Feline Calicivirus Antigen Rapid Test FCV Ag

(Secretions)

Package Insert

Intended Use

The Feline Calicivirus Antigen Rapid Test is a lateral flow immunochromatographic assay for the qualitative detection of feline Calicivirus antigen (FCV Ag) in secretions from cat's eyes, nasal cavities, and anus.

Principle

The The Feline Calicivirus Antigen Rapid Test is based on sandwich lateral flow immunochromatographic assay. The test device 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 monoclonal antibodies. If there is FCV antigen in the specimen, a visible T line will appears. 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 Feline calicivirus 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 • Swab

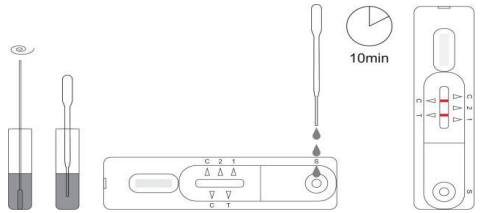
Materials Required But Not Provided

• 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.

1. Collect cat's ocular, nasal or anus secretions with the cotton swab and make the swab wet sufficiently.
2. Insert the swab into the provided assay buffer tube.Agitates it to get efficient sample extraction.
3. Take out the test card from the foil pouch and place it horizontally.
4.Suck the treated sample extraction from the assay buffer tube and place **3 drops** into the sample well "S" of the test device.
5.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: 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 Feline Calicivirus 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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