




The NGAL Test™

For your clinical chemistry analyzer

PERFORMANCE DATA AND APPLICATION NOTE FOR ABBOTT AEROSSET® 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
			
	1 x 35 mL	1 x 7 mL	3 x 1 mL x 2 levels

Number of determinations: 1 mL of immunoparticle suspension  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)

Not tested on this analyzer model. Refer to Instruction for Use for more information.

RANGE


The measuring range of The NGAL Test™ is 25 - 5000 ng/mL on Abbott Aeroset®.

SECURITY RANGE

The NGAL Test™ was tested for antigen excess with NGAL concentrations up to 40,000 ng/mL: no antigen excess was found for the NGAL concentrations below 28,000 ng/mL, however the results above 5000 ng/mL were marked with CNF. The user should consider the requirement for entering prozone check settings.

Theoretical NGAL level, ng/mL	Measured NGAL concentration, ng/mL	Mark
0.0	10.0	
4000	4171.5	
8000	6136.5	CNF
12,000	6193.5	CNF
16,000	5880.0	CNF
20,000	5561.0	CNF
24,000	5207.5	CNF
28,000	5018.5	CNF
32,000	4983.0	RAC
36,000	4920.5	RAC
40,000	4934.5	RAC

PRECISION

	Mean (ng/mL)	SD	CV %	n	Acceptance
ST003CA Low	206.7	5.4	2.6	10	<5 %
ST003CA High	510.6	11.5	2.3	10	<3 %

LIMIT OF QUANTIFICATION (LoQ)

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

25 ng/mL	Mean (ng/mL)	SD	CV %	n	Accept
	27.4	3.9	14.2	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 Abbott Aeroset® analyzer.

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. Aeroset® is a registered trademark of Abbott Laboratories, North Chicago, Illinois, USA.



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APPLICATION PARAMETERS

Outline

Assay Name: Assay#: Line: ▼

Omitted

Base

Reaction Mode: ▼ Wavelength-Prim/Sec: ▼ / ▼ Read time-Main/Flex: - / - Linearity %:

Sample Blank Test: ▼ Blank Read Time: - Abs Window: - Abs Limits: -

	S.Vol	DS.Vol	/	D.Vol	W.Vol		Rgt Name	/ Pos
Standard	<input type="text" value="3.0"/>	<input type="text" value="0.0"/>	/	<input type="text" value="0"/>	<input type="text" value="0"/>			
Dil 1	<input type="text" value="15.0"/>	<input type="text" value="3.0"/>	/	<input type="text" value="105"/>	<input type="text" value="0"/>	Diluent:	<input type="text" value="Saline"/>	<input type="text" value="*1"/> ▼
Dil 2	<input type="text" value="6.0"/>	<input type="text" value="0.0"/>	/	<input type="text" value="0"/>	<input type="text" value="0"/>	Type#	<input type="text" value="0"/>	
Reagent 1				<input type="text" value="150"/>	<input type="text" value="0"/>		<input type="text" value="NGAL R1"/>	<input type="text" value="*1"/> ▼
Reagent 2				<input type="text" value="50"/>	<input type="text" value="0"/>		<input type="text" value="NGAL R2"/>	<input type="text" value="*1"/> ▼

Reaction Check: ▼ Read Time - A/B: - / - Range: - Minimum:

Factor / Intercept: / Decimal Places: Units: ▼

*1: To be defined by operator.



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Calibration

Calib Mode		Interval (H)					
Spline ▼		0					
Blank/Calib Replicates		Extrapolation %		Span		Span Abs Range	
3 / 3		0		BLK - 1		0.0 - 0.0	
	Sample	S.Vol	DS.Vol	D.Vol	W.Vol	Blk Abs Range	
BLK	Saline ▼	3.0	0.0	0	0	0.0 - 0.0	
C 1	NGAL 1-150 ▼	3.0	0.0	0	0	Cal Deviation	
C 2	NGAL 2-600 ▼	3.0	0.0	0	0	0.0	
C 3	NGAL 3-1500 ▼	3.0	0.0	0	0	FAC Limit (%)	
C 4	NGAL 4-3000 ▼	3.0	0.0	0	0	20	
C 5	NGAL 5-5000 ▼	3.0	0.0	0	0		
C 6	----- ▼	3.0	0.0	0	0		
C 7	----- ▼	3.0	0.0	0	0		
C 8	----- ▼	3.0	0.0	0	0		

Wash

Rgt Probe		
Reagent	Wash	Vol
-----	-----	-----
Cuvette		
Assay Name	Wash	Vol
-----	-----	-----
Sample Probe		
Wash		

