Human Neutrophil Gelatinase-Associated Lipocalin (NGAL) Rapid Test (DTS-L001)

This product is for research use only and is not intended for diagnostic use.

PRODUCT INFORMATION

Size

10T

General Description

NGAL, also known as oncogene 24p3 or Lipocalin-2 (LCN2) is involved in innate immunity by sequestering iron that in turn limits bacterial growth. It is expressed in neutrophils and in low levels in the kidney, prostate, and epithelia of the respiratory and alimentary tracts.

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

Kidney health is most frequently measured by serum creatinine. Serum creatinine is a marker of kidney function, whereas NGAL is a marker of kidney injury. NGAL levels are a more precise and sensitive marker for diagnosing AKI than serum creatinine levels. In fact, the increase in urinary excretion of NGAL has been proven to be due to tubular alterations that take place before any damage can be detected by other methods. Therefore, monitoring NGAL levels reduces delayed AKI diagnosis and treatment. Using a more sensitive and specific marker allows for earlier diagnosis, correct responses to AKI, and reduced risk of morbidity and mortality.

Principles of Testing

The Neutrophil Gelatinase-Associated Lipocalin (NGAL) Rapid Test utilizes the principle of Immunochromatography (also called as lateral flow immunoassay, LFIA). A mouse antihuman NGAL antibody is immobilized on the nitrocellulose membrane as the test line (T line) in the test window of the test device. As the test sample flows through the membrane assembly within the test device, NGAL within the sample is bound by a second mouse anti-human NGAL antibody conjugated with colloidal gold and released from the sample pad. This antigen-antibody complex moves further on the membrane to the test region where it is immobilized by the first anti-human NGAL coated on the membrane, leading to the formation of a colored band, which confirms a positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line (C line) will always appear in the test window, regardless of the presence or absence of NGAL in the specimen.

Storage
Store the cards in their original packaging at room temperature. This product is stable for up to 18 months from the certified date. Freezing the strips is not recommended.

**Specimen Collection And Preparation**

1. No prior special preparation of the patient is required before sample collection by approved techniques.
2. Fresh morning urine is preferable. Urine may be stored at 2-8°C up to 3 days in case of delay in testing. For long-term storage, freeze the specimen at -20°C for 3 months or -70°C for longer periods.
3. Repeated freezing and thawing of the specimen should be avoided.
4. Do not use haemolysed, clotted, contaminated, lipamic and viscous/turbid specimen.
5. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.

Do not heat inactivate the sample.

**Assay Procedure**

1) Place the card horizontally.
2) Add 100 μL of biological fluids directly to the Sample Well.
3) Wait for 3-5 minutes

**Reference Values**

**Negative:** Only the control C line appears.

**Positive:** Both the C line and test T line appear, which indicates the presence of NGAL.

**Invalid:** If after 20 minutes no C line appears, the result is invalid. The test should be repeated with a new device.

**Sensitivity**

The assay has a sensitivity to detect NGAL down to 50 ng/mL.

**Precautions**

1. This kit is for IN VITRO research use and should be handled by PROFESSIONALS.
2. Read the instructions carefully before performing the test.
3. Follow standard lab procedure and biosafety guidelines, and handle all human specimens as potentially infectious. Wear gloves during the whole procedure.
4. When the assay procedure is complete, dispose specimens after autoclaving them at 121°C for at least 20 min. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal.

**Limitations**

1. The test is for qualitative detection of NGAL in human urine, but does not indicate the quantity of NGAL.
2. The test is for research use only, and should NOT be used for diagnosis.
3. As in case of all rapid tests, a definitive clinical diagnosis should not be based on the result of a single test but should rather be made after all the clinical findings have been evaluated.