REF TD-42578 - CAL L C5)

C5 CAL L	
Name	
6708	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-42579-H - CONTROL H C5)

C5 Control H
 Name

6709 Identification 120 Expiration (min)

Bottle size 2 ml

C5 Control H Control	C5-TD Assay
20.0 % permitted deviation	
dilution 1:20	
Sequence :	
<input type="checkbox"/> at the beginning of the sample series	
every 0 measurement(s)	first control after -1 measurement(s)
<input type="checkbox"/> at the end of the sample series	

Low Control (REF TD-42579-L - CONTROL L C5)

C5 Control L
 Name

6710 Identification 120 Expiration (min)

Bottle size 2 ml

C5 Control L Control	C5-TD Assay
20.0 % permitted deviation	
dilution 1:20	
Sequence :	
<input type="checkbox"/> at the beginning of the sample series	
every 0 measurement(s)	first control after -1 measurement(s)
<input type="checkbox"/> at the end of the sample series	

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Assay Name

Assay name			
<input type="text" value="C5-TD"/>	<input type="text" value="C5"/>		
Abbreviation	Assay name		
<input type="text" value="220"/>	<input type="text" value="220"/>	<input type="text" value="210614"/>	<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		Set the number to 0 in order to delete the connection to the original assay.	
<input type="text" value="Serum"/>			
<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 type="checkbox"/> Prereaction			
<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="1.0"/>	<input type="text" value="0.0"/>
Start prereaction	Stop prereaction [sec]	Factor	Constant to be added
<input type="text" value="30.0"/>	<input type="text" value="1080.0"/>	<input type="text" value="10"/>	
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:		<input type="checkbox"/> Clean cuvette after preincubation	
1 <input checked="" type="checkbox"/>	2 <input checked="" type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
5 <input type="checkbox"/>	1 <input type="checkbox"/>	1 <input type="checkbox"/>	<input type="checkbox"/> Clean cuvette for preparation
		Rinsing cycles	Transfer repeats
Transfer arm	right	1	1000000
		Washing program no.	Probe cleaning intensity
		10000000	Probe rinsing intensity
System liquid	Buffer	80	4
		Volume [µl]	Dispensing program no.
Reagent	Reagent... C5-Enh	20	2
		Volume [µl]	Dispensing program no.
Sample	Reagent...	60	2
		Volume [µl]	Dispensing program no.
...	Reagent...	0	1
		Volume [µl]	Dispensing program no.
...	Reagent...	0	1
		Volume [µl]	Dispensing program no.
Dispensing procedure:		0.600	7
		Mixing time [sec]	Dispensing program no.
<input type="checkbox"/> Preincubation [sec]	0	0	
	Minimum	Maximum	
<input type="checkbox"/> Start measurement after this transfer step			

Reagent selection

- Myo Suppl. Reag. "A"
- N FLC kappa
- N FLC lambda
- Plasminogena
- Prealbumina
- RbP
- REAG C1 q Ab
- REAG C1 q Enh
- REAG C5 Ab
- REAG C5 Enh

Influences reference curve

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Technical Parameters

Transfer Step no. 2

No. of transfer steps: 1 2 3 4 5

Clean cuvette after preincubation
 Clean cuvette for preparation

Rinsing cycles: 1 Transfer repeats: 1

Transfer arm: left Washing program no.: 1 Probe cleaning intensity: 0 Probe rinsing intensity: 0

System liquid: Buffer Volume [µl]: 60 Dispensing program no.: 1

Reagent: C5-AB Volume [µl]: 20 Dispensing program no.: 2

Volume [µl]: 0 Dispensing program no.: 1

Volume [µl]: 0 Dispensing program no.: 1

Volume [µl]: 0 Dispensing program no.: 1

Volume [µl]: 0 Dispensing program no.: 1

Volume [µl]: 0 Dispensing program no.: 1

Dispensing procedure: 0.600 Mixing time [sec]: 1 Dispensing program no.: 1

Preincubation [sec]: 0 Minimum Maximum

Start measurement after this transfer step

Reagent selection

- Mioglobina
- Myo Suppl. Reag. "A"
- N FLC kappa
- N FLC lambda
- Plasminogena
- Prealbumina
- RbP
- REAG C1q Ab
- REAG C1q Enh
- REAG C5 Ab

Influences reference curve