



Feline Infectious Peritonitis Antigen Rapid Test

(Serum/Ascites)

Package Insert

Intended Use

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

Principle

The FIPV Antigen Rapid Test Device is a lateral flow immunochromatographic assay based on sandwich format. The test device has a testing window. The testing window has T (test) region and C (control) region. During testing, sample is applied into the sample well on the device. FIPV antigens, if present in serum or ascites specimen, react with the pre-coated anti-FIPV antibodies in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with anti-FIPV antibodies on the membrane in the test line region. If the specimen contains FIPV antigens, a coloured line will appear in the test line region indicating a positive result. If the specimen does not contain FIPV antigens, a coloured line will not appear in the test line region indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred. means, the device can accurately indicate the presence of FIPV antigen 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

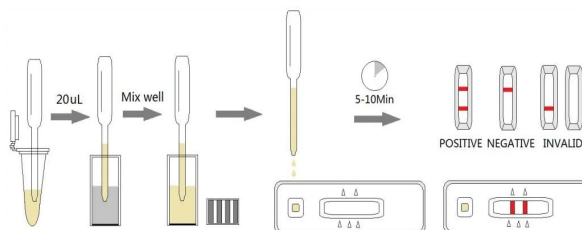
- Timer
- Sample containers

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.

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2. Read the result **in 5-10 minutes**. Do not interpret results after 10 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.

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 Antigen 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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