




The NGAL Test™

For your clinical chemistry analyzer

PERFORMANCE DATA AND APPLICATION NOTE FOR SIEMENS ADVIA® 2400¹

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
			
	1 x 35 mL	1 x 7 mL	5 x 1 mL
		150, 600, 1500, 3000, 5000 ng/mL	Low and High
			3 x 1 mL x 2 levels

Number of determinations: 1 mL of immunoparticle suspension  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)

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 on Siemens ADVIA® 2400.

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.

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	Accept
25 ng/mL	26.9	4.6	17.1	20	< 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 Siemens ADVIA® 2400.

PRECISION

	Mean (ng/mL)	SD	CV %	n	Acceptance
ST003CA Low	196.1	4.7	2.4	10	<5 %
ST003CA High	489.1	6.8	1.4	10	<3 %

CALIBRATION

The NGAL Test™ Calibrator Kit ( ST002CA) should be used the following way:

Calibration point	Kit calibrator	Level
1	Use saline as blank*	0 ng/ml
2	Calibrator 1 (150 ng/mL)**	50 ng/mL
3	Calibrator 1 (150 ng/mL)	150 ng/mL
4	Calibrator 2 (600 ng/mL)	600 ng/mL
5	Calibrator 3 (1500 ng/mL)	1500 ng/mL
6	Calibrator 4 (3000 ng/mL)	3000 ng/mL

* Saline is not included in the kit

** Special dilution, consult settings below

NB: ST002CA Calibrator 5 (5000 ng/mL) is not used for calibration on Siemens ADVIA® 2400 system.

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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APPLICATION PARAMETERS

Analytical conditions					
R1 volume	60.00	Serum reac.s.vol	7.50	Reaction time	10 min.
R2 volume	0.000	Serum dil.method	Special	Reagent 1 stir	Strong
R3 volume	20.00	Serum dil.s.vol	30.0	Reagent 2 stir	Strong
R1 diluent	0.000	Serum dil.volume	60.0	Reagent 3 stir	Strong
R2 diluent	0.000	Serum dil.posit	C- 0		
R3 diluent	0.000				

Sub Param. #	1 - 1	Standard setting																				
Sub-analy. Conditions		<table border="1"> <tbody> <tr> <td>BLK H</td> <td>9.99999</td> <td>Abnml(serum)H</td> <td>3000</td> </tr> <tr> <td>BLK L</td> <td>-9.9999</td> <td>Abnml(serum)L</td> <td>-999999</td> </tr> <tr> <td>STD H</td> <td>9.99999</td> <td>Abnml(urine)H</td> <td>3000</td> </tr> <tr> <td>STD L</td> <td>-9.9999</td> <td>Abnml(urine)L</td> <td>-999999</td> </tr> <tr> <td>FV</td> <td>1.00000</td> <td></td> <td></td> </tr> </tbody> </table>	BLK H	9.99999	Abnml(serum)H	3000	BLK L	-9.9999	Abnml(serum)L	-999999	STD H	9.99999	Abnml(urine)H	3000	STD L	-9.9999	Abnml(urine)L	-999999	FV	1.00000		
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FV	1.00000																					
Reanalysis conditions		Calculation method setting																				
Sample vol. (u)	3.75	M-DET.P.l	0	S-DET.P.p	24	*Reaction rate method																
Dilution mode (u)	No	M-DET.P.m	28	S-DET.P.r	24	Cycle	3															
Diluted sample vol. (u)	0.000	M-DET.P.n	29			Factor	3.0															
Diluent vol. (u)	0.000	Check D.P.l	0			Reac. Typ	Increase															
Diluent position (u)	0	Limit value	0.003			E2 corre	No															
Sample vol. (d)	15.00	Variance	30.00			Blank (u)	9.9999															
Dilution mode (d)	Special	*Prozone				Blank (d)	-9.999															
Diluted sample vol. (d)	30.00	Prozone form.	None			Sample (u)	9.9999															
Diluent vol. (d)	60.0	Prozone limit	9.999			Sample (d)	-9.999															
Diluent position (d)	0	Prozone judge	Upper			*Endpoint method																
		Judge limit	9.999			Re.absorb (u)	9.9999															
		M-DET.P.m	0	S-DET.P.p	0	Re.absorb (d)	-9.999															
		M-DET.P.n	0	S-DET.P.r	0																	

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	**	50.0	Special	10.0	80.0	C-	0	9.99999	-9.9999
2		150.0	Special	30.0	60.0	C-	0	9.99999	-9.9999
3		600.0	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

* Use saline as blank solution
 ** Use ST002CA Calibrator 1 (150 ng/mL) to make the 1st calibration point 50 ng/mL
 *** ST002CA Calibrator 5 (5000 ng/mL) is not used for calibration on Siemens ADVIA® 2400 system

