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*FAST*est® D-PHYTE Strip

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Test-kit for the qualitative detection of veterinary relevant dermatophyte spp. in pocket pets, pets and farm animals

INSTRUCTIONS FOR USE

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1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® D-PHYTE** Strip contains:
- 1*, 5** or 10*** dipsticks coated with monoclonal antibodies
- 1 dropper bottle **A** with *1.0 ml, **3.0 ml or ***5.0 ml buffer diluent
- 1, 5 or 10 sample tubes with squeezer
- 1, 5 or 10 disposable plastic spatulas
- 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

TL – TEST line, **CL** – 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 86.7 % – Specificity 93.5 %
(Comparison Method: PCR)

2. INTRODUCTION

Dermatophytoses/ringworm belong to the most frequent infectious dermatoses in pocket pets, pets and farm animals, but also in humans (zoonosis).

They are caused by dermatophytes, filamentous fungi using keratin (skin, hair, claws and horns) as carbon source. The clinically most relevant species in veterinary diagnostics are Trichophyton (*T. verrucosum*), Nannizzia (*N. gypsea* [earlier *Microsporum gypseum*], *N. persicolor* [earlier *Microsporum persicolor* / *Epidermophyton persicolor* / *Trichophyton mentagrophytes*]) and Microsporum (*M. canis*). Beside age and immunosuppression, breeding (especially persian cats) and keeping conditions (breeding, animal shelter, hunting dog, multiple species keeping), travelling, lactation (transmission of infection to puppies) as well as e.g. ectoparasite based diseases and debilitated animals play an important role in developing a ringworm disease. Warm and humid climate is an additional trigger.

In case of clinical suspicion, the ***FAST*est® D-PHYTE** Strip guarantees rapid clarification of the suspected clinical diagnosis and enables quick and reliable identification of dermatophytosis and the initiation of targeted therapy.

3. SAMPLE MATERIAL AND SAMPLING

- **IDEALLY USE STERILE SCALPEL, NOT COTTON SWAB!**
- Samples should be taken before local antimycotic therapy or two weeks after the end of treatment. This is not mandatory (see also 9. Information for the interpretation, point 2).
- All test-kit components and sample material should have **room temperature** (15–25 °C) at the time of application.
- The sample stored at room temperature (15–25 °C) should be tested immediately or at least on the same day. The samples can be stored at 2–8 °C up to max. 14 days.

a. We strongly recommend to **shorten the hair to approx. 1 cm** before sampling **and disinfection of the favoured sampling area with 70 % alcohol** in order to largely reduce a potential saprophytic contamination (especially with molds like Aspergillus, Penicillium, Fusarium etc.).

b. Remove **from the edge of the lesion (transition between affected and healthy skin)**
- scraping from skin (with scalpel) to get surface epithelium, dandruff and crusts

and
- pluck at least 20–30 of the shortened hair or feathers with their respective follicles (with tweezers)
- scrape off superficial remains of horn from infected claws (with scalpel)

Alternatively (latently infected animals), sample material can also be obtained using a (sterile) disposable toothbrush (MacKenzie method).

c. **The sample material** (also from spaces between the toothbrush) **must be thoroughly homogenised** using tweezers, scalpel and/or the enclosed disposable spatula or scissors (hair shredding, if not shortened to 1 cm, → 3.a) **before use. Attention: Dispose of laboratory equipment after each sample or disinfect it thoroughly.**

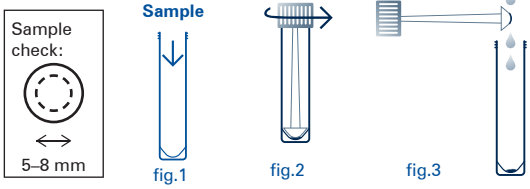

fig.1

fig.2

fig.3

4. SAMPLE PREPARATION

a. Open the sample tube and place the **pea-sized sample (ø min 5, max 8 mm)** in the middle of the sample tube (fig.1).

b. Destroy the sample by closing the blue cap with the attached squeezer tightly into the sample tube (fig.2).

c. Open the sample tube again. Hold the dropper bottle **A** vertically and add **minimum 5 (250 µl) up to maximum 10 (500 µl) drops of buffer diluent**. In case of any sample remains on the squeezer, let the 5 to 10 drops flow over the squeezer into the sample tube (fig.3).

d. Mix the squeezed sample material homogeneously with the buffer diluent by twisting and untwisting the blue cap for several times (see fig.2).

e. If sample material (especially hair) sticks to the squeezer or the sample tube wall, take the plastic spatula and slide the material into the sample buffer mixture (SBM).

f. For pre-incubation of the sample material in the SBM, place the sample tube on a flat and horizontal surface for 2 minutes (fig.4).

5. TEST PROCEDURE

1. Remove the dipstick from its foil pouch shortly before use.
2. Introduce the dipstick vertically and with the arrows pointing downwards into the sample tube for at least 1 minute. The liquid level (meniscus!) must not exceed white arrowheads (fig.5).
3. Remove the dipstick from sample tube soonest the SBM has reached the CONTROL line (CL). If so, the pink CL will appear slowly but surely (fig.6/7). If the CL does not appear after 5–10 minutes, a new SBM must be prepared and sedimented for at least 5 minutes. The dipstick must be held in the supernatant until the LF has reached the CL (see also 7. Precautions for users*).
4. Place the dipstick on a flat and horizontal surface for incubation.

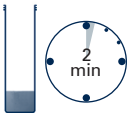

fig.4

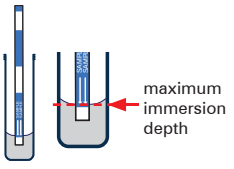

fig.5

6. READING OF THE TEST RESULT

Read the test result within the incubation time of **5–30 minutes**.

POSITIVE TEST RESULT (fig.6)
A pink-purple TEST line **of any intensity** (varying from very weak to strongly intensive) **and** a pink CONTROL line appear.

NEGATIVE TEST RESULT (fig.7)
Only a pink 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 dipstick *.

fig.6
POSITIVE TEST RESULT

fig.7
NEGATIVE TEST RESULT

9. INFORMATION FOR THE INTERPRETATION

- The interpretation of the test result should always be based on anamnestic and **clinical data** (blotchy alopecia on the face, ears, forelimbs. There is usually no itching. Exception adult cats with moderate to intense itching) as well as the therapy and prophylaxis possibilities.
- Common dermatophyte drugs (terbinafine, griseofulvin, itraconazole) have no effect on the test result of the ***FAST*est® D-PHYTE** Strip in the usual concentration.
- Any non-described colour or contour variation of TL and/or CL (e.g. greyish, shadow-like lines) has to be considered as unspecific reaction and therefore as negative test result.

Positive test result
– depending on the antigen concentration (high), a TL may already appear during LF. The result can be already read after 5 minutes
– the animal must be seen as potentially zoonotic for humans, especially for children.
- If confirmatory testing or dermatophyte species differentiation by PCR is required, we recommend sending it to a specialised veterinary laboratory.

ATTENTION: Homogenisation of original sample is an indispensable criterion before testing with ***FAST*est® D-PHYTE** Strip and before partial sampling for sending to the veterinary laboratory. If this is not guaranteed, statistically it is not the same original sample.

Negative test result
may be due to despite a suspected clinical diagnosis
– sampling in the wrong place
– too little and/or inadequate material
– no homogenisation before testing
– too little sample quantity for testing
→ take another sample at a different suspicious location and homogenise the sample well and use sufficient sample material for the test.

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 dipstick to ensure a precise assignment.
- Use a new sample tube and a new spatula 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 regarded as potentially infectious and must be disposed of properly with the test-kit components used, after the test has been carried out.

* To avoid an application error/external influence (e.g. too much sample material, too short sedimentation time, components in the sample that clog the pores of the suction pad), the test can be repeated. Use a new dipstick and carefully observe the sample preparation. It is advisable to only hold the dipstick in the supernatant when repeating the test until the LF has reached the CL.

8. TEST PRINCIPLE

The ***FAST*est® D-PHYTE** Strip is based on an immunochromatographic "sandwich principle".

The dermatophyte antigens present in the sample will react at the conjugate pad with mobile antibodies, which are conjugated to colloidal gold particles. These antigen-antibody complexes are migrating along the nitrocellulose membrane ("lateral flow", **LF**) and are bound by fixed antibodies against dermatophytes forming a pink-purple TEST line (**TL**). The intensity or width of the TL depends on the concentration of dermatophyte antigen in the introduced amount of sample.

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