



Feline Infectious Peritonitis Antibody Rapid Test (Serum/Ascites)

Package Insert

Intended Use

The Feline Infectious Peritonitis (FIPV Antibody Rapid Test Device is a lateral flow immunochromatographic assay for the qualitative detection of FIPV antibody in feline serum or ascites.

Principle

The Feline FIPV Ab Test is based on sandwich method lateral flow immunochromatographic assay. The test card has a testing window for the observation of assay running and result reading. The testing window has an invisible T (test) zone and a C (control) zone before running the assay. When the treated sample was applied into the sample hole on the device, the liquid will laterally flow through the surface of the test strip and react with the pre-coated FIPV recombinant antigens. If there are FIPV antibodies in the specimen, a visible T line will appear. The C line should always appear after a sample is applied, which indicates a valid result. By this means, the device can accurately indicate the presence of FIPV antibodies in the specimen.

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.

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.

Additional Special Equipment

Materials Provided

- Test devices
- Droppers
- Plastic tubes with buffer
- Package insert

Materials Required But Not Provided

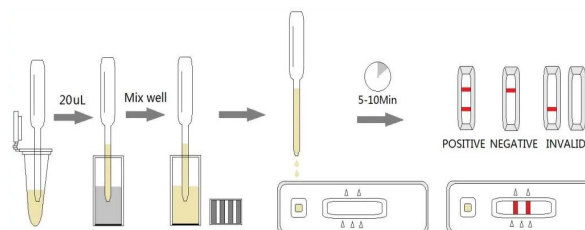
- Timer
- Sample containers

Direction For Use

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

For serum test:

1. Collect feline's fresh serum samples and ensure that the samples cannot be turbid or precipitated. 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. Collect **20µL of the prepared specimen** into a vial of assay buffer and mix well. Then drop **3 drops (approx. 120µL)** of the diluted sample into the sample well "S" of the test card. See illustration below.
4. Interpret the result **in 10 minutes**. Result after 15 minutes is considered as invalid.



For ascites test:

- a. Collect feline ascites with sample containers.
 - b. Place the test device on a clean and level surface. Hold the dropper vertically and transfer **1 drop of sample (approximately 40 µl)** and immediately add **3 drops of buffer (approximately 120 µl)** into the specimen well(S), then start the timer.
2. Read the result **in 5-10 minutes**. Do not interpret results after 15 minutes

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.

Cat.No.: VE90040

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: 95.12% (95%CI*: 83.47%-99.40%)

Relative Specificity: 95.87% (95%CI*: 90.62%-98.65%)

Accuracy: 95.68% (95%CI*: 91.30%-98.25%)

*CI = confidence interval compared to RT-PCR method

Limitations

The FIPV Antibody Rapid Test Device is for in vitro diagnostic use only for feline. All results should be considered with other clinical information available from veterinarian. For confirming the results, confirmatory methods such as PCR are recommended.



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