



# NGAL

## Fast Test Kit

### (Immunofluorescence Assay)

#### User Manual

#### INTENDED USE

NGAL Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of neutrophils gelatinase associated lipocalin (NGAL) in human serum and urine samples. This test is used as an aid in the early diagnosis of acute kidney injury (AKI), risk classification and treatment monitoring. For professional and laboratory use only.

#### SUMMARY

The inclining incidence of chronic kidney disease which has led to high mortality and immense medical burden over the past decades has become a distressing concern in epidemiology. Unfortunately, the number of biomarkers that allow the monitoring of chronic kidney disease (CKD) is limited. NGAL is an emerging biomarker which has been shown to be able to aid the diagnosis of kidney injuries.

The evidence for the role of NGAL measurements in a variety of clinical situations leading to AKI (cardiac surgery, kidney transplantation, contrast nephropathy, haemolytic uraemic syndrome and in the intensive care setting) or to CKD (lupus nephritis, glomerulonephritides, obstruction, dysplasia, polycystic kidney disease, IgA nephropathy) is explored. The emerging utility of standardized clinical platforms for reliable measurement of NGAL in plasma (Triage NGAL Device; Biosite Incorporated) and urine (ARCHITECT analyzer; Abbott Diagnostics) is also discussed. It will be important in future studies to validate the sensitivity and specificity of NGAL concentration measurements in clinical samples from large cohorts and from multiple clinical situations. Such studies will be facilitated by the anticipated widespread availability of standardized commercial tools in the near future.

#### PRINCIPLE

NGAL Fast Test Kit (Immunofluorescence Assay) adopts a double-antibody sandwich method to quantitatively detect the concentration of NGAL in human serum and urine samples. After the sample has been applied to the test card, the fluorescently labelled NGAL monoclonal antibody binds with NGAL in sample and forms a marked antigen-antibody complex. The complex moves to the detection area by capillary action, then it is captured by NGAL polyclonal antibody coated on the detection area of nitrocellulose membrane, forming a double-antibody complex. The fluorescence intensity of the test line increases in proportion to the amount of NGAL in sample. Fluorescent signals intensity can be analyzed by applicable device thus the NGAL in sample be detected quantitatively.

#### APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer  
Getein 1160 Immunofluorescence Quantitative Analyzer  
Getein 1180 Immunofluorescence Quantitative Analyzer  
Getein 1200 Immunofluorescence Quantitative Analyzer  
Getein 1600 Immunofluorescence Quantitative Analyzer

#### CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
NGAL test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10 tubes	25 tubes	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

\*NGAL test card

A test card consists of: Fluorescently labelled NGAL monoclonal antibody, NGAL polyclonal antibody and polyclonal IgG antibody.

\*\* Sample diluent

(1) Sample diluent for Getein 1100/ Getein 1160/ Getein 1180 in each tube mainly consists of: Phosphate buffer (20 mmol/L), Na<sub>3</sub> (<0.1%).

(2) Sample diluent for Getein 1200/ Getein 1600 is an

independent packing box mainly consists of:

- Phosphate buffer (20 mmol/L), Na<sub>3</sub> (<0.1%) (25 mL/ bottle for Getein 1200,40 mL/bottle for Getein 1600),
- Box with pipette tips (96 tips/box),
- Mixing plate (1 piece/box).

**Note:**

- The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
- Do not mix or interchange different batches of kits.

#### STORAGE AND STABILITY

**Realtime stability:**

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

**In-use stability:**

- For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.
- For test card of Getein 1200/Getein 1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

#### PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
- It is recommended that operators take necessary self-protection measures (work clothes, goggles and disposable gloves, etc) when touching kits or samples.

#### SPECIMEN COLLECTION AND PREPARATION

- This test can be used for serum and urine samples. Samples should be free of hemolysis.

- Urine sample can be preserved at room temperature for 4 hours, please test it as soon as possible. If testing is delayed, urine sample may be stored up to 3 days at 2~8 °C before testing.
- Serum sample can be preserved at room temperature for 4 hours. If testing is delayed, serum samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing.
- Samples should be brought to room temperature before testing.
- Do not use frozen urine samples.
- Do not use heat-inactivated samples.
- SAMPLE VOLUME (for Getein 1100/Getein 1160/Getein 1180): 10 µL.**

#### TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

- (1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- (2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- (3) Remove the test card from the sealed pouch before use. Horizontally place the test card.
- (4) Deliver 10 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.
- (5) **Reaction time: 10 minutes.** After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

- (1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.
- (2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- (3) Remove the test card from the sealed pouch before

use. Horizontally place the test card.  
 (4) Deliver 10 µL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 µL of sample mixture into the sample well on the test card.

(5) Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (10 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

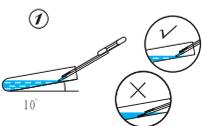
**For Getein 1200/Getein 1600:**

- (1) Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.
- (2) Place the sample diluent at the correct position in Getein 1200/Getein 1600.
- (3) Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/ Getein 1600 will do the testing and print the result automatically.

**Note:**

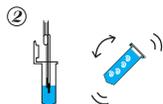
1. It is required to perform "SD card" calibration when using a new batch of kits for Getein 1100/ Getein 1160/ Getein 1180.
2. The directions for using disposable pipet are as follow:

**Directions to use disposable pipet**

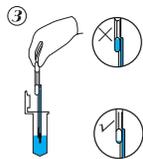


Insert the disposable pipet into the sample tube, gently touch the liquid surface with the capillary tip, and draw the sample.

**Note: Do not immerse the exhaust pipe below the liquid level.**



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, gently squeeze the suction bulb to perform 2-3 aspiration washing cycles, then mix the dilution manually.



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, firmly squeeze the suction bulb to aspirate the mixed sample.



Squeeze the suction bulb and drop the mixed sample vertically into the sample well on the test card.

**RESULTS**

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

**LIMITATIONS**

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Creatinine	10 g/L
Glucose	10 g/L
Urea	100 g/L
Hemoglobin	5 g/L
Triglyceride	25 g/L
Bilirubin	0.1 g/L

**EXPECTED VALUE**

The expected normal value for NGAL was determined by testing samples from 319 apparently healthy individuals.

The 95<sup>th</sup> percentile of the concentration for NGAL in serum is 200.0 ng/ml. The 95<sup>th</sup> percentile of the concentration for NGAL in urine is 100.0 ng/ml.

It is recommended that each laboratory establish its own expected values for the population it serves.

**PERFORMANCE CHARACTERISTICS**

Measuring Range	50.0~5000.0 ng/ml
Limit of Detection	≤50.0 ng/ml
Within-Run Precision	≤10%
Between-Lot Precision	≤15%

**REFERENCES**

1. Wasilewska A, Taranta-Janusz K, Dębek W, et al. KIM-1 and NGAL: new markers of obstructive nephropathy. *Pediatr Nephrol.* 2011, 26(4):579-586.
2. Clerico A, Galli C, Fortunato A, et al. Neutrophil gelatinase-associated lipocalin (NGAL) as biomarker of acute kidney injury: a review of the laboratory characteristics and clinical evidences. *Clin Chem Lab Med.* 2012, 50(9): 1505-1517.
3. Shemin D, Dworkin LD. Neutrophil gelatinase-associated lipocalin (NGAL) as a biomarker for early acute kidney injury. *Crit Care Clin.* 2011, 27(2):379-389.
4. EN ISO 18113-1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling)-Part 1: Terms, definitions and general requirements.
5. EN ISO 18113-2:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labelling)-Part 2: In vitro diagnostic reagents for professional use.

**DESCRIPTION OF SYMBOLS USED**

The following graphical symbols used in or found on NGAL Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Caution

Thank you for using NGAL Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

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Catalogue number	Applicable analyzer	Package specification
IF1010-10T	Getein 1100	10 T/kit
IF1010	Getein 1100	25 T/kit
IF5010-10T	Getein 1160	10 T/kit
IF5010	Getein 1160	25 T/kit
IF3010-10T	Getein 1180	10 T/kit
IF3010	Getein 1180	25 T/kit
IF4010	Getein 1200	2*24 T/kit
IF4010-96T	Getein 1200	2*48 T/kit
IF2010	Getein 1600	2*24 T/kit
IF2010-96T	Getein 1600	2*48 T/kit