Canine Influenza Virus Antigen Rapid Test

(Secretions)

Package Insert

Intended Use

The Canine Influenza Virus (CIV) Antigen Rapid Test Device is a sandwich lateral flow immunochromatographic assay for the qualitative detection of CIV antigens in canine ocular and nasal secretions.

Principle

The CIV Antigen 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 Canine Influenza Virus antigen in the sample, a visible T line will appear in the T zone. 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 Canine Influenza Virus antigen 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.

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
- Swabs
- Plastic tubes with buffer
- Package insert

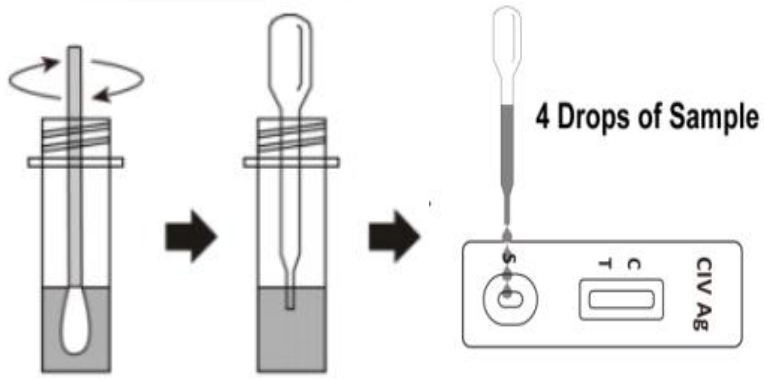
Materials Required But Not Provided

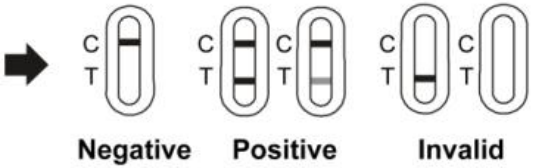
- Timer

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 canine's ocular and nasal secretions with the swab stick. Make the swab wet sufficiently.
2. Insert the wet swab into the provided buffer tube. Agitate it to assure good sample extraction.
3. Place the test device on a clean and level surface. Hold the dropper vertically and transfer **4 drops of extracted sample (approximately 100 µl)** to the specimen well (S) of the test device, then start the timer. See illustration below.
3. 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.

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: 90.00% (95%CI*: 55.50%-99.75%)

Relative Specificity:> 99.9% (95%CI*: 98.97%-100.00%)

Accuracy: 99.67% (95%CI*: 98.15%-99.99%)

*CI = confidence interval compared to RT-PCR method

Limitations

CIV Antigen 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

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative

IVD	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 4-30°C	LOT	Lot Number	REF	Catalog #

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