

APPLICATION NOTE FOR

BECKMAN COULTER AU®5800 series¹

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.	ST001RA		ST002RA	ST003RA
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.



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®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 st .	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			
Calibration Type	6AB	Formula	Spline	Counts	2		
<Calibrator Parameters>				Slope Check			
	Calibrator	OD	Conc.	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.	Low	High	Stability	
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		
Logic Check 1 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		Logic Check 2 Check Point 1: [] Check Point Interval: [] Decision Value 1: [] Decision Value 2: [] Limit Point 1: [] Limit Point 2: []		Logic Check 3 Check Point 1: [] Check Point Interval: [] Decision Value 1: [] Decision Value 2: [] Limit Point 1: [] Limit Point 2: []	
Edit		Set Prozone Parameters		Print	

To be defined by operator