VECHEK™

FPV Antigen Rapid Test Cassette (Feces/Vomit) Package Insert

REF VIFP-602	English

INTENDED USE

The FPV Antigen Rapid Test Cassette (Feces/Vomit) is a lateral flow immunochromatographic assay for the qualitative detection of Feline Panleucopenia Virus (FPV Ag) in cat's feces or vomit.
For veterinary use only.

PRINCIPLE

The FPV Antigen Rapid Test Cassette is a lateral flow immunochromatographic assay based on sandwich format. The test cassette has a testing window with a T (test) region and C (control) region. During testing, sample is applied into the sample well on the test cassette. FPV antigens, if present in specimen, react with anti-FPV antibodies coated colloidal gold particles in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with anti-FPV antibodies on the membrane in the test line region. If the specimen contains Feline Panleucopenia Virus, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain FPV antigens, a colored line will not appear in the test line region indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

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 cassette 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 cassette from its pouch until immediately before use.
- Do not reuse the test kit.
- Do not mix components from different lots and different products.

MATERIALS

Materials Provided

• Test cassettes • Droppers • Plastic tubes with buffer
• Swabs • Package insert

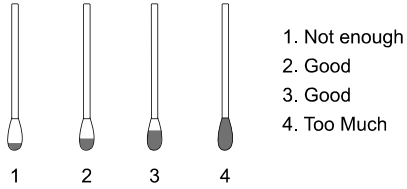
Materials Required but Not Provided

• Timer

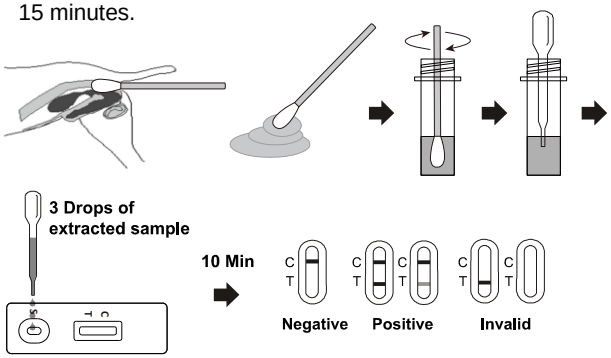
DIRECTIONS FOR USE

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

1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Collect cat's feces or vomit with the swab from cat's anus or on the ground. The amount of fecal swab as follows:



3. Insert the wet swab into the provided assay buffer tube. Agitate it to assure good sample extraction.
4. Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 drops of extracted sample** (approximately 120 µL) to the specimen well (S) of the test cassette, then start the timer. See illustration below.
5. **Read the result at 10 minutes.** Do not interpret results after 15 minutes.



INTERPRETATION OF RESULTS

Positive: The presence of both C line and T line, regardless of T line being strong or faint.
Negative: Only clear C line appears.
Invalid: No colored line appears in C region, regardless of T line's appearance.

ACCURACY

The FPV Antigen Rapid Test Cassette has been evaluated with specimens obtained from veterinary hospital. Commercial control test is used as the reference method for the FPV Ag Test. Specimens were considered positive if commercial control test indicated a positive result.

FPV Antigen Rapid Test Cassette	Commercial Control Test		Total
	Positive	Negative	
Test Positive	62	3	65
Test Negative	5	100	105
Total	67	103	170

Relative Sensitivity: 92.54% (95%CI*: 83.44%~97.53%)
Relative Specificity: 97.09% (95%CI*: 91.72%~99.40%)
Accuracy: 95.29% (95%CI*: 90.94%~97.95%) *Confidence Interval

FPV Antigen Rapid Test Cassette	PCR Control Test		Total
	Positive	Negative	
Test Positive	45	0	45
Test Negative	1	4	5
Total	46	4	50

Relative Sensitivity: 97.83% (95%CI*: 88.47%~99.94%)
Relative Specificity: 100.00% (95%CI*:39.76% ~100.00%)
Accuracy: 98.00% (95%CI*: 89.35%~99.95%) *Confidence Interval

CROSS-REACTIVITY

The FPV Antigen Rapid Test Cassette has been tested by FIV, FeLV, Infectious Peritonitis virus, Calicivirus positive specimens. The results showed no cross-reactivity.

INTERFERING SUBSTANCES

The following potentially interfering substances were added to FPV negative and FPV middle positive specimens, respectively.

Analytes	Conc.
Amoxicillin	0.5mg/dL
Cephalosporin	50mg/dL
QuLuo Stan	0.5mg/dL

None of the substances at the concentration tested interfered in the assay.

LIMITATION

The FPV Antigen Rapid Test Cassette is for diagnostic use only for felines. All results should be considered with other clinical information available from veterinarian. For confirming the results, confirmatory methods such as PCR are recommended.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	2°C 30°C	Temperature limit
	Manufacturer	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Use-by date		Do not re-use

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

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