CE IVD

One Step Test for NGAL

(Colloidal Gold)

Instructions for Use

REF CG1010 for FIA8000
CG3010 for FIA8600

INTENDED USE

One Step Test for NGAL (Colloidal Gold) is intended for *in vitro* quantitative determination of neutrophils gelatinase associated lipocalin (NGAL) in serum and urine. 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 colloidal gold and an anti-human NGAL monoclonal antibody coated on the test line. After the sample has been applied to the test strip, the gold-labelled anti-human NGAL polyclonal antibody binds with the NGAL in sample and forms a marked 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 resulting in a purplish red streak appears on the test line. The color intensity of the test line increases in proportion to the amount of NGAL in sample.

Then insert test card into FIA8000/FIA8600 Quantitative Immunoassay Analyzer (hereinafter referred to as FIA8000 and FIA8600), the concentration of NGAL in sample will be measured and displayed on the screen. The value will be stored in FIA8000/FIA8600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for FIA8000/FIA8600 contains:

Package specifications: 25 tests/box, 10 tests/box

1）Getein NGAL test card in a sealed pouch with desiccant
2）Capillary pipet
3）Sample diluent
4）Instructions for use: 1 piece/box
5）SD card: 1 piece/box

2. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (a colloidal gold-labelled anti-human NGAL polyclonal antibody is coated at the border of the nitrocellulose membrane and sample pad, 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.

3. Sample diluent composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

FIA8000 Quantitative Immunoassay Analyzer
FIA8600 Quantitative Immunoassay Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months.
Use the test card within 1 hour once the foil pouch is opened.
Store the sample diluent at 0~30℃ with a valid period of 24 months.
Store the sample diluent at 2~8℃ for better results.

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 is damaged.
4. Do not open pouches 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 instructions for use 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. If testing is delayed, serum sample may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing.
3. Urine sample can be preserved at room temperature for 4 hours, please test it as soon as possible. If testing will be delayed, urine sample may be stored up to 3 days at 2~8℃ 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: ***10 μL***.

TEST PROCEDURE

1. Collect specimen according to instructions for use.
2. Test card, sample should be brought to room temperature before testing.
3. Confirm SD card lot No. in according with test kit lot No.. Perform calibration when necessary (Details refer to FIA8000/8600 instructions for use).
4. On the main interface of FIA8000/FIA8600, press "ENT" button

(FIA8000) or click on “Measure” icon (FIA8000/8600) to enter testing interface.

5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. 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 port on the test card (for disposable capillary pipet using, please refer to the directions in the package) .
8. ***Reaction time: 3 minutes.*** Insert the test card into FIA8000 /FIA8600, press "ENT" button (FIA8000) or click on “Measure” icon (FIA8000/FIA8600) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

Notes:

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

TEST RESULTS

Valid: When a purplish-red band appears at the control area (C), use FIA8000/FIA8600 to analyze the test card and get the result.

Invalid: If no colored band appears in the control area (C), the test result is invalid. The test should be repeated and if the same situation happened again, please stop using this batch of products and contact your supplier.

Others: Dilute the sample which concentration is higher than the upper limit with saline, the dilution ratio should be less than 4 times.

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%.) 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
Lower Detection Limit	≤50.0 ng/ml
Within-Run Precision	≤10%
Between-Run Precision	≤15%

Method Comparison:

The assay was compared with Abbott Architect i2000 Analyzer and NGAL test kits of Beijing Strong with 200 urine samples (157 positive samples and 43 negative samples) and 200 serum samples (130 positive samples and 70 negative samples). The correlation coefficient (r) of urine samples is 0.990 and the correlation coefficient (r) of serum samples is 0.988.

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. Samples containing interferents 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

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. EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.
4. 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 the test kit 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
	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 One Step Test for NGAL (Colloidal Gold). Please read this instructions for use carefully before operating to ensure proper use.

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