

FELINE HEARTWORM-FELINE LEUKEMIA VIRUS ANTIGEN-FELINE IMMUNODEFICIENCY VIRUS ANTIBODY TEST KIT

WITNESS™ | FFH

ENGLISH

I. GENERAL INFORMATION

Rapid Immuno Migration (RIM™) test for IN VITRO detection of Feline Heartworm (FHW) antigen, Feline Leukemia Virus (FeLV) antigen and Feline Immunodeficiency Virus (FIV) antibody in feline whole blood, serum, or plasma.

II. TEST PRINCIPLES

WITNESS™ FFH is a simple test based on Rapid Immuno Migration (RIM™) technology. FHW antigen is detected using anti-heartworm antibodies. FeLV antigen is detected using antibodies directed against the circulating p27 capsid protein. FIV antibody is detected based on the presence of antibodies against the transmembrane region of the virus, using a synthetic peptide from the gp40 protein.

In all three cases, sensitized particles bound to the targeted analyte present in the sample (whole blood, serum or plasma) migrate along a membrane.

The complex is then captured on a sensitized reaction zone where its accumulation causes the formation of a clearly visible pink/red band.

A control band located at the end of the reading window (C) ensures that the test was performed correctly.

III. SAMPLE MATERIAL

- The test can be performed on unclotted whole blood anticoagulated with EDTA or heparin, serum, or plasma.
- Always collect samples with a sterile needle and syringe.
- Hemolysis does not significantly interfere with the test, but strongly hemolyzed samples may partly obscure a weak positive band.

IV. SAMPLE STORAGE

Fresh, anticoagulated whole blood should preferably be tested immediately after collection but not longer than 4 hours after collection, if stored at room temperature.

If testing is further delayed, samples should be kept refrigerated (whole blood samples up to 24 hours and serum or plasma up to 7 days at +2 °C to 7 °C).

For long term storage, samples (serum or plasma only) should be kept frozen (-20 °C or colder).

V. KIT CONTENTS

- 10 or 25 Pouches, each containing 1 test device and desiccant.
- 10 or 25 Pipettes.
- 2 or 3 Buffer bottles (5.0 mL each).
- Instructions for use.

VI. PRECAUTIONS

- Do not use this kit or any of its components after the expiration date.
- Kit should be stored at +2 °C to 25 °C. Kit should not be frozen.
- Use the test immediately after the pouch is first opened (within 10 minutes).
- Avoid touching or damaging the membrane in the sample wells or the results windows.
- The WITNESS™ device should be placed on a flat, horizontal surface while performing the test.
- Use a separate pipette for each sample.
- Hold pipette and buffer bottle vertically when dispensing sample and buffer respectively.
- Handle all samples as biohazardous material.
- Saline buffer is preserved with sodium azide.
- For veterinary use only.

VII. TEST PROCEDURE

Important: Allow samples and buffer drops to fall onto the membrane in each sample window. Do not touch pipette tip, buffer bottle tip, or the sample or buffer drops directly to the membrane.

1. SAMPLE APPLICATION

- Tear open a pouch provided and place the test device on a flat horizontal surface.
- Holding the provided pipette vertically, add one drop of sample to each test well.

2. BUFFER DISPENSING

- Check that the sample has fully absorbed into the membrane.
- Remove the cap from the buffer bottle, hold it vertically and add two drops of buffer to each test well.
- Leave the test device flat during migration of the sample/reagent complex through the reading windows.

3. READING TEST

After 10 minutes, observe the presence or absence of pink/red bands in the reading windows (T) and (C).

Note:

- It is possible to read the test before 10 minutes if two pink/red bands are clearly visible in the results windows (T) and (C).
- The presence of only one band in control window (C) prior to the end of the development time (10 minutes), does not mean that the test is complete, as a test band may appear more slowly than the control band.

VIII. RESULTS

Valid Results

Test is valid if a pink/red band is present in reading window (C).









Interpretation of Results

- Positive: One pink/red band in reading window (T), with one pink/red band in reading window (C); sample is positive for the analyte.
- Negative: No band in reading window (T), with one pink/red band in reading window (C); sample is negative for the analyte.
- Invalid test: No pink/red band in reading window (C).

Note:

- A test result should always be interpreted in the context of all available clinical information and history for the cat being tested. Cats testing negative for heartworm antigen may benefit from other diagnostic tests, including heartworm antibody assays.

SYMBOL DESCRIPTIONS

 Use by Date	 Consult Instructions for Use
 Batch Code	 In Vitro Diagnostics
 Serial Number	 Manufacturer
 Temperature Limitation	 Date of manufacture


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Distributed by:
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Kalamazoo, MI 49007, USA
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