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NGAL

Fast Test Kit

(Immunofluorescence Assay)

IF1010 for Getein1100
IF5010 for Getein1160
IF3010 for Getein1180
IF4010 for Getein1200
IF2010 for Getein1600

User Manual REF

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.

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

The test uses an anti-human NGAL polyclonal antibody conjugated with fluorescence latex and an anti-human NGAL monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human NGAL polyclonal antibody binds with the NGAL in sample and forms an antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human NGAL monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of NGAL in sample.
Then insert test card into Getein1100/Getein1160/Getein 1180 Immunofluorescence Quantitative Analyzer/automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentration of NGAL in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading.The result can be easily transmitted to the laboratory or hospital information system.

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1. A kit for Getein1100/Getein1160/Getein1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) NGAL test card in a sealed pouch with desiccant
2) Capillary pipet
3) Sample diluent
4) User manual: 1 piece/kit
5) SD card: 1 piece/kit

2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein NGAL test cards
2) User manual: 1 piece/kit

Materials required for Getein1200/Getein1600:
1) Sample diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit

3. Sample diluent composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

4. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with a fluorescence latex-labelled anti-human NGAL polyclonal antibody, the test line is coated with an anti-human NGAL monoclonal antibody, and the control line is coated with rabbit anti-goat IgG antibody), absorbent paper and liner.
Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30℃ with a valid period of 24 months.
Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.
For test card of Getein1200/Getein1600: 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

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and urine samples***. Samples should be free of hemolysis.
2. 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℃ before testing.
3. If testing is delayed, serum samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing.
4. Samples should be brought to room temperature before testing.
5. Do not use frozen urine samples.
6. Do not use heat-inactivated samples.
7. SAMPLE VOLUME ***(for Getein1100/Getein1160/Getein 1180): 10 μL***.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample should be brought to room temperature before testing.

For Getein1100:
1. Confirm SD card lot No. in accordance with test kit lot No..Perform “SD card” calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
3. Put the test card on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver ***10 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample well on the test card (for disposable capillary pipet using, please refer to the directions in the package).
5. ***Reaction time: 10 minutes.*** Insert the test card into Getein1100 and press "ENT" button or click on “Start” icon (for Android Getein 1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:
1. Confirm SD card lot No.in accordance with test kit lot No..Perform “SD card”calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180.
3. Remove the test card from the sealed pouch immediately before use.Label the test card with patient or control identification.
4. Put the test card on a clean table,horizontally placed.
5. Using sample transfer pipette,deliver ***10 μL*** of sample into one tube of sample diluent,mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample well on the test card.
6. Insert the test card into Getein1160/Getein1180 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 Getein1200/Getein1600:

1. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent at the correct position in Getein-1200/Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits for Getein1100/Getein1160/Getein1180.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1160/Getein1180.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1160/Getein1180/Getein1200/Getein1600.

EXPECTED VALUE

The expected normal value for NGAL was determined by testing samples from 319 apparently healthy individuals. The 95th percentile of the concentration for NGAL in serum is 200.0 ng/ml. The 95th percentile of the concentration for NGAL in urine is 100.0 ng/ml. (The probability that value of a normal person with serum below 200.0 ng/ml is 95%, the probability that value of a normal person with urine below 100.0 ng/ml is 95%.)

PERFORMANCE CHARACTERISTICS

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

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. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferents.

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

REFERENCES

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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 details 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*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
Σ	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community/ European Union
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing NGAL Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

Version: WIF14-S-12

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