For Research Use Only

APPLICATION NOTE FOR

ROCHE MODULAR® P[1]

The NGAL Test™ Reagent Kit

REF/Cat.No.	ST001RA		ST002RA	ST003RA
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.

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 product carefully. Each individual laboratory should validate the use of The NGAL Test™ on its system.

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] Modular® P is a registered trademark of Roche Diagnostics GmbH, Mannheim, Germany.

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Version: 04
Revision date: 25.06.2015

APPLICATION PARAMETERS

Assay/Time/Point	2-Point-End	10	18	34	0	0
Wave (2nd/Primary)	800	570				

Sample Volume			
Normal	3.0	0.0	0
Decrease	15.0	3.0	105
Increase	6.0	0.0	0

Reagent Vol.					Timing
R1	150	0	xxx	0	
R2	0	0	xxx	0	T2
R3	50	0	xxx	0	T3
R4	0	0	xxx	0	

Diluent
- ○ Water
- ● Diluent: 314 | 0

Abs. Limit	32000	Increase					
Prozone Limit	0	0	0	0	0	Lower	
Cell Detergent	Detergent 1						
Twin Test	Cancel						

CALIBRATION

Calibration Type	SPLINE	
Point	6	
Span	6	
Weight	0	
Update Type	none	
Isozyme Q Channel	Cancel	
SD Limit	999	
Duplicate Limit	99	32000
Sensitivity Limit	-99999	99999
S1-Abs Limit	-32000	32000

V Auto Masking

Auto Calibration

Change Over	
Modul	Cancel
Lot	Cancel
Bottel	Cancel

- ● Timeout
- ☐ Blank: 1 — 2 Point: 1
- ☐ Span: 1 — Full: 1

QC Violation

Method	Blank	Rule	1s
Control	None		
	None		
	None		

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RANGE

Application Code	**xxx**		
Unit	**ng/mL**		
Report Name	**NGAL**		
Data Mode	**Active**		
V Automatic rerun			
Technical Limit	**25**	**3000**	
Repeat Limit	**-99999**	**999999**	
☐ Control Interval Time		**1**	

Qualitative

Control Interval Time		
(1)	**0**	**--**
(2)	**0**	**-**
(3)	**0**	**+/-**
(4)	**0**	**++**
(5)	**0**	**+++**
(6)		**++++**

Expected Ranges

Male

99	**Year**	**-99999**	**99999**
100	**Year**	**-99999**	**99999**
		-99999	**99999**

Female

99	**Year**	**-99999**	**99999**
100	**Year**	**-99999**	**99999**
		-99999	**99999**

Default

Sex

● Male ○ Female

Range

● Range 1 ○ Range 2 ○ Range 3

OTHERS

Standards

	(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**
Calibrator Code	**501**	**xxx**	**xxx**	**xxx**	**xxx**	**xxx**
Concentration	**0**	**50**	**150**	**600**	**1500**	**3000**
Rack No. – Pos.	**XXXXX**	XXXXXX	XXXXXX	XXXXXX	XXXXXX	XXXXXX
Sample Volume	**3.0**	**3.0**	**3.0**	**3.0**	**3.0**	**3.0**
Diluent S. Volume	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Diluent Volume	**0**	**0**	**0**	**0**	**0**	**0**

xxx: To be defined by operator.

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