

APPLICATION NOTE FOR

ROCHE COBAS® C501/C502¹


The NGAL Test™ Reagent Kit

REF/Cat. No.	ST001RA	ST002RA	ST003RA
Product name	The NGAL Test™ Reagent Kit		The NGAL Test™ Control Kit
	R1	R2	50, 150, 600, 1500, 3000 ng/mL
	1 x 35 mL	1 x 7 mL	5 x 1 mL
			Low and High
			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™ (ST001RA) and **cobas c pack MULTI** before transferring the reagents.

Regulatory status:

For Research Use Only. Not for use in diagnostic procedures.

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.

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 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. 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	1s	
S1 Abs. Limit	- 32000	Control1 None	
		Control2 None	
		Control3 None	
<input type="checkbox"/> Auto Masking			

Analyze	Calib.	Range	Other																																								
Application Code <input type="text" value="###"/> Unit <input type="text" value="ng/m"/> Report Name <input type="text" value="NGAL"/> Data Mode <input type="text" value="Active"/> <input type="checkbox"/> Automatic Rerun Technical Limit <table border="1" style="display:inline-table;"><tr><td>-9999</td><td>3000</td></tr></table> Report Limit <table border="1" style="display:inline-table;"><tr><td>-9999</td><td>99999</td></tr></table> <input type="checkbox"/> Control Interval Time <input type="text" value="0"/> <input type="checkbox"/> Automatic QC On Board Stability <input type="text" value="1"/>	-9999	3000	-9999	99999		<table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th colspan="4">Expected Values</th> </tr> <tr> <th colspan="4">Mal</th> </tr> <tr> <td></td><td></td><td><input type="text" value="-99999"/></td><td><input type="text" value="99999"/></td></tr> <tr> <td>99</td><td>Year</td><td><input type="text" value="-99999"/></td><td><input type="text" value="99999"/></td></tr> <tr> <td>100</td><td>Year</td><td><input type="text" value="-99999"/></td><td><input type="text" value="99999"/></td></tr> <tr> <th colspan="4">Female</th> </tr> <tr> <td></td><td></td><td><input type="text" value="-99999"/></td><td><input type="text" value="99999"/></td></tr> <tr> <td>99</td><td>Year</td><td><input type="text" value="-99999"/></td><td><input type="text" value="99999"/></td></tr> <tr> <td>100</td><td>Year</td><td><input type="text" value="-99999"/></td><td><input type="text" value="99999"/></td></tr> </thead></table>	Expected Values				Mal						<input type="text" value="-99999"/>	<input type="text" value="99999"/>	99	Year	<input type="text" value="-99999"/>	<input type="text" value="99999"/>	100	Year	<input type="text" value="-99999"/>	<input type="text" value="99999"/>	Female						<input type="text" value="-99999"/>	<input type="text" value="99999"/>	99	Year	<input type="text" value="-99999"/>	<input type="text" value="99999"/>	100	Year	<input type="text" value="-99999"/>	<input type="text" value="99999"/>	
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Analyze	Calib.	Range	Other			
Standards						
	(1)	(2)	(3)	(4)	(5)	(6)
Calibrator Code	<input type="text" value="*2"/>	<input type="text" value="*2"/>	<input type="text" value="*2"/>	<input type="text" value="*2"/>	<input type="text" value="*2"/>	<input type="text" value="*2"/>
Concentration	<input type="text" value="0"/>	<input type="text" value="50"/>	<input type="text" value="150"/>	<input type="text" value="600"/>	<input type="text" value="1500"/>	<input type="text" value="3000"/>
Rack No.-Pos	<input type="text" value="*2"/>	<input type="text" value="*2"/>	<input type="text" value="*2"/>	<input type="text" value="*2"/>	<input type="text" value="*2"/>	<input type="text" value="*2"/>
Sample Volume	<input type="text" value="3.0"/>	<input type="text" value="3.0"/>	<input type="text" value="3.0"/>	<input type="text" value="3.0"/>	<input type="text" value="3.0"/>	<input type="text" value="3.0"/>
Diluted S.Volume	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>
Diluent Volume	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>

Cassette type for cobas® 6000 (c501)
Type A

Bottle			
a	<input type="text" value="R1"/>	<input type="text" value="85"/>	<input type="text" value="18.0"/>
b	<input type="text" value="Cancel"/>	<input type="text" value="0.0"/>	<input type="text" value="0.0"/>
c	<input type="text" value="R3"/>	<input type="text" value="85"/>	<input type="text" value="7.0"/>

Cassette type for cobas® 8000 (502)
Type A

Bottle			
a	<input type="text" value="R1"/>	<input type="text" value="85"/>	<input type="text" value="18.0"/>
b	<input type="text" value="R1"/>	<input type="text" value="85"/>	<input type="text" value="0.0"/>
c	<input type="text" value="R3"/>	<input type="text" value="85"/>	<input type="text" value="7.0"/>

*2: To be defined by operator

