PERFORMANCE DATA AND APPLICATION NOTER FOR

ROCHE HITACHI 917

The NGAL Test™ Reagent Kit

REF/Cat. No.	ST001CA		ST002CA	ST003CA
Prod. 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.

LIMIT OF DETECTION (LoD)

The limit of detection was estimated as 7.3 ng/mL.

RANGE

The measuring range of The NGAL Test™ is 25 - 3000 ng/mL on the Roche Hitachi 917.

SECURITY RANGE

The NGAL Test™ showed no effect of antigen excess for NGAL concentrations below 40,000 ng/mL (the highest concentration tested). The user should consider the requirement for entering prozone check settings.

PRECISION

REF	Mean (ng/mL)	SD	CV %	n
ST003CA Low	197.7	6.3	3.2	10
ST003CA High	494.1	8.4	1.7	10

LIMIT OF QUANTIFICATION (LoQ)

The LoQ was determined to be 25 ng/mL on this analyzer model. Observed results:

	Mean (ng/mL)	SD	CV %	n
25 ng/mL	24.2	4.2	17.4	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) on Roche Hitachi 917 analyzer.

METHOD COMPARISON

NGAL measurements have been compared to measurements on commercially available NGAL ELISA. 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.

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Version: 05
Revision date: 23.06.2015

The NGALTest

CE IVD

APPLICATION PARAMETERS

Anayze	Calibration		Range	Standard Conc.
Assay / Time / Point	2Point End		10	18 34
Wavelength (2nd / Primary)	800 / 570			
S. Vol (Normal)	3.0	0.0	0	
S. Vol (Decrease)	15.0	3.0	105	
S. Vol (Increase)	6.0	0.0	0	
Diluent / Rgt.	(Saline)		0	
Reagent (T1)	150	0	0	
(T2)	0	0	0	
(T3)	50	0	0	
(T4)	0	0	0	
ABS. Limit	32000	Increase		
Prozone Limit	-32000	Lower		
Cell Detergent	*1		*1: Alkaline detergent	

Analyze	**Calibration**			Range	Standard Conc.
Calibration Type	Spline				
Point	6	Span Point	6		
Weight	0				
Auto Time Out Blank	0		Auto Change	Lot	Cancel
Span	0			Bottle	Cancel
2Point	0				
Full	0				
SD Limit	100.0				
Duplicate Limit	32000				
Sensitivity Limit	-99999	99999			
S1 ABS Limit	-32000	32000			

Analyze	Calibration			**Range**	Standard Conc.
Application Code		*****			
Unit		ng/mL			
Report Name					
Data Mode	On Board				
Control Interval	0				
Instrument Factor (Y= aX + b)	a=	1.0	b=	0.0	
Technical Limit		-9999	3000.0		
Expected Value				Qualitative	No
(Male) 100 Y	-99999	999999		(1)	0
100 Y	-99999	999999		(2)	0
	-99999	999999		(3)	0
(Female) 100 Y	-99999	999999		(4)	0
100 Y	-99999	999999		(5)	0
	-99999	999999		(6)	0

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Analyze	Calibration			Range		Standard Conc.
< STD >	(1)	(2)	(3)	(4)	(5)	(6)
Conc.	0	50	150	600	1500	3000
Posi.	*2	*2	*2	*2	*2	*2
Sample	3.0	3.0	3.0	3.0	3.0	3.0
< Pre Dil.>						
Pre.	0.0	0.0	0.0	0.0	0.0	0.0
Dil.	0	0	0	0	0	0
Calib.	0	0	0	0	0	0

*2: To be defined by operator.

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