Feline Immunodeficiency Virus (FIV) Antibody Rapid Test

(Serum/Plasma)

Intended Use

The Feline Immunodeficiency Virus (FIV) Antibody Rapid Test Device is a sandwich lateral flow immunochromatographic assay for the qualitative detection of FIV antibodies in feline serum or plasma specimens.

Principle

The FIV Antibody Rapid Test Device is based on sandwich lateral flow immunochromatographic assay. The test device has a testing window. The testing window has an invisible T (test) zone and C (control) zone. When sample is applied into the sample well on the device, the liquid will laterally flow on the surface of the test strip. If there is enough feline immunodeficiency virus antibody in the sample, a visible T line will appear. The C line should always appear after a sample is applied, indicating a valid result. By this means, the device can accurately indicate the presence of feline immunodeficiency virus antibody in the sample.

Storage and Stability

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use**. DO NOT FREEZE.** Do not use beyond the expiration date.

Additional Special Equipment

Materials Provided

• Test devices • Droppers • Buffer • Package insert

Materials Required but Not Provided

• Timer • Specimen container • Centrifuge (for plasma)

Direction For Use

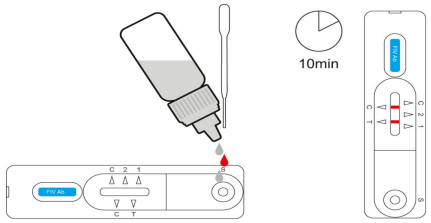
Allow the test device, specimen, buffer, and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

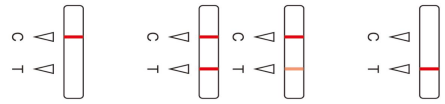
1. Collect feline's fresh serum or plasma from blood as soon as possible to avoid hemolysis. Only use clear, non-hemolyzed specimens. Do not leave the specimens at room temperature for prolonged periods. .

2.Take out the test card from the foil pouch and place it horizontally.

3.Using the capillary dropper to place **10 μ L of the prepared specimen** into the sample "S" of the test device. Then drop **2 drops (approx. 80 μ L)** of the assay buffer into the sample well immediately.

4. Interpret the result in **10 minutes.** Result after 15 minutes is considered as invalid.





Interpretation of Results

Positive: Two lines appear. One line should always appear in the control line region(C), and another one apparent colored line should appear in the test line region.

Negative: One colored line appears in the control region(C).No apparent colored line appear in the test line region.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Performance Characteristics

Relative Sensitivity: 97.50% (95%CI*: 86.84% - 99.94%)
Relative Specificity: 96.67% (95%CI*: 91.69% - 99.08%)
Accuracy: 96.88% (95%CI*: 92.86% - 98.98%)
*CI = confidence interval compared to RT-PCR method.

Precautions

- Do not use after expiration date.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.
- Do not remove test device from its pouch until immediately before use.
- Do not reuse the test kit.
- Do not mix components from different lot and different products.

Limitations

The FIV Antibody Rapid Test Device is for in vitro veterinary diagnosis use only. All results should be considered with other clinical information available from veterinarian. For an accurate result, it is suggested to apply other method such as PCR for final determination in practice.

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