Chuangxingwell

NGAL Rapid Test Kit
Package Insert

CE

A test for measuring NGAL in urine with the use of Fluorescence Immunoassay Analyzer.
For professional in vitro diagnostic use only.

IVD

【INTENDED USE】

The NGAL Rapid Test Kit is based on Fluorescence Immunoassay to measure NGAL in Urine.

【SUMMARY】

Neutrophil gelatinase-associated lipocalin (NGAL), also known as Lipocalin-2 (LCN2) or oncogene 24p3,is a protein that in humans is encoded by the LCN2 gene.[1,2,3] NGAL is involved in innate immunity by sequestrating iron that in turn limits bacterial growth.[4] It is expressed in neutrophils and in low levels in the kidney, prostate, and epithelia of the respiratory and alimentary tracts.[3,5] NGAL is used as a biomarker of kidney injury.[6]

In the case of acute kidney injury (AKI), NGAL is secreted in high levels into the blood and urine within 2 hours of injury.[7] Because NGAL is protease resistant and small, the protein is easily excreted and detected in the urine.[8] NGAL levels in patients with AKI have been associated with the severity of their prognosis and can be used as a biomarker for AKI.[7] NGAL can also be used as an early diagnosis for procedures such as chronic kidney disease, contrast induced nephropathy, and kidney transplant.[9]

【PRINCIPLE】

The NGAL Rapid Test Kit detects NGAL based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. NGAL in the urine will be captured by anti-NGAL antibody that conjugated with fluorescent microspheres. Then the compound will be captured by another anti-NGAL antibody coated on the membrane (Test line). The concentration of NGAL in the sample is inversely related to the intensity of the fluorescent signal captured on the T line. According to the fluorescence intensity and the standard curve, the concentration of NGAL in the sample can be calculated by Analyzer to show NGAL concentration in specimen.

【REAGENTS】

The test includes anti-NGAL antibody coated fluorescent microspheres and anti-NGAL antibody coated on the membrane.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The NGAL Rapid Test Kit should only be used with the Analyzer by approved medical professionals.

【STORAGE AND STABILITY】

1. The kit should be stored at 4-30 °C before the expiry date printed on the sealed pouch. Shelf life is 24 months.
2. The test must remain in the sealed pouch until use. Use the test kit within 1 hour once the foil pouch is opened.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

【SPECIMEN COLLECTION AND PREPARATION】

Use preferably only fresh morning urine for testing since physical effort can lead to an increase in albumin expulsion. Urine sample should be stored at 2-8 °C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20 °C. Samples that have been refrigerated must be equilibrated to room temperature before testing. Avoid repeated freezing and thawing of urine samples.

【MATERIALS】

Materials Provided

- Test Cassettes
- Package Insert
- Droppers
- ID Card
- Specimen Collection Tubes with Buffer

Materials Required But Not Provided

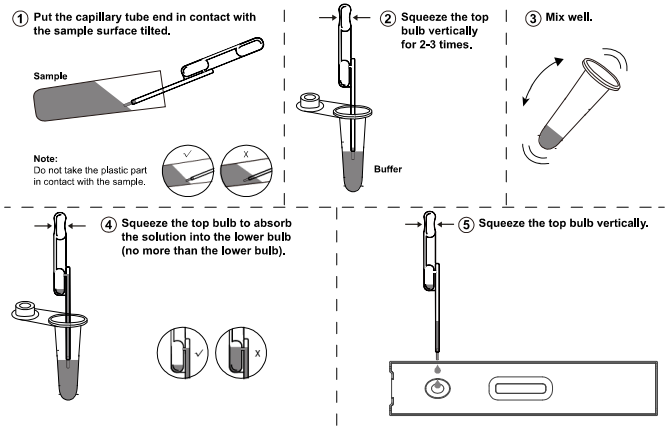
- Timer
- Centrifuge
- Specimen Collection Containers
- Fluorescence Immunoassay Analyzer
- Pipette

【DIRECTIONS FOR USE】

Refer to Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the analyzer. The test should be conducted in room temperature.

Allow the test, specimens and/or controls to reach room temperature (15-30 °C) prior to testing.

1. Turn on the Analyzer power. Then according to the need, select “Standard test” or “Quick test” mode.
2. Take out the ID card and insert it into the Analyzer port.
3. **To use a pipette**: Pipette **10 μL of sample** into the buffer tube; mix the specimen and the buffer well.
   To use a dropper: Without squeezing the dropper, put the glass capillary tube end in contact with the liquid sample surface tilted. Liquid sample will migrate into the capillary tube automatically. **Note:** Make sure do not take the plastic part of the dropper in contact with the sample.
   Then release the sample into the buffer tube by squeezing the bulb at the top end of the dropper vertically. Wash the tube 2-3 times by squeezing the top bulb. Mix the sample and the buffer well.
4. **To use a pipette**: Pipette **75 μL of diluted specimen** into the sample well of the cassette. Start the timer at the same time.
   To use a dropper: Immerse the tube end (plastic tube) into the diluted sample; squeeze the top bulb to absorb the solution into the lower bulb (no more than the lower bulb).
   Squeeze the top bulb vertically to release the diluted solution into the sample well of the test cassette and start the timer.



5. There are two test modes for Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of Fluorescence Immunoassay Analyzer for details.

“Quick test” mode: After **10 minutes** of adding sample，Insert the test cassette into the Analyzer, click “**QUICK TEST**”, fill the test information and click "**NEW TEST**" immediately. The Analyzer will automatically give the test result after a few seconds.

“Standard test” mode: Insert the test cassette into the Analyzer immediately after adding specimen, click “**STANDARD TEST**”, fill the test information and click **"NEWTEST"** at the same time, The Analyzer will automatically countdown **10 minutes**. After the countdown, the Analyzer will give the result at once.

【INTERPRETATION OF RESULTS】

Results read by Fluorescence Immunoassay Analyzer.

The result of tests for NGAL is calculated by Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of Fluorescence Immunoassay Analyzer.

Linearity range of NGAL Test is 10~1500 ng/mL.

Reference value: 0.7~9.6ng/mL

【QUALITY CONTROL】

Each NGAL Rapid Test Kit contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was inserted and read properly by Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on Fluorescence Immunoassay Analyzer indicating that the test should be repeated. An invalid result from the internal control causes an “N/A” message on Fluorescence Immunoassay Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【LIMITATIONS】

1. The NGAL Rapid Test Kit is for professional *in vitro* diagnostic use, and should only be used for the quantitative detection of NGAL.
2. The NGAL Rapid Test Kit will only indicate the presence of NGAL in the specimen.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The results of NGAL Tests are based on measuring the levels of NGAL in the specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

【EXPECTED RESULTS】

Concentrations	Clinical Reference
＜10ng/mL	Health
＜100ng/mL	Low risk for AKI
＞100ng/mL	High risk for AKI

【PERFORMANCE CHARACTERISTICS】

1. Accuracy

The test deviation is ≤±15%.

2. Sensitivity

The NGAL Rapid Test Kit can detect levels of NGAL as low as 10ng/mL in Urine.

3. Detection range

10~1500ng/mL

4. Linearity range

10~1500ng/mL, R≥0.990

5. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 50ng/mL, 200ng/mL of NGAL. C.V. is ≤ 15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 50ng/mL，200ng/mL of NGAL. C.V. is ≤15%.

6. interfering substances

The following substances do not interfere with the test results at the indicated concentration: 50mg/mL creatinine, 100mg/mL carbamide, 20mg/ml albumin.

【BIBLIOGRAPHY】

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9. Goldstein SL (2011). "Acute kidney injury biomarkers: renal angina and the need for a renal troponin I". BMC Med. 9: 135. doi:10.1186/1741-7015-9-135. PMC 3287120. PMID 22189039.

Index of Symbols

⚠	Caution	IVD	In Vitro Diagnostic Medical Device		Do Not Use if Package is Damaged
	Manufacturer	LOT	Batch Code	Σ	Contains Sufficient for <n> Tests
CE	CE Marking	REF	Catalogue Numbe	EC REP	Authorized representative in the European Community
	Keep Dry		Use-By Date		Keep Away From Sunlight
	Temperature Limit	2	Do Not Re-use		Date of Manufacture

Manufacturer
Jinan Chuangxingwell Biotech Co., Ltd.
Add.: Building 1-2B-402, Liando U Valley, Gangyuan Sixth Road, Jinan Zhangjin Comprehensive Bonded Zone, Gaoxin District, Jinan city, Shandong Province, China
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