

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.

To use BioPorto's The NGAL Test™ on the Siemens Dimension Vista® chemistry analyzer the reagent must be transferred into a new container. The appropriate containers are called Empty Flex® Reagent Cartridges¹ and can be ordered from your local Siemens representative. Please make sure to acquire the following item:

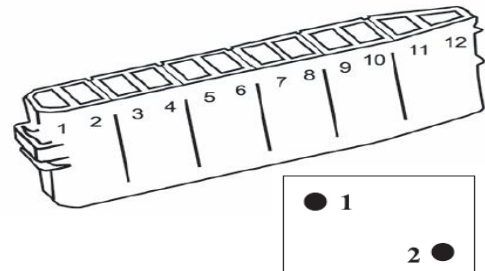
Item	Cat.No.	Product name	
Reagent container	KS999	Empty flex® Reagent Cartridges	Order from Siemens



Please read the Dimension Vista® System Operator's Guide and instruction for Siemens Empty Flex® Reagent Cartridge before transferring the reagents and loading the cartridge into the instrument.

FILLING THE SIEMENS EMPTY FLEX® REAGENT CARTRIDGE:

To fill the cartridge, the clear film that covers the individual wells will need to be punctured. The cartridge well must be vented before filling with reagents. For that, puncture the film at a corner of the well (1) and then fill the well from the opposite corner (2). Take care to minimize the size of the vent holes and filling without tearing the film. Fill the well with the reagents as listed in the table on the next page (the volumes shown are rounded up, allowing easier removal):



	Reagent	Volume per Well	Tests per Well
1	R1	3500	30
2	R1	3500	30
3	R1	3500	30
4	R1	3500	30
5	R1	3500	30
6	R1	3500	30
7	Empty		
8	Empty		
9	Empty		
10	Empty		
11	R2	3500	90
12	R2	3500	90

LOADING AND IDENTIFICATION OF THE FLEX®:

Place the reagent filled Flex® cartridge into the Reagent Load area and press [LOAD]

→ the cartridge will be identified as EMPTY

Press [ADVANCED] icon and then [INVENTORIES]

→ list displays onboard Flexes

Select the REAGENT INVENTORY from the menu and then click on the line of the reagent EMPTY in the NAME column

→ open the configuration window of the cartridge

Select the method XNGAL in the list of methods open channels

Select the lot number or create a new one

If new batch, enter the Lot ID and expiration date and [FINISH] to accept the data

→ the reagent cartridge is marked XNGAL now

For your clinical chemistry analyzer

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.

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)

The limit of detection was estimated as 15 ng/mL on Siemens Dimension Vista® system.

RANGE

The measuring range of The NGAL Test™ is 25-3000 ng/mL on the Siemens Dimension Vista® system.

SECURITY RANGE

The NGAL Test™ showed no effect of antigen excess for NGAL concentrations below 40,000 ng/mL.

PRECISION

REF	Mean (ng/mL)	SD	CV %	n	Acceptance
ST003CA Low	193.8	6.0	3.1	10	<20%
ST003CA High	477.7	5.7	1.2	10	<20%

CALIBRATION

The NGAL Test™ Calibrator Kit (REF ST002CA) should be used the following way:

Calibration point	Kit Calibrator	Level
1	Calibrator 1 (50 ng/mL)	50 ng/mL
2	Calibrator 2 (150 ng/mL)	150 ng/mL
3	Calibrator 3 (600 ng/mL)	600 ng/mL
4	Calibrator 4 (1500 ng/mL)	1500 ng/mL
5	Calibrator 5 (3000 ng/mL)	3000 ng/mL

LIMIT OF QUANTIFICATION (LoQ)

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

25 ng/mL	Mean (ng/mL)	SD	CV %	n	Accept
	21.4	4.2	19.6	20	<20%

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.

Dimension Vista® and Flex® are registered trademarks of Siemens Healthcare Diagnostics Inc., New York, USA.

For your clinical chemistry analyzer

METHOD PARAMETERS, CLICK ON THE FOLLOWING

- Main Menu
- [Advanced]
- [Setup]
- [user-defined methods]
- [Create]

Enter the following parameters:

Method name	XNGAL	Reagents needed	Ref
ID	Enter code	ST001 – NGAL reagents	R1
Unites	ng/mL	ST002 – NGAL calibrator	R2
Mode	Nephelometry		

Execution	Reagent	Calculation	Calibration	Sample				
Delivery	Time	Component 1	Remix	Component 2	Mix	Chase	Volume total	Mix
D1	-21	R1 100 µl	none	-- 0 µl	none	10 µl	110 µL	Gentle
S1	0	S 5 µl					5 µL	Moderate
D2	219	R2 33 µl	none	-- 0 µl	none	5 µl	38 µL	Moderate
D3	39	-- 0 µl	none	-- 0 µl	none	0 µl	0	none
S2	662	S 0 µl				0 µl	0	none
Volume total							153 µL	

Execution	Reagent	Calculation	Calibration	Sample
Well	Reagent	Test	Life (h)	Vol
1	R1	30	720	3310
2	R1	30	720	3310
3	R1	30	720	3310
4	R1	30	720	3310
5	R1	30	720	3310
6	R1	30	720	3310
7	empty	0	0	0
8	empty	0	0	0
9	empty	0	0	0
10	empty	0	0	0
11	R2	90	720	3338
12	R2	90	720	3338

On board stability (hours)

Execution	Reagent	Calculation	Calibration	Sample																					
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Execution	Reagent	Calculation	Calibration	Sample
Serum				
<input type="checkbox"/>	<input type="checkbox"/> Low <input type="checkbox"/> High	Predilute <input type="checkbox"/>	Autodilution <input type="checkbox"/> <input type="checkbox"/> Above <input type="checkbox"/> Below	
Assay Range	<input type="text" value="0"/> <input type="text" value="0"/>	Sample Vol	<input type="text" value="0"/>	Sample Vol <input type="text" value="10"/> <input type="text" value="10"/>
Reference range	<input type="text" value="0"/> <input type="text" value="0"/>	Dilution factor	<input type="text" value="1"/>	Dilution factor <input type="text" value="0"/> <input type="text" value="0"/>
Expiration (min)	<input type="text"/>	Diluent	<input type="text" value="SDIL"/>	Diluent <input type="text" value="SDIL"/>
Plasma				
<input type="checkbox"/>	<input type="checkbox"/> Low <input type="checkbox"/> High	Predilute <input type="checkbox"/>	Autodilution <input type="checkbox"/> <input type="checkbox"/> Above <input type="checkbox"/> Below	
Assay Range	<input type="text" value="0"/> <input type="text" value="3000"/>	Sample Vol	<input type="text" value="0"/>	Sample Vol <input type="text" value="10"/> <input type="text" value="10"/>
Reference range	<input type="text" value="0"/> <input type="text" value="0"/>	Dilution factor	<input type="text" value="0"/>	Dilution factor <input type="text" value="0"/> <input type="text" value="0"/>
Expiration (min)	<input type="text" value="12"/> <input type="text" value="0"/>	Diluent	<input type="text" value="SDIL"/>	Diluent <input type="text" value="Water"/>
Urine				
<input type="checkbox"/>	<input type="checkbox"/> Low <input type="checkbox"/> High	Predilute <input type="checkbox"/>	Autodilution <input type="checkbox"/> <input type="checkbox"/> Above <input type="checkbox"/> Below	
Assay Range	<input type="text" value="0"/> <input type="text" value="3000"/>	Sample Vol	<input type="text" value="0"/>	Sample Vol <input type="text" value="10"/> <input type="text" value="10"/>
Reference range	<input type="text" value="0"/> <input type="text" value="0"/>	Dilution factor	<input type="text" value="0"/>	Dilution factor <input type="text" value="0"/> <input type="text" value="0"/>
Expiration (min)	<input type="text" value="120"/>	Diluent	<input type="text" value="SDIL"/>	Diluent <input type="text" value="Water"/>

Please note: "Digits of precision" needs to be set to "3" on "Method configuration" screen

- Main Menu
- [Advanced]
- [Configuration]
- [Method configuration]