

PERFORMANCE DATA AND APPLICATION NOTE FOR

# BECKMAN COULTER AU®5800 series<sup>1</sup>

AU®5810, AU®5811, AU®5812, AU®5820, AU®5821, AU®5822, AU®5830, AU®5831, AU®5832, AU®5840, AU®5841 and AU®5842

## 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 30 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®5800 series chemistry analyzers.

#### PRECISION

REF		Mean (ng/mL)	SD	CV %	n
ST003CA	Low	197.6	8.54	4.32	10
ST003CA	High	520.3	10.14	1.95	10

#### LIMIT OF QUANTIFICATION (LoQ)

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

22 ng/mL	Mean (ng/mL)	SD	CV %	n
	20.6	3.61	17.54	20

#### SECURITY RANGE

The NGAL Test™ showed no effect of antigen excess for NGAL concentrations up to 35831 ng/mL: NGAL concentrations above 3000 ng/mL were marked with "F" (result higher than dynamic range). Concentrations ≥22693 ng/mL were marked with "Z" (prozone error). The user should consider the requirements for entering prozone check settings.

Theoretical NGAL level, ng/mL	Measured NGAL concentration, ng/mL	Mark
0	55	
1194	1190	
2389	2860	
4180	4053	F
8958	4572	F
22693	4562	ZF
35831	4451	ZF

#### **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.

<sup>1</sup> AU®5800 is a registered trademark of Beckman Coulter, Pasadena, California, USA

### APPLICATION PARAMETERS

<Specific Test Parameters>

Parameters		Specific Test Parameters						
General		LIH	ISE	Calculated Tests	Range			
Test Name	##.NGAL	Test No.	Type	Serum	Operation	Yes		
Sample vol.	2.0 µL	Dilution	0 µL	OD Limit				
Pre-dilution rate	1	Diluent bottle	OutSide	Min OD	-2.0000	OD Max.	3.0000	
Reagent vol.	R1(R1-1) 100 µL	Dilution	0 µL	Reagent OD Limit				
	R1-2	Dilution	0 µL	1 <sup>st</sup> .	Low	-2.0000	High	3.0000
	R2(R2-1) 33 µL	Dilution	0 µL	Last	Low	-2.0000	High	3.0000
Common reagent	Type None	Name	None	Dynamic range	Low	-999999.9	High	3000
Wavelength	Pri. 700 nm	Sec.	None nm	Correl. factor	A	1	B	0
Method	FIXED1			Factor for maker	A	1	B	0
Reaction slope	+			Onboard stability Period	28 Days			
Measuring Point-1	1st. 12	Last	21					
Measuring Point-2	1st.	Last						
Linearity Limit								
Lag Time Check								

## To be defined by operator

<Calibration Specific>

Parameters		Calibration Parameters					
Calibrators		Calibration Specific					
General		ISE					
Test Name	##.NGAL	Type	Serum	Cuvette			
		Unit No.	1	2	3	4	
Calibration Type	6AB	Formula	Spline	Counts	2		
<Calibrator Parameters>				Slope Check			
	Calibrator	OD	Conc.	OD Range			
				Low	High		
Point-1	Saline (not included)*		0.0	-2.0000	3.0000	Allowable Range Check	
Point-2	*		50.0	-2.0000	3.0000	Reagent Blank Calibration	
Point-3	*		150.0	-2.0000	3.0000	Advanced Calibration Operation	
Point-4	*		600.0	-2.0000	3.0000	Interval (RB/ACAL)	
Point-5	*		1500.0	-2.0000	3.0000	No	
Point-6	*		3000.0	-2.0000	3.0000	Lot Calibration	
Point-7							
Point-8							
Point-9							
Point-10							
<Point Cal. For Master Curve>		No. of Correction points			Use Master Curve		
	Calibrator	OD	Conc.	OD Range		Stability	
				Low	High		
Point-1						Reagent Blank	28 Day 0 Hour
Point-2						Calibration	28 Day 0 Hour
MB Type Factor		1-Point Calibration Point		With Cont-0			

## To be defined by operator

\* To be defined by operator

<Data Check Parameters>

Parameters		Misc.			
Checked Tests		Contamination Parameters		Data Check Parameters	
Test Name	##.NGAL	Type	Serum		
<b>Logic Check 1</b> Check Point 1: 12 Check Point 2: 16 Check Point 3: 27 Decision Value 1: 0.5000 Decision Value 2: 2.0000 Decision Value 3: 0.05000 Limit Point 1: 12 Limit Point 2: 27 Check Pattern: Pattern 1		<b>Logic Check 2</b> Check Point 1: <input type="text"/> Check Point Interval: <input type="text"/> Decision Value 1: <input type="text"/> Decision Value 2: <input type="text"/> Limit Point 1: <input type="text"/> Limit Point 2: <input type="text"/>		<b>Logic Check 3</b> Check Point 1: <input type="text"/> Check Point Interval: <input type="text"/> Decision Value 1: <input type="text"/> Decision Value 2: <input type="text"/> Limit Point 1: <input type="text"/> Limit Point 2: <input type="text"/>	
Edit		Set Prozone Parameters		Print	

## To be defined by operator