Version 04/2016

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of IgG antibodies in native blood, whole blood, plasma or serum of cattle

INSTRUCTIONS FOR USE

1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FASTest*® IgG** bovine contains:
- 2 or 10 test cassettes coated with monoclonal antibodies
- 1 dropper bottle **A** with 1.0 ml or 3.0 ml buffer diluent
- 4 or 20 disposable plastic pipettes
- 2 or 10 disposable sample tubes
- 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.

2. INTRODUCTION

An effective immunity is based on optimal levels of immunoglobulines (IgG, especially IgG1). This guarantees an optimal breeding success, especially in the peripartal stage and in new born calves, and is of economic importance to the livestock industry.

Due to the special placenta conditions, newborn calves often show no to hardly noteworthy IgG. Therefore the most important base for an immunoprophylaxis is an adequate supplementation with IgG.

IgG transfer mainly is based on the ingestion and resorption of colostrum (adequate passive transfer) directly after birth up to maximal 24 h later. Failure of passive transfer (FPT) may be caused by inadequate suckling (reduced vitality, neonatal respiratory depression a.s.o.), way of colostrum application, very low levels of IgG in the colostrum, inadequate absorption of IgG or environmental stress. The consequences of an immune deficiency syndrome (IDS) are weak calves with a higher vulnerability for infectious newborn diseases like enzootic pneumonia of calves, diarrhoea (neonatal calf diarrhoea; calf scours) and other septicaemic diseases.

The incidence for cows (dystocia, metritis, mastitis a.s.o.) in the peripartal period is as high as in no other farm animal. Latest investigations show following IgG1 concentrations in healthy cows with normal parturition and physiologic postpartal period:
- Ø 38 mg/ml at 7th month of gestation
- Ø 15 mg/ml physiologically low concentration peripartal
- Ø 30 mg/ml increasing from 4th month post partum

If the intrapartal IgG concentration is already significantly decreased (< 15 mg/ml), an increased incidence of genital associated diseases will be seen in the peripartal period.

The optimal test time slot for using ***FASTest*® IgG** bovine is between 24 to 48 h (max up to 7 days) post natum in calves and from 3rd to 7th day post partum in cows. ***FASTest*® IgG** bovine enables the veterinarian on-farm and without any technical costs to confirm (***FASTest*® IgG** bovine: IgG ≤ 12 mg/ml) or to exclude (***FASTest*® IgG** bovine: IgG > 12 mg/ml) a suspicion for FPT/IDS in the cow as well as in the calf.

3. INFORMATION ON THE SPECIMEN MATERIAL

Approximately **30–35 µl (1 drop of attached plastic pipette) 15–25 °C warm whole blood (WB**, with anticoagulant**), native blood (NB**, without anticoagulant**), plasma (P) or serum (S)** are needed. Mix the sample material well before use!

Non-cooled (**15–25 °C**), WB, P and S should be tested within 4 hours! At **2–8 °C**, WB, P and S can be stored up to 4 days. **Serum and/or plasma samples** can be permanently stored **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 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 T and C.**

4. SPECIMEN PREPARATION – ONLY WHOLE BLOOD/NATIVE BLOOD!

NB must be diluted immediately after withdrawal! EDTA, Citrate or Heparin blood (partially filled and/or insufficiently mixed) **could create invisible microclots resulting in lateral flow delay and/or unspecific reactions** (e.g. greyish shadow like lines).

a. Express **1 drop (30–35 µl) WB/NB** into the corresponding sample tube using the disposable plastic pipette (fig.1). Hold the pipette vertically!
b. Hold the dropper bottle **A** vertically and express **3 drops of buffer diluent (ca. 120–150 µl)** into the sample tube (fig.2).
c. Close the sample tube and mix the sample-buffer mixture (SBM) homogeneously.

fig.1

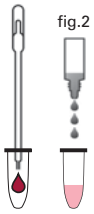


fig.2

5. TEST PROCEDURE

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

WHOLE BLOOD / NATIVE BLOOD

2. Add **3 drops (ca. 90–105 µl) of the SBM** into the sample window S of the test cassette using a new disposable plastic pipette (fig.3).
3. No further buffer addition required!

PLASMA/SERUM

2. Add **1 drop (ca. 30–35 µl) plasma/serum** into the sample window S of the test cassette using the disposable plastic pipette (fig.4).
3. Hold the dropper bottle **A** vertically and express **3 drops of buffer solution (ca. 120–150 µl)** into the sample window of the test cassette (fig.5).

fig.3

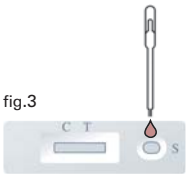


fig.4

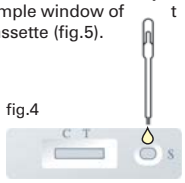


fig.5

6. READING OF THE TEST RESULT

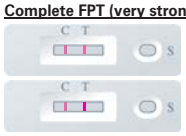
The test result must be read exactly **5 minutes** after addition of the drops (SBM/buffer) into the sample window S. Beyond this time, test results should not be interpreted!

Negative: < 12 mg/ml ← cut-off → Positive: ≥ 12 mg/ml

The colour intensity of the TEST line in proportion to the CONTROL line is important for correct test interpretation.

NEGATIVE TEST RESULT: IgG < 12 mg/ml

Complete FPT (very strong to complete lack of IgG):



A pink-purple coloured and well-defined TEST line with **equal (upper fig.) or stronger (lower fig.) intensity** than the pink-purple coloured and well-defined CONTROL line appears.

Partial FPT (IgG concentration too low):

A pink-purple coloured and well-defined TEST line with **lower intensity** than the pink-purple coloured and well-defined CONTROL line appears.

POSITIVE TEST RESULT: IgG ≥ 12 mg/ml

No pink-purple coloured and well-defined TEST line is visible. Only the pink-purple coloured and well-defined CONTROL line appears. This line indicates, irrespective of its intensity, that the test has been performed properly.

INVALID TEST RESULT

Only a weak to strong and well-defined pink-purple TEST line or no line at all appears. The test should be repeated using a new test cassette.

7. PRECAUTIONS FOR USERS

- Label sample material and associated test cassette to ensure a precise assignment.
- Use a new pipette and sample tube for each sample.
- The buffer diluent contains low concentrations of toxic sodium azide as a preservative, therefore avoid skin 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 ***FASTest*® IgG** bovine is designed on latest competitive lateral flow technology based on an immunochromatographic sandwich principle technique.

Due to the competitive test principle, the intensity of **T** is reciprocally proportional to the concentration of bovine IgG in the sample!

Depending on the concentration of bovine IgG antibodies (AB) of the sample (sample AB), there is a more or less strong binding of the detector ABs (highly specific, polyclonal, mobile, gold labelled) to the capture ABs (fixed monoclonal bovine IgG antibodies) on the TEST line **T**.

In case of missing/low AB concentration below the cut-off of the sample, no/few sample AB bind to the detector ABs. These free detector ABs are captured in high amounts by the capture ABs on **T** and produce a more or less weak to strong intensive **T**.

In case of sample AB concentration, many sample AB are bound to the detector ABs. These then cannot bind to **T** anymore. **T** is only weak to not visible.

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

Please note the two light-blue quality control lines on **T** and **C**. They indicate that the test membrane is of good quality and can be used.

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.
- Due to anticoagulated whole blood and/or red hemoglobin background of the test membrane, caused by hemolytic blood samples, the visibility of T, especially in case of weak positive samples, could be from worse to not visible.

Negative test result:
➜ Suspicion on partial to complete FPT/lack of IgG (IDS)
➜ IgG substitution required!

Positive test result:
➜ optimal passiver transfer/no lack of IgG

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