The NGAL Test™

For your clinical chemistry analyzer

PERFORMANCE DATA AND APPLICATION NOTE FOR

BECKMAN COULTER UniCel® DxC 800 Synchron®[1]

The NGAL Test™ Reagent Kit CE IVD

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	150, 600, 1500, 3000, 5000 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 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.

INTENDED USE

The presented application note is intended for the quantitative determination of NGAL on Beckman Coulter UniCel® DxC 800 Synchron® analyzer in **human urine samples only. Do not use plasma samples.**

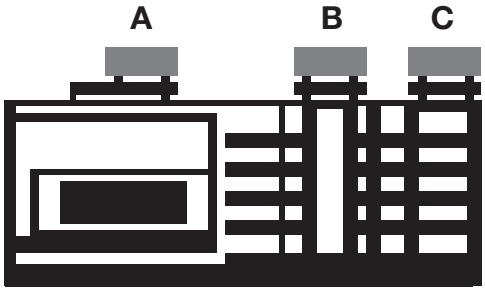
To use BioPorto's The NGAL Test™ on the UniCel® DxC 800 Synchron® chemistry analyzer the reagents must be transferred into a new container. The appropriate containers are called Beckman Coulter UDR cartridge and can be ordered from your local Beckman Coulter representative. Please make sure to acquire the following two items:

Item	Cat. No.	Product name	
Reagent container	442835	User-Defined Reagent (UDR) cartridge	Order from Beckman Coulter
Evaporation control caps for UDR cartridge	A65595	Environmental Caps	Order from Beckman Coulter

Please read the UniCel® DxC Synchron® Clinical Systems Instruction For Use before transferring the reagents.

FILLING THE BECKMAN COULTER UDR CARTRIDGE:

1. Turn the UDR cartridge towards you as shown at the right (compartment A to the left and compartment C to the right).
2. Unscrew the hard plastic caps on all the compartments and discard them.
3. Transfer the content of The NGAL Test™ Reaction buffer R1 into **Compartment A** on the left side and close it with the soft evaporation control cap for the UDR cartridge.
4. Transfer the content of The NGAL Test™ immunoparticles suspension R2 into **Compartment B** - the middle compartment and close it with the soft evaporation control cap for the UDR cartridge.
5. Leave the Compartment C on the right side of UDR cartridge empty.



NOTE

Before loading the UDR cartridge onto the instrument, it has to be defined for a User-Defined Reagent feature.
Optional Test/Kit optimization: The Beckman Coulter DxC UDR cartridge can hold 2 full The NGAL Test™ Reagent Kits (ST001CA). Thereby the test per kit ratio can be improved from 113 per kit (when 1 kit is applied) to 247 when two kits are filled into the cartridge. Do not mix the reagents with different lot numbers.

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PRECAUTIONS

Do not pipette by mouth.
Do not shake the reagents.
Use only clean containers if transferring reagents.
Do not pour reagents back into their original containers once transferred.
Do not use reagents after the expiry date on the labels.
Do not switch caps on reagent containers as it may cause contamination or mix-up.
Reagents with different lot numbers should not be mixed.
All solutions supplied should be handled carefully and disposed of in accordance with national and local regulations.
Use calibrated pipettes to prepare the 50 ng/mL calibrator.

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 50 - 3000 ng/mL on Beckman Coulter UniCel® DxC 800 Synchron®.

SECURITY RANGE

The NGAL Test™ showed no effect of antigen excess for NGAL concentrations below 25,000 ng/mL.

PRECISION

REF	Mean (ng/mL)	SD	CV %	n	Acceptance
ST003CA Low	205.4	3.6	1.7	10	<5 %
ST003CA High	479.8	7.9	1.7	10	<3 %

CALIBRATION

The NGAL Test™ Calibrator Kit (REF ST002CA) should be used in 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 hand-dilution, 50 µL Calibrator 1 (150 ng/mL) + 100 µL Saline (dilution 1/3)
NB: ST002CA Calibrator 5 (5000 ng/mL) is not used for calibration on Beckman Coulter UniCel® DxC 800 Synchron®.

LIMIT OF QUANTIFICATION (LoQ)

The LoQ was determined to be 50 ng/mL on this analyzer model. Observed results:

50 ng/mL	Mean (ng/mL)	SD	CV %	n	Accept
	58.1	7.5	12.9	20	< 20%

SAMPLE MATERIAL

NGAL concentrations can be determined only in human urine samples on the UniCel® DxC 800 Synchron® chemistry analyzer.

METHOD COMPARISON

NGAL measurements have been compared to measurements on a Hitachi 917. Data is available on request.

CALIBRATION STABILITY

The Beckman Coulter UniCel DxC Synchron Systems require recalibration every 2 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. UniCel® and Synchron® are the registered trademarks of Beckman Coulter Inc., Brea, USA

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NUMBER **[*]** CHEM **[NGAL]**

Chemistry Parameters					Page 1 of 3
Reaction Type		**[Endpoint 2]**			
Units		**[12.ng/mL]**			
Precision		**[X.X]**			
Reaction Direction		**[Positive]**			
Math Model		**[1]**			
Primary Wavelength		**[520]**			
Secondary Wavelength		**[700]**			
Calculation Factor		**[1.000]**			
No. of Calibrators		**[6]**			
Setpoints	**1**	**[0.0]**	**4**	**[600.0]**	
	2	**[50.0]**	**5**	**[1500.0]**	
	3	**[150.0]**	**6**	**[3000.0]**	
Cal Time Limit		**[336] hours**			
Cal Save		**[√]**			

Processing Parameters			Page 2 of 3
First Inject	Component	**[A]**	
	Dispense Volume	**[150] µL**	
Second Inject	Component	**[None]**	
	Dispense Volume	**[ ]**	
	Inject Time	**[ ] sec**	
Third Inject	Component	**[B]**	
	Dispense Volume	**[50] µL**	
	Inject Time	**[60] sec**	
Sample Volume**	**[6] µL**		
ORDAC Volume	**[3] µL**		
Blank	Start Read	**[70] sec**	
	End Read	**[100] sec**	
Initial (DxC only)	Start Read	**[9] sec**	
	End Read	**[24] sec**	
Reaction 1	Start Read	**[260] sec**	
	End Read	**[300] sec**	
Reaction 2	Start Read	**[ ] sec**	
	End Read	**[ ] sec**	

Error Detection Limits			Page 3 of 3
Blank	ABS Low/High Limits	**[-1.500]/[2.200]**	
	Rate Low/High Limits	**[-1.500]/[2.200]**	
	Mean Deviation	**[2.200]**	
Reaction 1	ABS Low/High Limits	**[-1.500]/[2.200]**	
	Rate Low/High Limits	**[-1.500]/[2.200]**	
	Mean Deviation	**[2.200]**	
Reaction 2	ABS Low/High Limits	**[-1.500]/[2.200]**	
	Rate Low/High Limits	**[-1.500]/[2.200]**	
	Mean Deviation	**[2.200]**	
Substrate Depletion			
	Initial Rate	**[99.999]**	
	Delta ABS	**[2.200]**	
Multipoint Span			
	1-2	**[0.001]**	**4-5** **[0.001]**
	2-3	**[0.001]**	**5-6** **[0.001]**
	3-4	**[0.001]**	**6-1** **[0.001]**
Usable Result Range			
	Low Limit	**[0.000]**	
	High Limit	**[99999.999]**	
ORDAC			
	Low Limit	**[0.000]**	
	High Limit	**[3000.0]**	

* User Defined
** Only urine

CALIBRATION

Setpoint 1 =	Saline	
Setpoint 2 =	50 ng/mL	
	50 µL Calibrator 1 (150 ng/mL) + 100 µL Saline (=dilution 1/3)	
Setpoint 3 =	150 ng/mL	Calibrator 1 (150 ng/mL)
Setpoint 4 =	600 ng/mL	Calibrator 2 (600 ng/mL)
Setpoint 5 =	1500 ng/mL	Calibrator 3 (1500 ng/mL)
Setpoint 6 =	3000 ng/mL	Calibrator 4 (3000 ng/mL)

NB: Calibrator 5 (5000 ng/mL) is not used for DxC Calibration

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