

Antibody Detection Kit

FELINE IMMUNODEFICIENCY VIRUS

Cat. No. 85FIV205/85FIV250
INSTRUCTION MANUAL

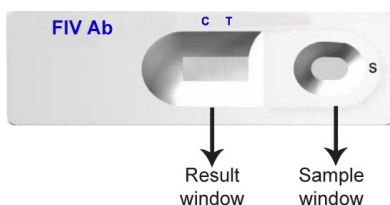
I. Intended Use Of The Kit

ImmunoRun FIV Antibody Detection Kit is intended for detection of Feline Immunodeficiency Virus (FIV) antibodies (Ab) in cat blood, serum or plasma. The kit contains all components required to perform the test.

II. General Information

ImmunoRun FIV Antibody Detection Kit contains individual devices intended for performing immunochromatographic assay to qualitatively detect FIV Ab in feline blood/plasma/serum. Each device contains 2 main windows. A round window which is the specimen application well and a square result window marked by 2 letters: "T" marks the test line and "C" marks the control line (See Fig. 1). Both lines are invisible before reaction takes place. The control purple line should appear with each ongoing reaction as it is used for validation of the test. The specially selected FIV antigen is used as both capture and detection reagents. Antibodies anti-FIV in specimen bind to the gold conjugated FIV antigen and form a complex that migrates to the area where it is captured, and its accumulation creates a band - a purple test line. These enable FIV Ab device to identify FIV antibodies in feline blood/plasma/serum with a high degree of accuracy.

Fig. 1: FIV Ab. device



III. Description Of The Disease

Feline immunodeficiency virus (FIV), a lentivirus, the causative agent of feline AIDS, is a common pathogen of domestic cats worldwide with incidence rate of 2.5% to 20%. Infection in cat may be persistent and characterized by a long latent period, which may ultimately cause immunosuppression. FIV is the only non-primate lentivirus to cause an AIDS-like syndrome; cats may live with no symptoms as carriers for many years but transmit the disease to other cats. Opportunistic infections, neurological disease and lymphoma are also well reported in cats infected with FIV.

IV. Diagnosis Of The Disease

The ImmunoRun FIV Antibody Detection Kit is the simplest screening diagnostic method available to detect the presence of antibodies against FIV. For best results strict adherence to the following step by step protocol is required. It has been compared with a leading commercial FIV Ab. test; the overall accuracy is greater or equal to 99.0%. Other Immuno-diagnostic methods may be used to quantitate antibody titer, while PCR may be used to verify the presence of the virus.

V. Kit Contents

Component	5 Tests Kit (85FIV205)	50 Tests Kit (85FIV250)
FIV Ab test device	5	50
Dropping bottle containing assay diluent	1	5
Disposable capillary tube with a 10µl marked line (See Fig. 2)	5	50
Instruction manual	1	1

Fig. 2: 10µl marked line on a capillary tube



VI. Storage And Handling

- Shipment may be performed at room temperature.
- Store at 2-30°C (room temperature or refrigerated). Avoid exposure to direct sunlight.
- Kit is stable for up to two years, do not use beyond expiration date stated on the package label.
- **Do not freeze!**
- Do not open or remove test kit from their individually sealed pouches until immediately before their use (do not use kit if the pouch or the device are damaged).
- Avoid touching exposed membrane in device windows.
- Components in this kit have been quality control approved as standard batch unit. Each component in the kit is for a single use only. Do not mix components from different lot numbers, and do not try to reuse a device.
- Handle and dispose of used samples, swabs, extraction buffer and used device in accordance with accepted sanitary requirements designated for biohazardous waste.

VII. Step By Step Protocol

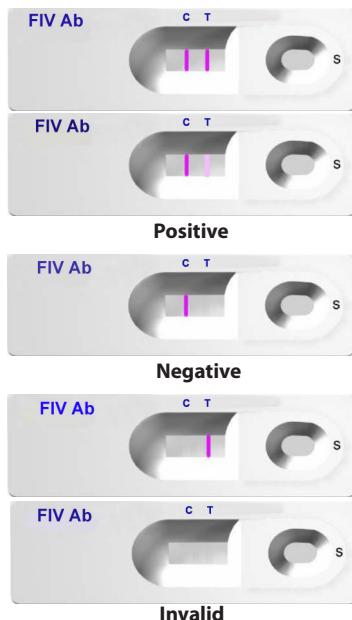
For best results, strict adherence to these instructions is required.

1. Collect blood from a cat. If any anticoagulant is used, blood sample should be tested within 24 hours.
2. If the test is delayed, centrifuge sample in order to separate plasma/serum from other blood components and store refrigerated (2-8°C) for up to 72 hours, or freeze (below -20°C) for a longer period.
3. Specimens containing precipitate may yield inconsistent results. Such specimens must be clarified by centrifugation prior to assaying.
4. Allow all kit components and specimen to reach room temperature prior to testing.
5. Remove the test cassette from the foil pouch prior to use.
6. Place the test cassette horizontally on a dry surface.
7. Using a capillary tube insert **1 drop** of blood/serum/plasma sample (~10µl) into the sample well. Using the dropper bottle, apply **2 drops** (~60µl) of **Diluting Buffer** into the sample well. If migration through result window (purple color) does not start within a minute, apply another drop of diluent.
8. Follow the control line ("C") as it appears in the result window. In case of a positive result, a test line ("T") should appear as well.
9. Reading test results must be done within **10 minutes** of sample application.

VIII. Reading And Interpreting The Results

- See Fig. 3.
- The presence of (any) **two** visible bands: the test band ("T") and the control band ("C") within the result window (no matter which band appears first) indicates a **positive** result, regardless of test band intensity.
- A lack of a test band, while control band is present within the result window, indicates a **negative** result.
- If the control band is not visible within the result window, the result is considered **invalid** (even if the test band appears).

Fig.3: FIV Ab. bands interpretation



IX. Limitations And Troubleshooting

- For veterinary *in vitro* use only. Do not use internally or externally in humans or animals.
- As with all diagnostic tests, a low incidence of false results can occur. All results must be considered with laboratory findings and other clinical information available to the veterinarian.
- This is a screening test. Additional follow-up testing using other laboratory methods is recommended.
- The test is not selective and may detect post FIV vaccination antibodies. Be aware of vaccination history in order to be able to interpret the results correctly.

X. References

- Hartmann K (1998) Feline immunodeficiency virus infection: an overview. Vet J.155(2):123-37. Review.
- Levy JK et al. (2004) Effect of vaccination against feline immunodeficiency virus on results of serologic testing in cats. J Am Vet Med Assoc. 15;225(10):1558-61.
- Pedersen N.C. et al. (1989) Feline immunodeficiency virus. Vet. Immunol. Immunopatol 21:111-129.
- Willett BJ et al. (1997) FIV infection of the domestic cat: an animal model for AIDS. Immunol Today. 18(4):182-89. Review.

For further information and assistance please contact your local distributor or Biogal Galed Labs. Acs. Ltd. Directly by e-mail: info@biogal.com or by tel: 972-4-9898605 / fax: 972-4-9898690.



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