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*FAST*est® SAA

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of Serum Amyloid A (SAA) in whole blood, plasma or serum of the cat and horse

INSTRUCTIONS FOR USE

Supplied Exclusively To The UK Veterinary Market By
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1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® SAA** contains:
- 2, 10 or 25 test cassettes coated with monoclonal antibodies
- 2, 10 or 25 dropper bottles **A** with 2.0 ml buffer diluent each
- 4, 20 or 50 disposable IC pipettes (5 µl)
- 1 instructions for use

STABILITY AND STORAGE

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

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.

ACCURACY

Sensitivity 96.6 % / Specificity 96.8 %
(Comparison Method: Automated agglutination system / Cobas L2-Vet)

2. INTRODUCTION

Acute phase proteins (APP) are used as biomarkers to assess the degree of inflammatory processes or tissue damage. Serum amyloid A (SAA) is a highly sensitive major APP, but it does not allow an aetiological diagnosis.

The serum concentration is very low during homeostasis, but increases dynamically (sometimes up to 1000-fold) within a very short time (approx. 12–24 h) and proportionally to the degree of inflammation or tissue damage. As soon as the inflammatory stimulus/tissue damage subsides due to successful therapy, the SAA concentration decreases within a few hours. In the event of recurrences or secondary complications, it can quickly rise again. SAA can thus be viewed as a "real-time marker". Depending on the literature, physiological SAA concentrations of less than 10 mg/l are given for cats and 0.5–20 mg/l for horses (Schattauer GmbH 2014; Moritz, Klinische Labordiagnostik in der Tiermedizin).

The higher cut-off (25–30 µg/ml) of the ***FAST*est® SAA** compared to the average laboratory reference values was chosen because experience has shown that lower values have no clinical relevance. The ***FAST*est® SAA** is therefore suitable for the veterinarian on site and without technical effort as an exclusion test for inflammatory processes of any kind.

3. INFORMATION ON THE SPECIMEN MATERIAL

Exactly **10 µl (of attached plastic IC pipette) 15–25 °C warm whole blood (WB**, with anticoagulant) or **5 µl plasma (P) or serum (S)** are needed. **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.

Basically, the sample material should be tested immediately after sampling. **ATTENTION**: At **15–25 °C**, P or S can be stored up to 24 hours. For long-time storage, the sample should be kept as soon as possible at **minimum −20 °C** (maximum 3 months). **Do not store in the fridge!** Avoid repeated freezing and thawing.

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, heterophilic antibodies, especially type IgA, as well as viscosity, pH value and excess EDTA) **as well as native blood can cause interferences** (matrix effects) **that can influence the target measurement. These can lead to an impaired LF and/or unspecific reactions on B and C.**

4. SPECIMEN PREPARATION

- No specimen preparation necessary.
- **ATTENTION:** Partially filled and/or insufficient mixed EDTA, Citrate or 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.

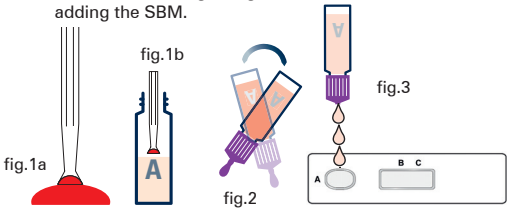
2a. **EDTA/heparin whole blood: 10 µl sample volume**
Hold the IC pipette vertically to the surface of the sample. The sample volume of 5 µl is aspirated automatically (fig.1a). Place the sample volume into the dropper bottle **A** containing the buffer diluent (fig.1b). Repeat the whole step with a new IC pipette to get the total sample volume of 10 µl.

2b. **Plasma or serum: 5 µl sample volume**
Hold the IC pipette vertically to the surface of the sample. The sample volume of 5 µl is aspirated automatically (fig.1a). Place the sample volume into the dropper bottle **A** containing the buffer diluent (fig.1b).

2c. Mix the sample-buffer mixture (SBM) thoroughly (fig.2).

3. Break the tip of the dropper bottle **A**, hold the dropper bottle **A** vertically, discard the first drop and add **3 drops (100–120 µl) SBM** into the sample window A of the test cassette (fig.3).

4. Add 1 additional drop of SBM into the sample window A if there is no beginning LF visible within 1 minute after adding the SBM.



6. READING OF THE TEST RESULT

15 min

Read the test result after an incubation time of **15 minutes**. After this time, the test result can no longer be interpreted.

POSITIVE TEST RESULT (fig.4)
A pink-purple TEST line **of any intensity** (varying from very weak to strongly intensive) and a pink-purple CONTROL line appear.

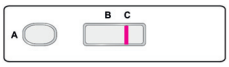
Negative: < 25 µg/ml ← Cut off → **Positive: ≥ 30 µg/ml**
Negative: < 25 mg/l ← Cut off → **Positive: ≥ 30 mg/l**

NEGATIVE TEST RESULT (fig.5)
Only a pink-purple CONTROL line appears. This line indicates, irrespective of its intensity, that the test has been performed properly.

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

fig.4
POSITIVE TEST RESULT

fig.5
NEGATIVE TEST RESULT



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 IC pipette, a new dropper bottle and a new test cassette for each sample.
- Take the required sample volume (**10 µl anticoagulated whole blood** or **5 µl plasma or serum**) only with the attached IC pipettes or with a calibrated laboratory pipette.
- 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® SAA** is based on an immunochromatographic "sandwich principle".

SAA molecules in the sample will bind in the conjugate pad with mobile monoclonal antibodies against SAA, which are conjugated to colloidal gold particles. These antigen-antibody complexes complexes are migrating ("lateral flow", **LF**) along the nitrocellulose membrane and bind to fixed monoclonal antibodies against SAA forming a pink-purple TEST line (**B**).

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.

Negative test (cat & horse)
→ **no** indication of increased inflammatory activity
→ if the symptoms are present/increasing, a second and/or third test at intervals of 12 hours is recommended to see whether the SAA concentration has risen above the Cut off

Positive test (cat & horse)
→ indication of **increased** inflammatory activity
→ further testing at intervals of 1–2 days each to see whether the inflammatory activity or the SAA concentration has fallen below the Cut off due to the therapy that has been initiated

Examples for potential diseases:
Cat: sepsis (abscesses etc.), FIP, pancreatitis, neoplasia, diabetes mellitus, traumata/surgery, nephropathy/FLUTD
Horse: sepsis (arthritis, abscesses, abortion etc.), EHV I/EIV, strangles, colic/enteritis, parasitoses, traumata/surgery

- Any non-described colour or contour variation of B and C (e.g. greyish, shadow-like lines) has to be considered as unspecific reaction and therefore as negative test result.
- Due to anticoagulated whole blood and/or red hemoglobin background of the test membrane, caused by hemolytic blood samples, the visibility of B, especially in case of weak positive samples, could be from worse to not visible.
- Wrong handling or wrong interpretation of the test could have a negative effect on the significance of the test and/or make the results inconclusive.