PERFORMANCE DATA AND APPLICATION NOTE FOR

SIEMENS ADVIA® 1800(1)

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 50 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 12 ng/ml

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 marked as out of calibration and assay range. Concentrations above 10,000 ng/mL are marked “P” (prozone).

PRECISION

REF	Mean (ng/mL)	SD	CV%	N
ST003CA Low	198.5	3.3	1.7	10
ST003CA High	502.0	4.6	0.9	10

LIMIT OF QUANTIFICATION (LoQ)

REF	Mean (ng/mL)	SD	CV%	N
Calibrator 50 ng/mL	51.2	4.9	9.6	20
QC fluid 25 ng/mL	26,1	7.5	28.9	13

INTERFERENCE

Interference has not been tested for these specific application settings.

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) ADVIA® is a registered trademark of Siemens Healthcare Diagnostics Inc., New York, USA.

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The NGALTest

CE IVD

APPLICATION PARAMETERS

Analytical conditions

R1 volume	60.00	Serum reac.s.vol	7.20	Reaction time	10 min.
R2 volume	20.00	Serum dil.method	Special	Reagent 1 stir	Strong
R1 diluent	0.000	Serum dil.s.vol	30.0	Reagent 2 stir	Strong
R1 diluent	0.000	Serum dil.volume	60.0		
		Serum dil.posit	0		

Sub Param. # 1 - 1 up down

Sub-analy. Conditions

Name	NGAL	Digits	0
Unit	ng/mL		
M-wave. L.	571 nm		
S-wave. L.	*****		
Analy.mthd	EPA		
Calc.mthd	MSTD		
Qualit.judg	Not do		

Reanalysis conditions

Sample vol. (u)	3.6
Dilution mode (u)	None
Diluted sample vol. (u)	0.000
Diluent vol. (u)	0.000
Diluent position (u)	0
Sample vol. (d)	3.00
Dilution mode (d)	Special
Diluted sample vol. (d)	30.00
Diluent vol. (d)	60.0
Diluent position (d)	0

Standard setting

FV	1.0000	Abnml(serum)H	3000
		Abnml(serum)L	-999999
		Abnml(urine)H	3000
		Abnml(urine)L	-999999

Calculation method setting

M-DET.P.l	0	S-DET.P.p	51	Reac. type	Inc.
M-DET.P.m	74	S-DET.P.r	53	Max Limit	2.500
M-DET.P.n	76			*Reaction rate method	
Check D.P.I	0			Cycle	3
Limit value	0.003			Factor	3.0
Variance	30.0			E2 corre	Not do
*Prozone				Blank (u)	9.9999
Prozone form.	Prozone formula			Blank (d)	-9.999
Prozone limit	0.150			Sample (u)	9.9999
Prozone judge	Upper limit			Sample (d)	-9.999
Judge limit	0.001			*Endpoint method	
M-DET.P.m	57	S-DET.P.p	49	Re.absorb (u)	9.9999
M-DET.P.n	59	S-DET.P.r	51	Re.absorb (d)	-9.999

Multi-STD

Cal. Mode: Corrected spline | Axis exchange: No | Points: 6

	FV	Dilution mode	Serum dil.s.vol	Serum dil.vol.	Serum dil.posit	STD-H	STD-L
BLK *1							
1	50	Special	30.0	60.0	C- 0	9.99999	-9.9999
2	150	Special	30.0	60.0	C- 0	9.99999	-9.9999
3	600	Special	30.0	60.0	C- 0	9.99999	-9.9999
4	1500	Special	30.0	60.0	C- 0	9.99999	-9.9999
5	3000	Special	30.0	60.0	C- 0	9.99999	-9.9999

*1: Use saline as blank solution

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