

N C3Pa Kit

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

REF TD-42720 - C3 Proactivator / Factor B - for *BN™ Series and Atellica® NEPH 630*

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Reagent Definition

Antiserum Reagent (REF TD-42715-RA - REAG Ab FB)

Reagent	
6704	
Identification	
REAG FB Ab	FB-Ab
Name	Abbreviation
Bottle size	5 ml

Enhancer Reagent (REF TD-42715-B - REAG Enh FB)

Reagent	
6794	
Identification	
REAG FB Enh	FB-Enh
Name	Abbreviation
Bottle size	5 ml

Calibrator Definition

Low Calibrator (REF TD-42727-L - CAL L FB)

FB CAL L	
Name	
6711	120
Identification	Expiration (min)
<input type="checkbox"/> zero calibrator	
Bottle size	2 ml

Points on curve	5
Start dilution	1:2.5
<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-42728-H - **CONTROL H FB**)

FB Control H
 Name

6712 120
 Identification Expiration (min)

Bottle size 2 ml

FB Control H Control	FB-TD Assay

20.0 % permitted deviation	dilution 1:5

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-42728-L - **CONTROL L FB**)

FB Control L
 Name

6713 120
 Identification Expiration (min)

Bottle size 2 ml

FB Control L Control	FB-TD Assay

20.0 % permitted deviation	dilution 1:5

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="FB-TD"/>	<input type="text" value="Factor B"/>		
Abbreviation	Assay name		
<input type="text" value="115"/>	<input type="text" value="115"/>	<input type="text" value="210615"/>	<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"/>	Set the number to 0 in order to delete the connection to the original assay.	
<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	2	3	4
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	1	1	<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	90	4
		Volume[μ l]	Dispensing program no.
Reagent	Reagent...	FB-Enh	35
			Volume[μ l]
Sample	Reagent...	15	2
			Volume[μ l]
...	Reagent...	0	2
			Volume[μ l]
...	Reagent...	0	1
			Volume[μ l]
		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

- N FLC lambda
- Plasminogena
- Prealbumina
- RbP
- REAG C1q Ab
- REAG C1q Enh
- REAG C5 Ab
- REAG C5 Enh
- REAG FB Ab
- REAG FB 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
 Rinsing cycles: 1 Transfer repeats: 1 Clean cuvette for preparation

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

System liquid: Buffer
 Reagent: Reagent... FB-Ab
 ... Reagent...
 ... Reagent...
 ... Reagent...

Volume [µl]: 80, 20, 0, 0, 0, 0
 Dispensing program no.: 1, 2, 1, 1, 1, 1

Dispensing procedure: 0.600
 Mixing time [sec]: 0 (Minimum) 0 (Maximum)

Preincubation [sec]: 0
 Start measurement after this transfer step

Reagent selection

- N FLC kappa
- N FLC lambda
- Plasminogena
- Prealbumina
- RbP
- REAG C1q Ab
- REAG C1q Enh
- REAG C5 Ab
- REAG C5 Enh
- REAG FB Ab

Influences reference curve