Version 07/2022

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*FAST*est® SARS-CoV-2 Ag ad us. vet.

***In vitro* diagnosticum**

Test-kit for the qualitative detection of SARS-CoV-2 antigens in nasal and/or throat secretions of the cat

INSTRUCTIONS FOR USE

The test is approved for cats 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® SARS-CoV-2 Ag** contains:
- 2 or 5 test cassettes, coated with monoclonal antibodies against SARS-CoV-2
- 2 or 5 sample tubes (working station rack), each filled with 0.35 ml extraction buffer
- 2 or 5 dropper bottle caps
- 2 or 5 disposable sample swabs
- 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 100 % – Specificity 90.47 %
(Comparison Method: RT-PCR)

2. INTRODUCTION

SARS-CoV-2 belongs to the group of β-coronaviruses and causes COVID-19 in humans. Individual transmissions to the cat are reported. However, transmission from cats to humans has not yet been confirmed. Until this is finally clarified, a potential risk of transmission can be assumed (risk of zoonosis). In accordance with the World Organisation for Animal Health (OIE), the risk of transmission from susceptible pets to humans is considered to be low (source: FLI 04/2020).

The Feline Coronavirus (FCoV) belongs to the group of α-coronaviruses and has no serological cross-reactivity to SARS-CoV-2.

By testing antigen in nasal or throat secretions, more infected animals can be identified: The antigen detection can be positive shortly after the incubation phase (2–14 days, Ø 5 days*) if IgG cannot yet be detected. This means that infected animals can be isolated at an early stage.

The present test provides valuable information about a possible infection of cats with SARS-CoV-2. However, it can only be used for the detection of SARS-CoV-2 antigens in nasal and/or throat swabs. Clarification of a positive test result by RT-PCR is always necessary to determine an infection. In Germany, due to reporting requirements if positive results occur, clarification by the National Reference Laboratory for SARS-CoV-2 infections in domestic animals at the Friedrich-Loeffler-Institute, Riems Island, is mandatory. Please check the requirements of your country!

Based on specific monoclonal antibodies, the ***FAST*est® SARS-CoV-2 Ag** is an important diagnostic tool for the clarification of clinical suspected SARS-CoV-2 cases in cats.

* Source: https://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/COV-19/A_Factsheet_SARS-CoV-2.pdf

3. INFORMATION ON THE SPECIMEN MATERIAL

***FAST*est® SARS-CoV-2 Ag** is suitable for testing nasal and/or throat secretions.

***FAST*est® SARS-CoV-2 Ag** should be done directly after sampling. If this is not possible: Storage of samples at 2–8 °C for max. 24 h or permanently 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.

Excess mucus, pus or blood in the sample material will interfere with lateral flow process and could lead to unspecific test results. Therefore any excess mucus, pus or blood should be removed before using the provided swab for sampling.

Endogeneous and exogeneous interfering substances of the sample (e.g. proteases, mucosa components, blood, but also viscosity or pH value) **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

1. **Roll sample swab for some seconds on the mucous membrane of the nose and/or throat for a few seconds in order to obtain sufficient sample material. Sampling only from the cat's saliva is not sufficient for the test to be carried out properly and for a valid test result.**
2. Dip the well-coated swab into the sample tube (fig.1). Stir the swab 5 times while pressing it against the sample tube wall. Discard the swab.
3. Put the dropper bottle cap on, press shut (fig.2). The sample-buffer mixture (SBM) is now ready for use.

5. TEST PROCEDURE

1. Remove the test cassette from its foil pouch shortly before use. Place it on a flat surface.
2. Drop **carefully** (allow each drop to absorb before adding the next one) **3 drops (approx. 120 µl) of the SBM** to the sample window S of the test cassette (fig.3). Avoid bubbles!
3. Start the stop watch (15–30 minutes).
4. Add 1 additional drop of SBM into the sample window S if there is no beginning LF visible within 1 minute after adding the SBM.

fig.1

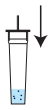

fig.2

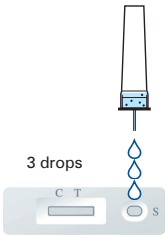

fig.3

6. READING OF THE TEST RESULT

Read the test result **15 minutes (maximum 30 minutes)** after the SBM has been added into the sample window S.

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 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

- Wear mouth-and-nose protection and the usual laboratory protective equipment during the test procedure (danger of zoonosis!).
- Label sample material and associated test cassette to ensure a precise assignment.
- Use a new sample tube, a new dropper bottle cap and a new test cassette for each sample.
- The buffer diluent contains low concentrations of toxic sodium azide as a preservative, therefore avoid eye/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® SARS-CoV-2 Ag** is based on an immunochromatographic "sandwich principle".

The SARS-CoV-2 antigens in the sample react in the conjugate pad area with mobile monoclonal antibodies, which are bound to colloidal gold particles. These antigen-antibody complexes are migrating along the nitrocellulose membrane ("lateral flow", **LF**) and will be captured by membrane-fixed capture antibodies forming a pink-purple TEST line (**T**).

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 and therefore as negative test result.
- Depending on the antigen concentration, positive test results can occur before the end of the 15-minute incubation period. Test results read thereafter cannot be interpreted!
- In case of bloody sample material, T can only be weakly or not visible due to the more or less reddish background of the test membrane.
- T can very both in intensity (from weak to intense pink-purple) and width. Therefore, any pink-purple line appearing within the required incubation time is to be interpreted as a positive test result.
- If the test is positive, this must be reported to the responsible authorities in your country! The further measures result from the orders of the responsible veterinary office and local health office. So far, there is no evidence that the virus has been transmitted from cats to humans. Please check the requirements of your country!
- Due to the reporting requirement in Germany, if positive results occur, clarification by the National Reference Laboratory for SARS-CoV-2 infections in animals kept at the Friedrich Loeffler Institute, Riems Island, is mandatory.