

PERFORMANCE DATA AND APPLICATION NOTE FOR

BECKMAN COULTER AU® 640¹

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, 3000ng/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)

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 the Beckman Coulter AU®640.

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	204.4	4.0	2.0	10
ST003CA High	510.9	7.9	1.5	10

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
	24.2	4.6	19.0	20

INTERFERENCE

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

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 AU® is a registered trademark of Beckman Coulter, Pasadena, California, USA.

APPLICATION PARAMETERS

<SPECIFIC TEST PARAMETER >

Sample vol.	[3.0]	Diluents vol. [0] µL	Sample OD value range
R1 vol.	[150]	Diluents vol. [0] µL	L [-2.0000] H [2.5000]
R2 vol.	[50]	Diluents vol. [0] µL	Reagent OD value range
			First L [-2.0000] First H [2.5000]
Wave length	Pri [700] Sub []		Last L [-2.0000] Last H [2.5000]
Method	[FIXED1]		Dynamic range
Reaction slope	[+]		L [-99999.9] H [99999.9]
Measuring point-1	FST [12] LST [21]		Correlation factor
Measuring point-2	FST [] LST []		A [1.000000]
Limit of linearity	1st [*1]% 2nd []%		B [0.000000]
NO-LAG-TIME	[]		

*1: Leave blank using the back space key.

<CALIBRATION SPECIFIC>

Calibration type -	[6AB]	Duplicate	[3]
	[Spline]	Process	[] Conc. []
	Conc.	Factor/OD range L	Factor/OD
Point 1	[0]	[-2.0000]	[2.5000]
Point 2	[50]	[-2.0000]	[2.5000]
Point 3	[150]	[-2.0000]	[2.5000]
Point 4	[600]	[-2.0000]	[2.5000]
Point 5	[1500]	[-2.0000]	[2.5000]
Point 6	[3000]	[-2.0000]	[2.5000]

<RE-RUN PARAMETER >

Dilution Re-Run		Normal Re-Run	
Sample vol.	[3.0] µL	Sample vol.	[3.0] µL
Diluents vol.	[105] µL	Diluents vol.	[0] µL
Sample Dilution ratio	[8]	Sampl Dilution ratio	[1]
Concentration Re-Run			
Sample vol.	[6.0] µL		
Diluents vol.	[0] µL		
Sample Dilution ratio	[1]		
Re-Run level	L: [-99999.9]		
	H: [3000.0]		

< DATA CHECK PARAMETER >

Logic check-1 [valid]	Logic check-2 [invalid]
Checkpoint 1 [12]	Checkpoint 1 [0]
Checkpoint 2 [16]	Check Point Interval [0]
Checkpoint 3 [27]	Decision Value 1 [0.0000]
Decision value 1 [0.5000]	Decision Value 2 [0.0000]
Decision value 2 [2.0000]	Limit point 1 [0]
Decision value 3 [0.0500]	Limit point 2 [0]
Limit point 1 [12]	Data check-3 [invalid]
Limit point 2 [27]	Checkpoint 1 [0]
	Check point Interval [0]
	Decision value 1 [0.0000]
	Decision value 2 [0.0000]
	Limit point 1 [0]
	Last point 2 [0]