Version 05/2026

*FAST*est® SDMA ad us. vet.

***In vitro* diagnosticum**

Test-kit for the qualitative detection of SDMA (symmetric dimethylarginine) in heparinised whole blood, heparinised plasma or serum from dogs, cats or horses

INSTRUCTIONS FOR USE

Manufacturer

megacor

6912 Hörbranz – AUSTRIA
www.megacor.com

1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® SDMA** contains:
- 2*, 5**, 10*** or 25**** test cassettes coated with monoclonal antibodies
- 1 dropper bottle **A** with *0.3 ml, **0.75 ml, ***1.5 ml or ****3.5 buffer diluent
- 2, 5, 10 or 25 disposable plastic pipettes
- 1 instructions for use

STABILITY AND STORAGE

15–25°C Store at 15–25 °C

Expiry date – see label

APPLICATION AND ABBREVIATIONS

For veterinary use only

LOT Lot number

In vitro diagnosticum

! Do not use test-kit components from different kits, lot numbers or beyond stated expiry date.

Follow instructions for use precisely

T – TEST line, **C** – CONTROL line, **LF** – Lateral flow
HB – heparinised whole blood, **HP** – heparinised plasma, **S** – serum

LIABILITY

The entire risk due to the performance of this product is assumed by the purchaser. The manufacturer shall not be liable for indirect, special or consequential damages of any kind resulting from the use of this product.

2. INTRODUCTION

Symmetric dimethylarginine (SDMA) is a reliable biomarker for assessing kidney function in animals. As a breakdown product of protein metabolism, 90% of it is excreted via the kidneys. An increase in SDMA indicates a decreasing glomerular filtration rate (GFR) and thus impaired kidney function. Unlike creatinine, SDMA is not influenced by muscle mass and also allows for significantly earlier detection of kidney dysfunction, even before typical symptoms such as loss of appetite, weight loss or polyuria/polydipsia occur.

The current upper limit for dogs, cats and horses is 14 µg/dl (Hokamp and Nabity 2026, review, Siwinska et al., 2020). In certain breeds (e.g., Greyhounds, Liffmann et al., 2018) or in foals (Siwinska et al., 2020), higher values may be measured physiologically.

Setting the cut-off at ≥ 14 µg/dl ensures that clinically significant elevations are reliably detected and that the test can be optimally used as a screening tool to rule out GFR impairment: whilst a negative result makes the presence of renal insufficiency highly unlikely, a positive result is considered an important warning sign of kidney disease. In such cases, further investigation – such as a precise laboratory determination of the SDMA value, a complete urinalysis or the measurement of the urine protein-to-creatinine ratio – is strongly recommended.

The ***FAST*est® SDMA**, as an early marker of GFR, enables vets to assess kidney health in dogs, cats and horses on-site. In the event of elevated values, a comprehensive diagnostic investigation of kidney function can thus be initiated in a targeted manner.

3. INFORMATION ON THE SPECIMEN MATERIAL

Approximately **80 µl (2 drops of attached plastic pipette) 15–25 °C warm heparinised whole blood (HB) or 40 µl heparinised plasma (HP) or serum (S)** are needed. **Do not use EDTA or citrate! Native blood without anticoagulant should not be used due to potential micro agglutination** (e.g. migration delay on the membrane, unspecific reaction).

Mix the sample material well before use.

Non-cooled (**15–25 °C**), HB, HP and S should be tested as fresh as possible. At **2–8 °C**, WB, HP and S can be stored up to 3 days. **HB and S** can be stored for 2 months **at minimum −20 °C**.

Keep in mind that the sample material, as well as all used test-kit components, should have reached **room temperature** at the time of application.

Endogeneous and exogeneous interfering substances of the sample (e.g. albumin, fibrinogen, lipids, CRP, heterophilic antibodies, especially type IgA, as well as viscosity, pH-value) **as well as native blood (NB) can cause interferences** (matrix effects) **that can influence the target measurement. These can lead to an impaired LF and/or unspecific reactions on T and C.**

4. SPECIMEN PREPARATION

- No specimen preparation necessary.
- **ATTENTION**: Partially filled and/or insufficient mixed heparin tubes could create invisible microclots resulting in lateral flow delay and/or unspecific reactions (e.g. greyish shadow like lines).

5. TEST PROCEDURE

1. Remove the test cassette from its foil pouch shortly before use. Place it on a flat surface.

2a. <u>Heparinised whole blood (HB)</u>: **80 µl sample volume**
Take the **disposable plastic pipette** and **place 2 drops (80 µl) of HB bubble-free** into the sample window S of the test cassette. Hold the pipette vertically (fig.1a).

2b. <u>Heparinised plasma (HP) or serum</u>: **40 µl sample volume**
Take the **disposable plastic pipette** and **place 1 drop (40 µl) of HP/S bubble-free** into the sample window S of the test cassette. Hold the pipette vertically (fig.1b).

3. Hold the dropper bottle **A** vertically and express **2 drops of buffer diluent (ca. 80 µl)** without bubbles into the sample window S (fig.2). The specified sample and buffer volumes must not be exceeded.

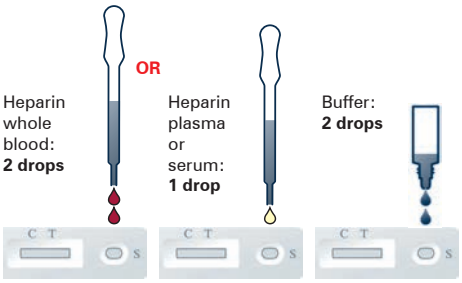


fig.1a fig.1b fig.2

6. READING OF THE TEST RESULT

10 min

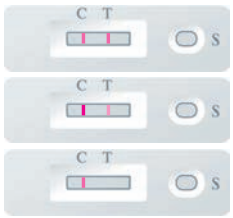
The test result must be read **10 minutes** after addition of the buffer into the sample window S.

Due to the competitive assay principle, the intensity of **T** is reciprocally proportional to the concentration of SDMA in the sample.

NEGATIVE TEST RESULT: SDMA < 14 µg/dl

Colour intensity **T > C**

POSITIVE TEST RESULT: SDMA ≥14 µg/dl



Colour intensity **T = C**

Colour intensity **T < C**

Only **C** visible

INVALID TEST RESULT
No CONTROL line visible. The test should be repeated using a new test cassette.

7. PRECAUTIONS FOR USERS

- The guidelines for working in medical laboratories must be observed. It is recommended to wear disposable gloves and other personal protective equipment (protective clothing, possibly a face mask). Wash and disinfect hands after completing the test.
- Label sample material and associated test cassette to ensure a precise assignment.
- Use a new pipette and a new test cassette for each sample.
- The buffer diluent contains low concentrations of toxic sodium azide as a preservative, therefore avoid skin/eye contact and/or ingestion.
- The sample material must be seen as potentially infectious and disposed of accordingly, together with the used test-kit components.

8. TEST PRINCIPLE

The ***FAST*est® SDMA** is a competitive immunochromatographic assay.

SDMA is immobilised on the TEST line **T**, where it competes with the SDMA in the sample for binding to mobile, gold-labelled SDMA antibodies.

Due to the competitive nature of the test, the intensity of **T** is inversely proportional to the concentration of SDMA in the sample: the lower the SDMA concentration in the sample, the more antibodies bind to the immobilised SDMA (= strong **T**). The higher the SDMA concentration in the sample, the fewer antibodies bind to the fixed SDMA (= weak **T**), as these are captured by the SDMA in the sample.

A correct test procedure will be indicated by a second pink-purple CONTROL line **C**.

9. INFORMATION FOR THE INTERPRETATION

- The interpretation of the test result should always be based on anamnestic and clinical data as well as the therapy and prophylaxis possibilities.
- Any non-described colour or contour variation of T and C (e.g. greyish, shadow-like lines) has to be considered as unspecific reaction. The test result is invalid, the test should be repeated.
- Poor sample quality (severe hemolysis, lipemia) or an insufficient sample volume can affect the colour intensity or visibility of T and C, thereby making it difficult to interpret the results correctly (false-positive results are possible).

Negative test result:
- There is no evidence of renal dysfunction.
- Early-stage kidney disease cannot be reliably ruled out with a single test. If clinical signs are present, the test must be repeated after 2–4 weeks. Further diagnostic tests (e.g. urinalysis, specific gravity, UPC ratio) are recommended.

Positive test result:
- There is evidence of renal dysfunction
- In the presence of symptoms such as polyuria/polydipsia, weight loss, loss of appetite or dehydration, the test result indicates the presence of renal dysfunction
- In clinically unremarkable animals, a repeat test should be carried out in 2–4 weeks. If the SDMA value remains positive, this indicates early-stage chronic kidney disease (see IRIS Staging of CKD, modified in 2023) and requires further diagnostic tests (e.g. urinalysis, specific gravity, UPC ratio).
- Certain breeds (e.g. Greyhounds or Sacred Burmese cats) physiologically exhibit higher SDMA levels. This must be taken into account when interpreting the test result.