The NGAL Test™

For your clinical chemistry analyzer

PERFORMANCE DATA AND APPLICATION NOTE FOR

ROCHE COBAS® C501/C502[1]

The NGAL Test™ Reagent Kit CE IVD

REF/Cat. No.	ST001CA		ST002CA	ST003CA
Product name	The NGAL Test™ Reagent Kit		The NGAL Test™ Calibrator Kit	The NGAL Test™ Control Kit
	R1	R2	150, 600, 1500, 3000, 5000 ng/mL	Low and High
	1 x 35 mL	1 x 7 mL	5 x 1 mL	3 x 1 mL x 2 levels

Number of determinations: 1 mL of immunoparticle suspension R2 provides 20 cuvette readings with the provided settings in this application. The dead volume of the analyzer and reagent container should be added when calculating the required amount of reagent.

To use BioPorto's The NGAL Test™ on the cobas® c 501/c502 chemistry analyzer the reagents must first be transferred into new containers. The appropriate containers are called cobas® c pack MULTI1 and can be ordered via your local Roche representative.
Please make sure to acquire the following two items:

Item	Cat. No.	Product name	
Empty reagent carrier	04593138 190	cobas® c pack MULTI	Order from Roche
Open/close tool			Request from Roche

Read the instructions for The NGAL Test™ (ST001) and cobas® c pack MULTI before transferring the reagents.

FILLING THE COBAS C PACK MULTI:

1. Turn the **cobas** c pack MULTI towards you as shown at the right.
2. Unscrew the screw cap of the bottle in **position A** in the center of the **cobas c** pack MULTI using the open/ close tool.
3. Pipette 18 mL of The NGAL Test™ Reaction Buffer R1 into the open bottle of the cobac c pack MULTI (position A)*.
4. Close the bottle tightly using the open/close tool.
5. Unscrew the screw cap of the bottle in **position C** on the right side of the **cobas c** pack MULTI using the open/close tool.
6. Pipette the full volume (7 mL) of The NGAL Test™ Reagent R2 into the open bottle of **cobas c** pack (position C).
7. Close the bottle tightly using the open/close tool.
8. Leave the bottle in position B on the left side of the **cobas c** pack MULTI empty.

* The remaining 17 mL of Reaction Buffer R1 are surplus and can be discarded.

NOTE

Before loading the **cobas c** pack MULTI onto the instrument, it has to be reserved for a development channel application.
Once a cobas c pack MULTI is removed from the instrument, it cannot be reloaded. When loaded onto the instrument, each **cobas c** pack MULTI is registered as full in the reagent inventory. Therefore, if a used and/or only partially filled cobas c pack MULTI is loaded onto the instrument, the number of tests may be reduced or it may be refused by the instrument.

PRECAUTIONS

Do not pipette by mouth.
Do not shake the reagents.
Use only clean containers if transferring reagents.
Do not pour reagents back into their original containers once transferred.
Do not use reagents after the expiry date on the labels.
Do not switch caps on reagent containers as it may cause contamination or mix-up.
Reagents with different lot numbers should not be mixed.
All solutions supplied should be handled carefully and disposed of in accordance with national and local regulations.

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51009/22062012/e · Revision APP2012-08 IVD

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PERFORMANCE DATA

The performance data shown were obtained by the manufacturer for this particular analyzer model. For additional performance data and product application, please read the instructions for use accompanying the products carefully. Each individual laboratory should validate the use of The NGAL Test™ on its system.

LIMIT OF DETECTION (LoD)

Not tested on this analyzer model. Refer to Instructions for Use for more information.

RANGE

The measuring range of The NGAL Test™ is 25-5000 ng/mL

SECURITY RANGE

The NGAL Test™ showed no effect of antigen excess for NGAL concentrations below 40,000 ng/mL (the highest concentration tested).

PRECISION

REF	Mean (ng/mL)	SD	CV %	n	Acceptance
ST003CA Low	204.5	4.3	2.1	10	<5 %
ST003CA High	500.4	5.5	1.1	10	<3 %

LIMIT OF QUANTIFICATION (LoQ)

The LoQ is 25 ng/mL, which was verified on this analyzer model:

25 ng/mL	Mean (ng/mL)	SD	CV %	n	Accept
	24.8	3.35	13.55	20	< 20%

INTERFERENCE

No interference was detected with hemoglobin up to 5 g/L, conjugated bilirubin up to 300 mg/L, free bilirubin up to 300 mg/L, and up to 5% v/v of a 10% v/v lipid emulsion (corresponding to 5 g/L).

METHOD COMPARISON

NGAL measurements have been compared to measurements on a Hitachi 917. Data is available on request

CALIBRATION STABILITY

It is recommended to recalibrate every 4 weeks, when reagent lots change or quality control results fall outside the range as established by the individual laboratory.

TROUBLE SHOOTING

If performance is unacceptable, try to recalibrate. Check reagents and procedure. If the problem persists, please contact instrument supplier or reagent supplier.

1. Cobas® is a registered trademark of F. Hoffman-La Roche Ltd, Basel, Switzerland
2. "The cobas c501 module and the cobas c502 module are modular parts for the cobas 8000 modular analyser series and the cobas 6000 analyser series, respectively"

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APPLICATION PARAMETERS

Analyze | Calib. | Range | Other

Assay/Time/Point			2Point End	**10**	**37**	**70**	0	0		
Wavelength(2nd/Prl.)			**800**	**570**						
Sample Volume										
Norm.	**3.0**	0.0	0							
Dec.	15.0	3.0	105							
Inc.	6.0	0.0	0							
Dilution										
○ Water										
● Diluent	Saline									
Linearity Limit			%		%					
Prozone Limit		**-100**	**0**	**36**	**37**	**64**	**65**	**Inside**	**100**	**0**
Abs.Limit	**32000**		**Increase**							
Cell Detergent	***1**			Stirring Level		**2**				

Cassette Configuration

Code	#######	
Expiration Days	99	

Reagent Volume

R1	**150**	0	Inactive
R2	0	0	Inactive
R3	**50**	0	Inactive

Stirring Setting		M1	M2	M3
UP	Stirring	LOW	Stirring	Stirring	Stirring

***1: Alkaline detergent**

Analyze | **Calib.** | Range | Other

Calibration Type	**Spline**		
Point	**6**		
Span	**6**		
Weight	0		
Update Type	None	0	0
SD Limit	50		
Duplicate Limit	99	%	32000 Abs.
Sensitivity Limit	-99999		99999
S1 Abs. Limit	-32000		32000

□ Auto Masking

Auto Calibration

○ Timeout

Cassette	Cancel	
	0	Day

Changeover

Cassette	Cancel

○ QC Violation

Method	Blank
Rule	1s
Control1	None
Control2	None
Control3	None

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Analyze	Calib.	**Range**	Other

Application Code	###		
Unit	ng/mL		
Report Name	NGAL		
Data Mode	Active		
□ Automatic Rerun			
Technical Limit	-9999	5000	
Report Limit	-9999	99999	
□ Control Interval Time	0		
□ Automatic QC On Board Stability	1		

Expected Values

Male

		-99999	999999
99	Year	-99999	999999
100	Year	-99999	999999

Female

		-99999	999999
99	Year	-99999	999999
100	Year	-99999	999999

□ Qualitative

(1)	0	L	0
(2)	0	H	0
(3)	0	I	0
(4)	0		
(5)	0		
(6)			

Default

Sex

○ Male ○ Female

Range

○ Range 1 ○ Range 2 ○ Range 3

Analyze	Calib.	Range	**Other**

Standards

	(1)	(2)	(3)	(4)	(5)	(6)
Calibrator Code	***2**	***2**	***2**	***2**	***2**	***2**
Concentration	0	150	600	1500	3000	5000
Rack No.-Pos	***2**	***2**	***2**	***2**	***2**	***2**
Sample Volume	3.0	3.0	3.0	3.0	3.0	3.0
Diluted S.Volume	0.0	0.0	0.0	0.0	0.0	0.0
Diluent Volume	0	0	0	0	0	0

***2: To be defined by operator**

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