

FASTest® KOI HV

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In vitro diagnosticum

Test Kit for the qualitative detection of Koi Herpesvirus (KHV) antigen in gill swabs of common carp and Koi carp

INSTRUCTIONS FOR USE

1. INFORMATION ON THE TEST KIT TEST KIT COMPONENTS

- 1 Test Kit **FASTest® KOI HV** contains:
- 2, 10 or 25 test cassettes, coated with monoclonal anti-KHV antibodies
 - 2, 10 or 25 sterile specimen collection swabs
 - 2, 10 or 25 sample tubes, filled with 250 µl buffer diluent each
 - 2, 10 or 25 disposable plastic pipettes
 - 1 instructions for use

[EXPLANATION OF THE SYMBOLS] FOR VETERINARY USE ONLY

Store at 15–25 °C

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Follow instructions for use carefully.

Expiry date

LOT Number

STORAGE AND STABILITY

- Store at room temperature (15–25 °C).
- Stored correctly, the Test Kit can be used up to the labelled expiry date.
- Avoid the Test Kit being subjected to excessive heat or freezing.

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.

2. INTRODUCTION

The Cyprinid herpesvirus 3, also known as Koi herpesvirus (KHV), belongs to the family of Alloherpesviridae. It is spread world-wide, mainly by intensive international fish trading, and strains from different countries were shown to have high similarities. The virus causes a highly contagious and acute viraemia in common carp (*Cyprinus carpio carpio*) and its variant, the Koi carp (*C. c. koi*). This devastating virus disease may result in mortality rates between 70 and 100 %. Interestingly, the disease is temperature dependent, mostly occurring between 16

and 25 °C. All age groups of carp appear to be susceptible to KHV, although, generally, younger fish up to one year are more susceptible to clinical disease. The mode of transmission of KHV is horizontal, but vertical transmission cannot be ruled out. Horizontal transmission may be direct or vectorial, water being the major abiotic vector. KHV remains active in water for at least 4 hours at water temperatures of 23–25 °C. Virulent virus is shed via faeces, urine, gills and skin mucus. Infection mainly occurs via the skin. After entry, the virus spreads systemically from the portal of entry to superficial and internal organs. High levels of virus DNA have been shown to be present in skin, gills, spleen, liver and gut tissues. Clinical signs of KHV can be difficult to distinguish from other fish diseases and generally include an evident hypersecretion of mucus in the early stage of infection. Additional typical clinical signs are loss of appetite, discolouration of skin and gills as well as skin lesions. Sunken eyes (enophthalmia) and necrotic gills are frequently seen. Due to its potential to cause considerable economic damage, the disease is listed as a notifiable disease by the world animal health organization OIE (www.oie.int). To limit disease spread, a rapid identification of KHV in diseased or dead fish is crucial.

The use of **FASTest® KOI HV** as a fast “pond-side” test enables veterinarians, Koi owners and breeders, importers and / or pet shops a fast aetiological diagnosis of a fresh and acute KHV infection. Proof or exclusion of a KHV infection is an important criterion for the initiation of follow-ups like separation, disinfection and / or quarantine measures.

3. INFORMATION ON THE TEST SPECIMEN MATERIAL

The sample material must be taken shortly before use. Make sure to cover the entire surface of the gills for optimal antigen recovery. The swab may colour slightly red.

Any contact after sampling between swab and surfaces other than the sample tube may result in sample loss and loss of sensitivity.

4. SAMPLE PREPARATION

1. Remove the test cassette from the foil pouch, label it with a patient name or ID number and make sure that the test cassette is on a level surface.

2. Label the prefilled sample tube with a patient name or ID number. Prepare it for the use in step 5.

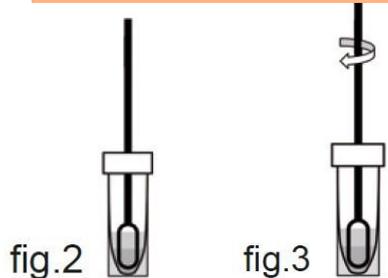
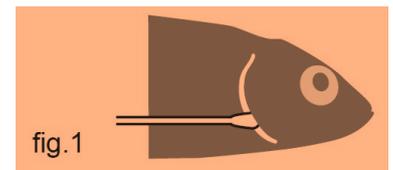
3. Remove the diseased fish from the water and immobilise the fish.

4. Remove the swab from its package.

5. Thoroughly swab the whole surface of both gills (fig.1). The aim is to take up as much antigen material as possible. Do not touch anything with the swab thereafter except the sample tube! Loss of antigen material means loss of sensitivity! Transfer the swab immediately after sampling into the prefilled sample tube. Leave the swab in the sample tube (fig.2).

6. Release the fish.

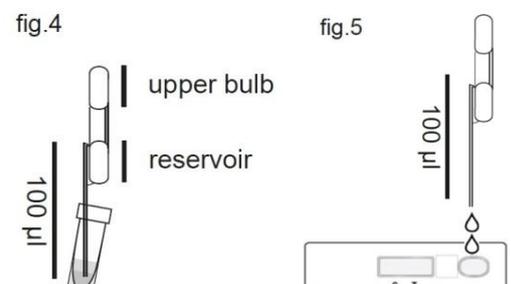
7. Mix the sample homogeneously with the buffer diluent swirling the swab between your thumb and index finger while pressing the flocked tip of the swab against the tube wall (fig.3). Squeeze the swab against the tube wall to remove all liquid out of the swab.



5. TEST PROCEDURE

8. By strongly squeezing the upper bulb of the plastic pipette (fig.4), the capillary part of the pipette will fill up first, containing 100 µl. Excess volume will drop into the reservoir. By gently squeezing the upper bulb again, the 100 µl in the capillary part will be dispensed into the SAMPLE window of the test cassette (fig.5). NOTE: Do not express fluid from the reservoir!

9. Incubation for 15 minutes.

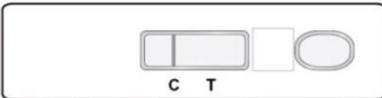


6. READING OF THE TEST RESULTS

Read the test results 15 minutes after the extraction sample has been dropped into the round sample window of the test cassette.

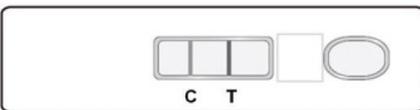
NEGATIVE TEST RESULT

Only the CONTROL zone "C" shows a pink-purple coloured CONTROL line "C", indicating the sample being negative for KHV antigens in the gill tissue. Additionally, this CONTROL line indicates a proper test performance.



POSITIVE TEST RESULT

The TEST zone "T" and CONTROL zone "C" each show a pink-purple line indicating the presence of KHV antigens in the sample. Even a weak T line in the TEST zone "T" should be interpreted as a positive result. Different intensities between the lines in the TEST "T" and CONTROL "C" zones may occur but do not affect the interpretation of the positive test result.



In case of only one pink-purple line in the TEST zone "T" or no pink-purple lines in TEST "T" and CONTROL "C" zones, the test is not valid indicating the test has to be repeated using a new test cassette.

7. PRECAUTIONS FOR USERS

• FOR VETERINARY USE ONLY!

- The FASTest® KOI HV can only be used for common carp (*Cyprinus carpio*) and Koi carp, not for other cyprinids.
- Do not use the test once the expiry date has passed.
- Do not use reagents from different kits.
- Do not remove any test components (room temperature!) from their individually sealed pouches until immediately before use.

- The sample material must be seen as potentially infectious. Therefore appropriate laboratory safety measures should be taken while sampling, testing and disposing.

- The buffer diluent contains low concentration of toxic sodium azide as a preservative; therefore avoid any skin contact and / or ingestion.

- Follow instructions for use precisely.

8. TEST PRINCIPLE

The FASTest® KOI HV is based on a direct solid phase immunochromatographic "sandwich principle" for the qualitative detection of KHV antigens in swab samples taken from gill tissue. The KHV antigens in the sample react with gold labelled KHV specific antibodies forming antigen-antibody complexes. These antibody complexes migrate through the nitrocellulose membrane ("lateral flow") and will be captured by membrane-fixed capture antibodies in the test line zone producing a more or less intensive coloured pink-purple TEST line "T". A second pink purple CONTROL line "C" will show a correct test procedure.

9. INFORMATION FOR THE TEST EVALUATION

Detection limit of **FASTest® KOI HV**: **10⁴-10⁶ KHV / ml**

Carp with distinct clinical symptoms (acute phase of infection: alive or just died)

A positive test result is normally shown by a clear and distinct pink-purple TEST line "T". However, any TEST line, independent of its intensity, has to be interpreted as positive. In combination with suspicious clinical signs, this indicates an ongoing KHV infection with a high likelihood.

A negative test result, combined with signs suspicious for KHV and beyond the acute phase, excludes an ongoing KHV infection with a high likelihood. Other fish diseases causing similar clinical signs should be an option of differential diagnosis.

Carp without distinct clinical symptoms / asymptomatic carrier fish

In carp and Koi carp during the early infection phase (appearingly healthy) or

in the late phase of infection (latent or chronic), the KHV concentration normally is below the detection limit of the **FASTest® KOI HV** (10⁴-10⁶ KHV / ml), therefore the test result in these animals can be **negative**.

An on-site test of suspicious fish population or in suspicious animals principally needs confirmatory analyses in a national reference laboratory commissioned for KHV diagnostics. This is considered to be necessary, especially for a negative **FASTest® KOI HV** test.

Other Fish Disease Test Kits:

Fastest BKD Strip

Fastest IPNV Strip

Many other Diagnostic test kits, laboratory equipment and consumables available... Please visit our website for further information...

www.vetlabsupplies.co.uk



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