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*FAST*est® CHLAM Ag

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In vitro diagnosticum

Test-kit for the qualitative detection of *Chlamydia* spp. antigens in discharge, extracts, organs or feces of animals

INSTRUCTIONS FOR USE

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Manufacturer:
DIAGNOSTIK MEGACOR
6912 Hörbranz – AUSTRIA
www.megacor.com

1. INFORMATION ON THE TEST-KIT

TEST-KIT COMPONENTS

1 test-kit ***FAST*est® CHLAM** Ag contains:
- 2 or 10 test cassettes, coated with mono- and polyclonal antibodies against *Chlamydia* spp.
- 1 dropper bottle **A** with 2.0 ml or 10.0 ml buffer diluent
- 2 or 10 sample tubes (working station rack) with special filter cap
- 2 or 10 specimen collection 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

B – 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 93 % – Specificity 99.5 %
(Comparison Method: Cell Culture)

2. INTRODUCTION

Chlamydia are obligate intracellular bacteria in animals (low host specificity) and humans (high host specificity) world-wide. Chlamydia with zoonotic potential are *C. psittaci, C. abortus, C. trachomatis* and *C. pneumoniae*. Depending on country and species, chlamydiosis is a notifiable or reportable disease!

In the **cat**, esp. in kittens, *C. felis* has an important role in the cat flu complex. Infection normally occurs via direct contact/droplet infection. Unilateral, sometimes bilateral serous-purulent conjunctivitis with a strong chemosis are typical. In principle, all cats of a population should be tested and positive cases treated (ABCD guidelines) and vaccinated after the clinical symptoms have disappeared (non-core vaccination). Untested and untreated animals can develop a carrier status with possible recurrences.

In the **bird** (*C. psittaci*: psittacosis of psittacids; ornithosis of poultry and wild birds), infection occurs especially via feces, nasal discharge, droplet infection and contaminated dust. The clinical symptoms vary from ruffled feathers, emaciation, conjunctivitis, inflammation of the upper respiratory tract with eye and nasal discharge to light green coloured feces and diarrhoea with death in some cases. Latent infected psittacids are a considerable pathogen source for other birds and humans.

In **ruminants** (cattle, sheep, goat; esp. *C. abortus, C. pecorum, C. psittaci*) infections often are subclinical. High abortion rates (in small ruminants mainly during second half of gestation), perinatal calf losses, subclinical mastitis as well as joint, hoof and limb diseases are a hint onto a population problem with chlamydia.

In **horses**, *C. abortus, C. pneumoniae* were proven in conjunction with pneumonia, rhinitis, keratoconjunctivitis, abortion etc., but also in clinically healthy horses. Transmission is oral, aerogen, via mucosa, wounds or via mating as well as via nasal and bronchial discharge, abortion, sperm or urine.

The **dog** (*C. caviae, C. felis, C. psittaci, C. pneumoniae, C. trachomatis*) gets infected via direct contact, droplet infection, uptake of bird feces or infected dead birds. Clinical symptoms (fever up to 42 °C, bronchopneumonia, cough, keratoconjunctivitis, inappetence, diarrhoea, vomitus or tonic-clonic attacks) are diverse and therefore often not associated with Chlamydia.

Due to the highly infectious and zoonotic potential of *Chlamydia* spp. and the vague prevalence of some species, animals suspicious for chlamydiosis should be tested via ***FAST*est® CHLAM** Ag. Animals, especially dogs, with unclear clinic (exclusion diagnostics) should also be tested.

The ***FAST*est® CHLAM** Ag gives a fast aetiological diagnosis of a *Chlamydia* spp. infection. Especially due to the often unclear symptoms and the high infectiveness for animal and human, an on-site test is necessary. As a consequence, appropriate treatment, vaccination and quarantine measures can be initiated immediately.

3. INFORMATION ON THE SPECIMEN MATERIAL

***FAST*est® CHLAM** Ag is designed for testing a variety of secretions, excretions, feces and organs of animals.

Sampling should be done only with the special rayon/dacron tipped swabs provided. Do not use wooden-shafted, cotton or calcium alginated-tipped swabs for sampling, because these are toxic for *Chlamydia* spp.!

Due to the fact that *FAST*est® CHLAM Ag **needs no viable *Chlamydia* spp. antigens,** swab samples can be stored dry in their original wrapping material refrigerated at 4–8 °C up to 3 days or at −20 °C up to 2 weeks. **Do not place swab in transport medium as this may interfere with the test.**

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

Cervix and/or tissue extracts (cattle, sheep, goat): Remove any excess mucus, pus or blood. Rotate the swab for 30 seconds in the endocervical area to collect epithelial cells. For extract sampling roll the swab directly on the surface of placental tissues.

Conjunctiva (dog, cat): Remove any excess mucus, pus or blood. Rotate the swab for 30 seconds on the lower conjunctival membrane to collect conjunctival cells. Each eye must be tested separately (1 swab per test!)

Throat (horse): Remove any excess mucus, pus or blood. Rotate the swab for 30 seconds in the throat to collect epithelial cells.

Cloaca (birds): Remove any excess mucus, pus or blood. Rotate the swab for 30 seconds in the cloaca to collect epithelial cells.

Droppings (birds): Push the swab 3 times into the dropping at 3 different locations.

Organs (birds): Roll the swab directly on the surface of organs e. g. liver, lung cell material.

4. SPECIMEN PREPARATION

a. Fill the sample tube (working rack) with **22 drops (0.9 ml) of buffer diluent** of the dropper bottle **A** (fig.1).
b. Dip the well-coated swab into the sample tube. Mix the swab until the sample has been dissolved into the buffer diluent, at least for 10 seconds. **Leave the swab in the sample tube** (fig.2).
c. Extraction: Incubate the sample tube with the swab for **10–15 minutes** at room temperature. Swirl the swab 2–3 × for some seconds against the tube wall.
d. Squeeze the swab after incubation time against the tube wall to remove all liquid from the swab. Discard the swab.
e. Put the special filter cap on, press shut (fig.3). The swab extract can remain in the sample tube at room temperature for up to 30 minutes without affecting the test result.

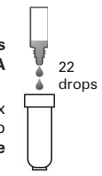


fig.1 fig.2

5. TEST PROCEDURE

1. Remove the test cassette from its foil pouch shortly before use. Place it on a flat surface.
2. Drop **carefully** (allow each drop to absorb before adding the next one) **4 drops (approx. 150 µl) of swab extract** to the sample window A of the test cassette (fig.4). Avoid bubbles!
3. Add 1 additional drop of swab extract into the sample window A if there is no beginning LF visible within 1 minute after adding the swab extract.

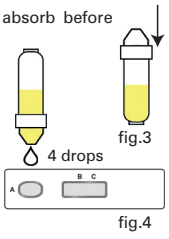


fig.3 fig.4

6. READING OF THE TEST RESULT

Read the test result **20 minutes** after the swab extract has been added into the sample window A.

POSITIVE TEST RESULT (fig.5)
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.6)
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.5
POSITIVE TEST RESULT

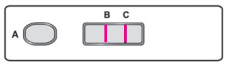
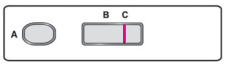


fig.6
NEGATIVE TEST RESULT



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 and associated test cassette to ensure a precise assignment.
- Use a new sample tube, a new swab 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, due to the zoonotic potential of *Chlamydia* spp. It must be disposed of accordingly, together with the used test-kit components.**

8. TEST PRINCIPLE

The ***FAST*est® CHLAM** Ag is based on an immunochromatographic "sandwich principle" for the qualitative detection of genus-specific lipopolysaccharide (LPS) antigens of *Chlamydia* in different exudates, extracts of organs and feces of animals.

Genus-specific LPS antigens of *Chlamydia* spp. in the sample react with a highly specific mixture of mono- and polyclonal antibodies forming antigen-antibody complexes. These complexes are migrating ("lateral flow", **LF**) along the nitrocellulose membrane and will be captured by membrane-fixed capture antibodies forming a pink-purple TEST line (**B**).

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

The used antibodies guarantee a high level of specificity for the aetiologic detection of *Chlamydia* spp. antigens.

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 B and C (e. g. greyish, shadow-like lines) has to be considered as unspecific reaction and therefore as negative test result.
- B 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.
- The use of customary local anesthetic to simplify the sampling does not influence the test result.
- Result is only significant in a positive case. A single negative result does not exclude the infection with chlamydia.

Positive test result

In the sample material used, *Chlamydia* spp. are present.
- Confirmation of suspicion "chlamydiosis" in non-vaccinated cats
- Endemic proof in a cat group (e. g. breeding, shelter)

Negative test result

In the sample material used, no *Chlamydia* spp. could be proven.
- No confirmation of suspicion "chlamydiosis" in non-vaccinated cats
- Time of sampling was too early, chlamydia concentration of the sample used below the cut-off → test repetition after 1–2 days is recommended
- Sampling of only one eye → immediate testing of the other eye!
- Confirmation of therapy → vaccination possible!