

PERFORMANCE DATA AND APPLICATION NOTE FOR
ROCHE COBAS® C501/C502¹


The NGAL Test™ Reagent Kit

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	50, 150, 600, 1500, 3000 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 MULTI 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™ (ST001CA) and **cobas c** pack MUTI 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 **cobas 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 (7mL) of the NGAL Test™ Reagent **R2** into the open bottle of **cobas c** pack MULTI (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.

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 25-3000 ng/mL.

SECURITY RANGE

The NGAL Test™ was tested for antigen excess with NGAL concentrations up to 40,000 ng/mL: NGAL concentrations above 3000 ng/mL are above the measuring range. concentrations $\geq 12,000$ ng/mL were marked with error (>Kin). The user should consider the requirement for entering prozone check settings.

Theoretical NGAL level, ng/mL	Measured NGAL concentration, ng/mL	Mark
3000	3271	
4000	6126	
8000	8101	
12,000	7885	>Kin
16,000	6964	>Kin
20,000	6489	>Kin
24,000	6349	>Kin
28,000	5540	>Kin
32,000	5330	>Kin
36,000	5268	>Kin
40,000	4870	>Kin

PRECISION

REF	Mean (ng/mL)	SD	CV %	n
ST003CA Low	201.3	4.3	2.1	10
ST003CA High	509.5	6.8	1.3	10

INTERFERENCE

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

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.

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
	19.4	3.2	16.5	20

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 Roche Diagnostics GmbH, Mannheim, Germany
2. "The cobas c501 module and the cobas c502 module are modular parts for the cobas 6000 modular analyzer series and the cobas 8000 analyzer series, respectively."

APPLICATION PARAMETERS

Analyze	Calib.	Range	Other
Assay/Time/Point	2Point End	10	37 70 0 0
Wavelength (2nd/Prl.)	800	570	
Sample Volume	Cassette Configuration		
Norm. 3.0 0.0 0	Code #####		
Dec. 15.0 3.0 105	Expiration Days 99		
Inc. 6.0 0.0 0	Reagent Volume		
Dilution	R1 150 0 Inactive		
<input type="radio"/> Water	R2 0 0 Inactive		
<input checked="" type="radio"/> Diluent Saline	R3 50 0 Inactive		
Linearity Limit	%	%	
Prozone Limit	-100 10	36 37	64 65 Inside 100 0
Abs.Limit	32000	Increase	
Cell Detergent	*1	Stirring Level	2
Stirring Setting	M1 M2 M3		
UP	Stirring LOW	Stirring	Stirring

*1: Alkaline detergent

Analyze	Calib.	Range	Other
Calibration Type	Spline	Auto Calibration	
Point	6	<input type="radio"/> Timeout	
	6	Cassette Cancel	
Weight	0	0 Day	
Update Type	None 0 0	Changeover	
		Cassette Cancel	
SD Limit	50	<input type="radio"/> QC Violation	
Duplicate Limit	99 % 32000 Abs.	Method Blank	
Sensitivity Limit	-99999 99999	Rule 1s	
S1 Abs. Limit	-32000 32000	Control1 None	
		Control2 None	
		Control3 None	
<input type="checkbox"/> Auto Masking			

Analyze	Calib.	Range	Other																																				
Application Code ### Unit ng/mL Report NGAL Data Mode Active <input type="checkbox"/> Automatic Rerun Technical Limit -9999 3000 Report Limit -9999 99999 <input type="checkbox"/> Control Interval Time 0 <input type="checkbox"/> Automatic QC On Board Stability 1		<table border="1" style="width:100%; border-collapse: collapse;"> <tr><th colspan="4">Expected Values</th></tr> <tr><th colspan="4">Mal</th></tr> <tr><td></td><td></td><td>-99999</td><td>99999</td></tr> <tr><td>99</td><td>Year</td><td>-99999</td><td>99999</td></tr> <tr><td>100</td><td>Year</td><td>-99999</td><td>99999</td></tr> <tr><th colspan="4">Female</th></tr> <tr><td></td><td></td><td>-99999</td><td>99999</td></tr> <tr><td>99</td><td>Year</td><td>-99999</td><td>99999</td></tr> <tr><td>100</td><td>Year</td><td>-99999</td><td>99999</td></tr> </table>	Expected Values				Mal						-99999	99999	99	Year	-99999	99999	100	Year	-99999	99999	Female						-99999	99999	99	Year	-99999	99999	100	Year	-99999	99999	
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Analyze	Calib.	Range	Other			
Standards						
	(1)	(2)	(3)	(4)	(5)	(6)
Calibrator Code	*2	*2	*2	*2	*2	*2
Concentra-	0	50	150	600	1500	3000
Rack No.-	*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

Cassette type for cobas® 6000 (c501)
Type A

Bottle		
a	R1	85 18.0
b	Cancel	0.0 0.0
c	R3	85 7.0

Cassette type for cobas® 8000 (502)
Type A

Bottle		
a	R1	85 18.0
b	R1	85 0.0
c	R3	85 7.0

*2: To be defined by operator