Your partner for rapid testing

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KI SCREENING TEST

The first rapid test for semi-quantitative detection of NGAL in urine for early screening of kidney damage in dogs.

For professional use only.

REF 800087

800087_IFU_02_1.0 05/2023

INSTRUCTIONS FOR USE

NGAL PROTEIN

Neutrophil Gelatinase Associated Lipocalin (NGAL), a protein synthesised by many tissues, is freely filtered by the glomeruli and reabsorbed by renal tubules. Tubular damage results in increased NGAL in the urine due to reduced reabsorption of the filtered NGAL from the plasma and an increased release of NGAL from damaged proximal and distal tubules. The role of NGAL as an **early marker** of Acute Kidney Injury (AKI), Chronic Kidney Disease (CKD) and Urinary Tract Infection (UTI) has been the subject of recent studies in dogs, which confirm its clinical utility and prognostic role in enabling **rapid therapeutic intervention.**

PRINCIPLE AND USE OF THE TEST

KI SCREENING TEST is a lateral flow immunochromatographic device, for professional use, for semi-quantitative detection of NGAL in dog urine samples. By comparing the intensity of the test line (T) with the colour chart provided, the concentration of NGAL in the urine can be semi-quantitatively detected, which is directly proportional to the severity of kidney damage and indicative of potential clinical settings.

PRECAUTIONS AND LIMITATIONS

1. Read these instructions carefully before testing. The test is reliable if the instructions are carefully followed.
2. This kit is for canine veterinary use only, do not use it on other animals. Treat samples as potentially infected and use good laboratory practice (wear protective clothes, gloves, and eye protection).
3. Do not use the test after the expiry date or if the packaging is damaged.
4. Do not mix kit components from different batches.
5. Store kit components at a temperature of +4°C to +30°C. Do not freeze.
6. Do not open the foil package unless it is to be used.
7. After use, dispose of all components in compliance with local regulations.
8. All components of the kit are to be considered disposable, with the exception of the instructions for use.
9. The presence of a high number of leukocytes in the urine could cause an increase in urinary NGAL, since the biomarker is produced by neutrophil granulocytes. In the clinical study, a significant increase in urinary NGAL was found for leukocyte concentrations of >20 WBC/hpf.
10. The presence of significant leukocytosis could cause an increase in urinary NGAL. Clinical studies have found a tendency for urinary NGAL to increase with increasing WBC/µL of blood, especially neutrophil granulocytes.
11. Do not eat, drink or smoke in the area where samples or kits are handled.
12. The test is for external use only. Do not ingest the extraction buffer or other components in the box. If swallowed, seek immediate medical advice.

PERFORMANCE STUDIES

ANALYTICAL PERFORMANCE

The test was evaluated on 180 urine samples from different clinical settings of urinary tract disease by comparing it with the gold standard (ELISA, BioPorto Diagnostics inc).
The analytical performance, understood as the ability of the device to detect the presence of NGAL above the Limit of Detection (LoD), measured were as follows:

SENSITIVITY: 99.21% (CI 95%: 95.67-99.86%)

SPECIFICITY: 98.15% (CI 95%: 90.23-99.67%)

ACCURACY: 98.90% (CI 95%: 96.06-99.70%)

CLINICAL PERFORMANCE

When used in the setting of a clinical trial on dogs, the device showed that a urinary NGAL concentration of 20 ng/mL was the cut-off capable of distinguishing the presence of AKI, with a sensitivity of 97.6%.
The device was therefore found to be a clinically relevant diagnostic tool for identifying the risk of AKI in the clinical setting.

INTERFERENCE

No interference was observed in the presence of the following substances: ethanol, ultrasound gel, haemoglobin, bilirubin, glucose, ketones, leukocytes, nitrites, total protein, urobilinogen, and under different urinary pH conditions, even non-physiological (pH = 3 and pH = 9).

BIBLIOGRAPHY

1. *Davis J, Raisis AL, Miller DW, Hosgood GL, Rossi G. Analytical validation and reference intervals for a commercial multiplex assay to measure five novel biomarkers for acute kidney injury in canine urine. Res Vet Sci. 2021 Oct;139:78-86.*
2. *Lee YJ, Hu YY, Lin YS, Chang CT, Lin FY, Wong ML, Kuo-Hsuan H, Hsu WL. Urine neutrophil gelatinase-associated lipocalin (NGAL) as a biomarker for acute canine kidney injury. BMC Vet Res. 2012 Dec 28;8:248.*
3. *Nabity M, Hokamp J. Urinary Biomarkers of Kidney Disease in Dogs and Cats. Vet Clin North Am Small Anim Pract. 2023 Jan;53(1):53-71. doi: 10.1016/j.cvsm.2022.07.006. Epub 2022 Oct 19. PMID: 36270837.*
4. *Steinbach S, Weis J, Schweighauser A, Francey T, Neiger R. Plasma and urine neutrophil gelatinase-associated lipocalin (NGAL) in dogs with acute kidney injury or chronic kidney disease. J Vet Intern Med. 2014 Mar-Apr;28(2):264-9. doi: 10.1111/jvim.12282.*

CONTENTS

**for the exact number of components listed, please see the label on the outside of the kit.*

*rapid tests
*single-use pre-dosed bottles
*pipettes
*colour chart
1 instructions for use

Materials required but not provided: timer, urine sample container.

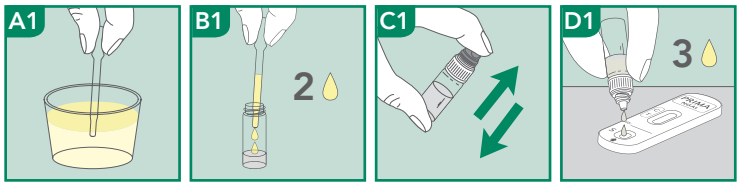
PREPARATION AND COLLECTION OF THE SAMPLE:

1) Collect the patient's urine in a clean, dry container using the collection method deemed most appropriate.
2) Centrifuge the patient's urine (5000 rfc for 5 minutes). Centrifugation of the sample is recommended but not essential.

If not used immediately, storage at +2°/+8° C is recommended. If not used within 24 hours at this temperature, freezing at -20°C is recommended.

TEST PROCEDURE

If stored cool, allow the kit components and/or sample to reach room temperature (15-30°C) before testing.



1) Open the thinner bottle by unscrewing the white portion of the cap and prepare the necessary material as follows: open the aluminium bag, take out only the cassette and place it on a flat, dry surface. Discard the desiccant bag. Using the pipette provided, collect the urine sample. - FIG. A1
2) Transfer 2 drops of sample into the diluent bottle. - FIG. B1
3) Close the diluent bottle with the cap and mix by gently turning the bottle upside down 3-5 times. - FIG. C1
4) Open the dropper of the bottle by unscrewing the blue portion of the cap and dispense 3 drops of solution into the well (S) of the test cassette. Wait 1-2 seconds between each drop. - FIG. D1
5) **Wait 10** minutes and place the cassette on the dotted section of the colour chart provided. Read the result displayed by comparing the intensity of the test line (T) with the colour chart provided.

SYMBOLOGY

Read the instructions for use carefully	*Manufacturer*
Use by (last day of the month)	*Product code*
Store out of sunlight	*Product batch*
Sufficient for <n> tests	*Do not reuse*
Temperature limits	*Importer*

INTERPRETATION OF THE RESULTS

Results must be read after 10 minutes and no later than 12 minutes.

The intensity of the test line (T) is directly proportional to the NGAL concentration present in the sample analysed.

The intensity of the control line (C), as long as it is visible, is of no importance for the reading of the result.

RESULT	ASSOCIATED 0CLINICAL SETTING
NGAL ~90 ng/mL or greater The intensity of the test line (T) is similar to the 90 ng/mL line shown on the colour chart (strong intensity test line)	This result suggests a high risk of AKI or AKI/CKD (chronic kidney damage).
NGAL ~20 ng/mL The intensity of the test line (T) is similar to the 20 ng/mL line shown on the colour chart (medium intensity test line)	This result suggests an intermediate risk of AKI. Consider the possible presence of CKD or UTI in differential diagnostics.
NGAL ~4 ng/mL The intensity of the test line (T) is similar to the 4 ng/mL line shown on the colour chart (weak intensity test line)	This result suggests a low risk of AKI.
NGAL <4 ng/mL No line appears in the test line area (T).	This result suggests no kidney damage.
Note: The limit of detection (LoD) of the test is 2.4 ng/mL. Therefore, samples with a concentration below 4 ng/mL but equal to or above the LoD may give a positive result with a test line (T) of less intensity than that shown on the colour chart yet still visible. In such cases, monitoring the patient and repeating the test after a few hours to check for a potential increase of NGAL in the urine is recommended.	
INVALID The test is considered invalid if the control line (C) does not appear. The most common reasons for the absence of the control line (invalid result) are insufficient sample volume or performing the procedure incorrectly. Review the procedure and repeat the test with a new device. 	

Importer and distributor: