

## Neutrophil Gelatinase-Associated Lipocalin Assay Kit (NGAL)

Amino acetic acid buffer	50mmol/L
<b>Reagent 2 (R2)</b>	
latex particles of sensitized NGAL antibody liquid	0.25w/v%

**Method:** Latex Enhanced IT

Cat . No.	Size	Instrument
GB8300S	R1:1×60 ml R2:1×20 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS8301S	R1:1×60 ml R2:1×20 ml	For Hitachi917 & OlympusAU640/400/600
GT8301S	R1:3×20 ml R2:1×20 ml	For TASHIBA
GX8301S	R1:1×60 ml R2:1×20 ml	For SYNCHRON CX4-5-7-9/ LX20/DXC600-800
GD8301S	R1: 24×3.8 ml R2:12×2.6 ml	For DATE DIMENSION

### INTENDED USE

For the *in vitro* quantitative determination of NGAL in urine or plasma samples.

### CLINICAL SIGNIFICANCE

NGAL (Neutrophil Gelatinase-Associated Lipocalin), a 25-kDa glycoprotein covalently bound to gelatinase, it is synthesized and secreted by tubular epithelial cells of the proximal and distal segment. In healthy kidneys, it is barely detectable in either plasma or urine. However, in the setting of acute tubular injury, NGAL undergoes rapid and profound up regulation with large increases in both urine and plasma. Distinct from traditional markers of function such as creatinine, this rapid response enables NGAL to identify injured kidney much earlier than was previously possible.

In experimental and clinical studies, NGAL has been investigated extensively and would be one of the most frequently investigated and most promising early biomarkers of AKI. NGAL has been investigated across a range of different clinical settings of AKI, such as after cardiac surgery, in critically ill patients, in patients receiving intravenous contrast media infusion for coronary angiography, and in patients admitted to the emergency department et al.

### ASSAY PRINCIPLE

The antigen-antibody reaction occurs between NGAL in a sample and anti-NGAL antibody which has been coated to latex particles. It results in agglutination. This agglutination is detected as an absorbance change (570 nm), with the magnitude of the change being proportional to the

quantity of NGAL in the sample. The actual concentration is then determined by a calibration curve prepared from calibrators of known concentration.

### REAGENT COMPOSITION

Contents	Concentration of Solutions
<b>Reagent 1 (R1)</b>	

### SPECIMEN COLLECTION AND PREPARATION

Urine or plasma (EDTA) sample.

Urine should be centrifuged. Cap the prepared specimens. If the assay can not be performed within 24 hours, freeze the specimens at -20°C or below.

### STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.

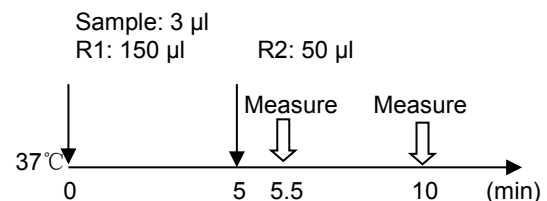
Stable up to the expiry date when stored at 2-8°C.

### ASSAY PROCEDURE

Test Procedure for Analyzers (Hitachi 7180)

Assay Mode: 2 Point End, 19 - 34

Wavelength(main/sub) 570 nm / 800 nm



### CALIBRATION

Gcell NGAL calibrators (Cat.No: GC-NGAL).

### CALCULATIONS OF RESULTS

Plot calibrator concentrations against the corresponding  $\Delta A$  values using graph paper. The concentration of NGAL in the sample is obtained by reading of a value from the calibration curve. Do not attempt to extrapolate above or below the range of the calibrators.

### QUALITY CONTROL

Gcell NGAL Controls (Cat.No:GQ-NGAL/2 for high level, GQ-NGAL/1 for low level). Quality control materials are intended for use only to monitor accuracy and precision. The values for these controls should fall within specified limits. If the control values fall outside these ranges and repetition precedes technical error the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

### NORMAL VALUE

Urine: 0.9-100 ng/ml

Plasma: 37-180 ng/ml

It is recommended that each laboratory should assign its own normal range as this is dependent upon geographical location.

### MAIN PERFORMANCE CHARACTERISTICS

#### LINEARITY

The assay is linear up to 4920 ng/ml. If the concentration is above the upper limit. Please dilute the sample with 0.9% NaCl and assay the diluted sample repeatedly. Multiply the result by dilution factor.

**PRECISION**

 The CV of the test should be  $\leq 5\%$ 

Intra precision		
N=20	Level 1	Level 2
Mean	120ng/ml	485ng/ml
SD	4.2	9.5
CV	3.54%	1.96%

Inter assay precision			
N=5	Batch 1	Batch 2	Batch 3
Mean(ng/dl)	154.3	149.09	152.82
$\bar{x}$	152.07		
$(X_{max}-X_{min})/\bar{x}$	$(154.3-149.09)/152.07*100=3.43\%$		

**INTERFERENCE**

The following analytes were tested up to the levels indicated and found not to interfere:

Hemoglobin:	up to 500 mg/dl
Bilirubin:	up to 30 mg/dl
Intralipid:	up to 1500mg/dl
VC:	up to 50 mg/dl










**SAFETY PRECAUTIONS AND WARNINGS**

1. For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.
2. Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
3. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
4. Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
5. Reagents with different lot numbers should not be interchanged or mixed.

**REFERENCES**

1. Bennett M, Dent CL, Ma Q, et al. Urine NGAL predicts severity of acute kidney injury after cardiac surgery: a prospective study. *Clin J Am Soc Nephrol.* 2008; 3:665-673.
2. Haase-Fielitz A, Bellomo R, Devarajan P, et al. Novel and conventional serum biomarkers predicting acute kidney injury in adult cardiac surgery—a prospective cohort study. *Crit Care Med.* 2009;37:553-560.
3. Wheeler DS, Devarajan P, Ma Q, et al. Serum neutrophil gelatinase-associated lipocalin (NGAL) as a marker of acute kidney injury in critically ill children with septic shock. *Crit Care Med.* 2008;36:1297-1303.d
4. Hirsch R, Dent C, Pfriem H, et al. NGAL is an early predictive biomarker of contrast-induced nephropathy in children. *Pediatr Nephrol.* 2007;22:2089-2095.

**INDEX OF SYMBOLS**

	Manufacture
	Catalogue Number
	Lot number
	Date of manufacture
	Use by(Expiration date)
	For In-Vitro Diagnostic use only
	Stored at 2-8°C
	Attention:See instruction for use
	Authorized Representative in the European Company