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*FAST*est® AIV Ag

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of Avian Influenza Virus Type A antigens (subtypes H1–H15) in swab samples from cloaca, trachea, kidney or feces of birds

INSTRUCTIONS FOR USE

The test is approved for birds only.

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® AIV** Ag contains:
- 20 dipsticks coated with monoclonal antibodies
- 20 sample tubes with 1.0 ml buffer diluent each
- 20 test tubes (in racks)
- 20 collection swabs
- 20 disposable plastic pipettes
- 1 instructions for use

STABILITY AND STORAGE

Store at 15–25 °C

Expiry date – see label

APPLICATION AND ABBREVIATIONS

For veterinary use only

In vitro diagnosticum

Follow instructions for use precisely

LOT Lot number

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

TL – TEST line, **CL** – CONTROL line, **LF** – Lateral flow

SBM – Sample-buffer mixture

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 100% / Specificity 100 %
(Comparison Method: Hemagglutination)

2. INTRODUCTION

Avian Influenza (Bird flu) is a notifiable disease in birds caused by Avian Influenza Virus Type A (family of Orthomyxoviridae) that infects chickens, turkeys, geese, ducks, wild water birds and other birds world-wide.

Clinical symptoms are mild (decrease of egg production and/or fertility) up to highly pathogenic variants with sudden death cases. The classical avian influenza, caused by the subtypes H5 and H7, is considered to be the severe form of avian influenza. Moreover, H5N1 is considered as elicitor of the avian influenza ("bird flu") in humans. In the classical avian influenza, the clinical symptoms develop suddenly and heavily (especially respiratory symptoms, bloody nasal and throat discharge as well as greenish diarrhoea, cyanoses and oedemata in the head region and on comb and wattles, changes in colour of thighs and feed due to ecchymosis) up to sudden deaths with mortality rates up to 100 %.

***FAST*est® AIV** Ag is suitable as screening test for the fast and simple detection of all AIV type A subtypes in suspicious poultry stocks. It is applicable on-site. This enables the veterinarian an on-site confirmation of the clinical suspicion as well as the immediate initiation of epizootic mandatory measures to prevent a threatening pandemic.

3. INFORMATION ON THE SPECIMEN MATERIAL

Basically it is recommended to use **single samples** for testing. With pool samples, there is a danger that too many frenzy particles (matrix effects, unspecific reactions) or too few antigenic material (problem "antigenic dilution") may be present in the SBM. **The sample material** (cloaca, trachea or kidney swab or feces) **should be tested directly after sampling.**

Storage is possible at 2–8 °C for max. 2 d and permanently at a minimum of –20 °C.

Due to the normally inhomogeneous or nest-like dissemination of antigens in the sample, the specimen material has to be mixed up homogeneously (spatula, vortex-mixer) before sampling.

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. proteases, mucosa components, blood, but also viscosity, pH-value as well as grass) **can cause interferences** (matrix effects) **that can influence the target measurement. These can lead to an impaired LF and/or unspecific reactions on the TL and CL.**

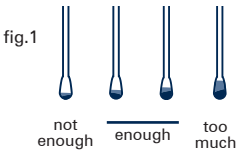

fig.1


fig.2


fig.3

4. SPECIMEN COLLECTION AND PREPARATION

ATTENTION! The amount of sample material is a decisive factor, therefore, with wrong sample amount a false negative or false positive is possible!

a. Introduce the collection swab into the cloaca or the feces (fig.2) and collect **as much sample as indicated in fig.1**.
b. Immerse the covered swab into the sample tube filled with 1 ml buffer diluent. Rotate the swab until the sample has dissolved homogeneously in the buffer solution (fig.3). Squeeze the swab against the tube wall afterwards to remove all liquid from the swab. Discard the swab properly.
c. **For sedimentation of gross particles place the sample tube on a flat and horizontal surface for 2 minutes.**

5. TEST PROCEDURE

1. Take one test tube for each sample.
2. Draw the SBM up using the disposable plastic pipette completely (without sediment!) and without air bubbles (fig.4). Hold the pipette vertically and drop **10 drops** (280 µl) into the sample tube (fig.5).
3. Remove the dipstick just now from its foil pouch and introduce it vertically and with the arrows pointing downwards into the sample tube. The liquid level (meniscus!) must not exceed the white arrowheads (fig.6).
4. If the CL will not appear after 5 minutes, a new test must be prepared.


fig.4

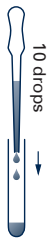

fig.5

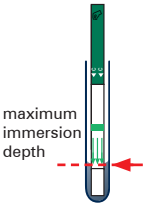

fig.6

6. READING OF THE TEST RESULT

Read the test result after **20 minutes**. Positive test results may be observed earlier, depending on the concentration of antigen in the sample.

POSITIVE TEST RESULT (fig.7)
A weak to strong and well-defined **pink-purple** TEST line **and** CONTROL line appear.

NEGATIVE TEST RESULT (fig.8)
Only a **pink-purple** 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 dipstick.

fig.7
POSITIVE TEST RESULT

fig.8
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, associated sample and test tube and the dipstick to ensure a precise assignment.
- Use a new swab, a new pipette, a new sample and test tube and a new dipstick 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 ***FAST*est® AIV** Ag is based on latest rapid immunochromatographic technique.

Positive samples containing Avian Influenzavirus Type A antigens (subtypes H1–H15) react in the conjugate pad area with mobile monoclonal anti-AIV antibodies (anti-AIV mAbs), which are bound to colloidal gold particles. Migrating ("lateral flow", **LF**) along the nitrocellulose membrane, these specific antigen-antibody complexes are bound by fixed anti-AIV mAbs producing a pink-purple TEST line (**TL**). These anti-AIV mAbs guarantee a high level of specificity for the aetiologic detection of AIV.

A correct test procedure will be indicated by a second, pink-purple CONTROL line (**CL**).

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 TL and CL within the indicated incubation time or after more than 30 minutes (e.g. greyish, shadow-like lines) has to be considered as unspecific reaction and therefore as negative test result.
- TL can vary both in intensity (from weak to strong pink-purple) and in width. Therefore, any pink-purple line which appears within the required incubation time has to be interpreted as a positive test result.
- ***FAST*est® AIV** Ag detects all Avian Influenza Virus Type A subtypes regardless of their pathogenicity.
- There are no cross reactions with clinically similar infectious diseases (e.g. Newcastle Disease Virus (NDV), Infectious Bronchitis Virus (IBV), *Mycoplasma* spp.).

PROCEDURE WITH SUSPICION ABOUT AVIAN INFLUENZA

1. **Clinical-epidemiological criteria fulfilled**
2. **Suspicious case:** "Avian Influenza" or "Classical Bird Flu"
3. **On-site testing** using ***FAST*est® AIV** Ag
   a. Negative ***FAST*est® AIV** Ag
      → Repetition of the test as long as the clinical suspicion persists!
   b. Positive ***FAST*est® AIV** Ag
      → Suspicion on Avian Influenza substantiated
      → Report according to animal health regulations (duty of notification)

Important information

An on-site test in suspicious poultry flock or in suspicious wild birds in principle needs a confirmation test prescribed by law in a national reference laboratory that is in charge for the diagnostics of Avian Influenza. This is valid for a negative as well as a positive ***FAST*est® AIV** Ag.

Due to the potential risk of RNA degradation by RNases in the sample material, a new swab of the same suspicious animal should be taken as sample material and shipped immediately and in accordance with the transport conditions prescribed by the reference laboratory.

Further information can also be ordered at

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or at the related government authorities in your country.