Version 06/2022

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*FAST*est® DISTEMPER Strip

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***In vitro* diagnosticum**

Test-kit for the qualitative detection of Canine Distempervirus (CDV) antigens in eye or nasal discharge, urine or liquor of the dog

INSTRUCTIONS FOR USE

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1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® DISTEMPER** Strip contains:
- 2 or 10 dipsticks coated with monoclonal antibodies
- 1 dropper bottle **A** with 1.5 ml or 5.0 ml buffer diluent
- 2 or 10 sample tubes
- 2 or 10 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

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 98.8 %
Specificity 97.7 %
(Comparison Method: RT-PCR)

2. INTRODUCTION

Canine Distemper is caused by the canine Distemper virus (CDV), a Morbillivirus of the subfamily Paramyxovirinae. It infests dogs and other carnivores like fox, wolf, coyote, jackal, ferret, mink, raccoon and seal world-wide.

Infected animals excrete the virus via all secretion (saliva, ocular or nasal discharge) and excretion (feces and urine) from day 8 on post infection.

The infection is passed on via direct animal contact, indirect via ingestion of contaminated food or water or intrauterine. It can occur in animals of any age, but it most commonly affects unvaccinated puppies at the age of 3–6 months that have lost their maternal immunity or younger puppies that have received inadequate concentrations of maternal antibodies.

In case of young dogs with symptoms like higher temperature up to 41 °C, anorexia, vomiting, diarrhoea and especially serous nasal or ocular discharge, Distemper should be generally considered as a suspicious diagnosis. Clinical signs vary depending on virulence of the virus strain, environmental conditions, host age and immune status. Depending on viraemia and distribution in different organs, the symptoms can be respiratory (cough, dyspnoea), intestinal (diarrhoea, vomitus), neurologic (uncontrollable muscle twitch), cutaneous (hardened footpads) or a mixture of these. According to the severity of etiopathology and the involvement of secondary infections, the lethality is between 30 and 80 %.

The use of ***FAST*est® DISTEMPER** Strip enables the veterinarian a fast aetiological diagnosis of Distemper infection, a fast therapy start as well as the initiation of prescribed quarantine procedures.

3. INFORMATION ON THE SPECIMEN MATERIAL

Choice of material and date of sampling are most important.

Optimal date of sample collection is **7–10 days post infection** and sample of choice is ocular discharge followed by nasal discharge, urine sediment and liquor. Plasma* and serum* as well as feces may be applicable with limitation (*tendency for false positive results) and therefore are not recommended to be used as sample material for ***FAST*est® DISTEMPER** Strip.

All samples should be collected freshly and should be preferably tested within 4 hours after collection. Exceptionally the sample swab coated with ocular and/or nasal discharge (stored in a closed foil pouch), urine and liquor could be kept at 2–8 °C up to 3 days.

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 the TL and CL.**

4. SPECIMEN COLLECTION AND PREPARATION

Take the sample tube.

a. OCULAR AND NASAL DISCHARGE, LIQUOR

1. Add **10 drops of buffer diluent** (400–500 µl) from the dropper bottle **A** into each sample tube (fig.1a).
2. Using the disposable sample swab, take a portion of secretion of eye or nasal discharge (fig.1b) or liquor. Insert the well-moistened sample swab into the sample tube with the buffer diluent.

fig.1b

3. Mix the swab until the sample has been dissolved into the buffer diluent (fig.1c). Squeeze out the swab thoroughly to get all fluid into the sample tube. Discard the swab.

b. URINE

1. Fill the sample tube with the urine sample.
2. Centrifuge the urine sample for 5 minutes at 2000 rpm to obtain sediment.
3. Discard the supernatant.
4. Add **10 drops (400–500 µl) of buffer diluent** from the dropper bottle **A** onto the urine sediment in the sample tube (fig.2a).
5. Mix the sample-buffer mixture (SBM) thoroughly.

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 the lower limit of the green "stop" arrows (fig.1d/2b).
3. Remove the dipstick from sample tube soonest the sample-buffer mixture (SBM) has reached the CL. If so, the pink-purple CL will appear slowly but surely (fig.3/4). If the CL will not appear after 5–10 minutes, a new SBM must be prepared. The dipstick must be held only in the supernatant until the LF has reached the CL.
4. Place the dipstick on a flat and horizontal surface for incubation.

6. READING OF THE TEST RESULT

10 min

Read the test result after **10 minutes**. Positive test results may be observed earlier, depending on the concentration of antigen in the sample.

POSITIVE TEST RESULT (fig.3)
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.4)
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 dipstick.

fig.3
POSITIVE TEST RESULT

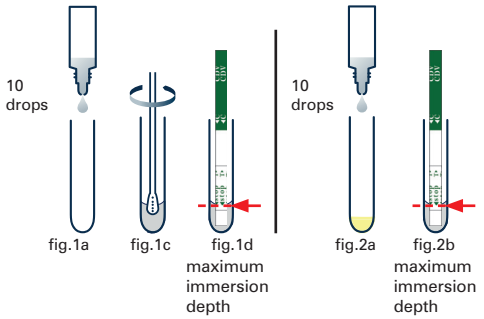
TL CL

fig.4
NEGATIVE TEST RESULT

CL

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 tube and dipstick to ensure a precise assignment.
- Use a new sample tube, a new disposable sample swab and a new dipstick 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 seen as potentially infectious and disposed of accordingly, together with the used test-kit components.



8. TEST PRINCIPLE

The ***FAST*est® DISTEMPER** Strip is based on latest rapid immunochromatographic technique.

Positive samples contain Canine Distemper Virus (CDV) antigens. These antigens will react in the conjugate pad area with mobile monoclonal anti-CDV antibodies, which are bound to gold particles. Migrating ("lateral flow", **LF**) along the nitrocellulose membrane, these specific antigen-antibody complexes are bound by fixed anti-CDV antibodies producing a pink-purple TEST line (**TL**). The intensity or width of the test line depends on the concentration of CDV antigens in the tested sample.

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 (e.g. greyish, shadow-like lines) has to be considered as unspecific reaction and therefore as negative test result.
- Due to host immunity, CDV spreading in the infected animal is quite different.
- Dogs with inadequate immunity (poor antibody response) show widespread invasion of all epithelial tissues and CNS, whereas dogs with adequate immunity (good antibody response) often show "only" an invasion into the CNS.
- **False negative test results** possible:
  – too low CDV concentration (used amount of sample)
  – false sample collection date
  – adequate immunity status of the dog