BISAF VET

For Canine & Feline Only

Toxoplasma gondii Antigen Test kit

INTENDED USE

The Toxoplasma gondii Antigen Test kit Device is a sandwich lateral flow immuno-chromatographic assay for the qualitative detection of Toxoplasma gondii antigen (Toxo Ag) in animal (canine / feline) faeces.

PRINCIPLE

The Toxoplasma gondii Antigen Test kit Device is based on sandwich lateral flow immunochromatographic assay. The test device has a testing window. The testing window has an invisible T (test) line region and C (control) line region. 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 Toxoplasma gondii antigens in the sample, a visible T line will appear in the T region. 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 Toxoplasma gondii antigen in the sample.

Performance

Sensitivity & Specificity

Toxo Ag Test	PCR Test		
	Positive	Negative	Total
Positive	63	2	65
Negative	4	265	269
Total	67	267	334
PPA	63/67,94.03%(95%CI: 85.63% to 97.65%)		
NPA	265/267,99.25%(95%CI: 97.31% to 99.79%)		
TPA	328/334,98.20% (95%CI: 96.14% to 99.17%)		

* CI: Confidence Interval

Materials provided (1 test/kit)

1) Test cassette
2) Dilution buffer
3) Disposable swab
4) Instruction of use
5) Collection bag

STORAGE AND STABILITY

- Store in a dry place at 2-30°C
- Do not freeze
- Keep away from direct sunlight
- 24 months of shelf life (Production date to the expiration date).

PRECAUTIONS

1. Do not use after expiration date.
2. 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.
3. Wear disposable gloves and eye protection when specimens are being tested.
4. Humidity and temperature can adversely affect results.
5. Do not remove test device from its pouch until immediately before use.
6. Do not reuse the test kit.
7. Do not mix components from different lot and different products

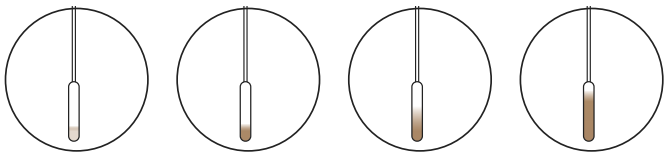
Sample Preparation

1.Canine or feline fecal swab should be used for this test.

2.The samples should be tested immediately after collection.

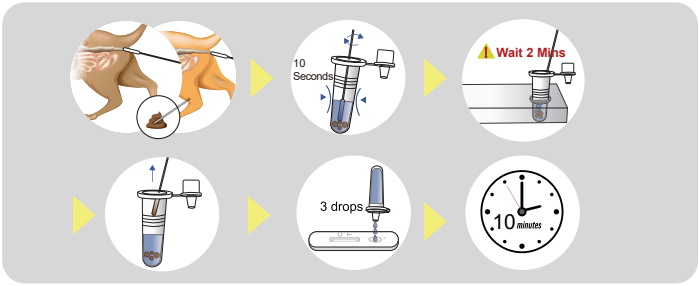
3.If samples cannot be tested immediately, they should be stored at 2-8°C(35.6-46.4°F) for up to 24 hours. For longer storage, freeze at -20°C (-4°F) or below. Frozen samples should be brought to roomtemperature(15-30°C/59-86°F) before use.

4.The amount of fecal sample with swab may affect the results. It is required to follow the swab amount of feces as shown in the picture below. The excessive fecal amount may induce a false positive result and slow migration.



Insufficient | Appropriate | Excessive

1.All reagents and samples must be at room temperature (15~30°C/59~86 °F) before use.
2. Collect fecal sample using a swab.
3.Put the swab into the sample dilution buffer and stir the solution with the swab to disperse the sample into the buffer (approximately 10 seconds).
4.Wait for 2 minutes to settle down the large particles
5.Remove the swab from the sample dilution buffer.
6. Remove the test device from the pouch and place it on a flat and drysurface.
7.Apply 3 drops of the mixed sample solution into the sample holes foreach , drop by drop vertically.
8.Read test results at 10 minutes.



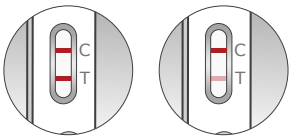
[Summary of Test Procedure]

READING OF THE TEST RESULT

Positive(+)

Presence of two color bands "T"and "C"

Two lines, one nextto C and one next to T, even faint lines, shows the test is positive.



Negative (-)

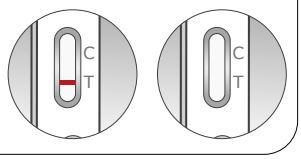
No presence of color band ("T")

One red-coloredline only next to "C" indicates a negative result.

Invalid

No presence of color band ("C")

If the red-colored line in the control region "C" is not visible, the result is invalid. Run a new test.



LIMITATION

The Toxoplasma gondii Antigen Test kit 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 microscopic examination or pathogen isolation test for final determination in practice.

Index of Symbols

	Attention, see instructions for use		Tests per kit		Do not reuse
IVD	For in vitro diagnostic use only		Use by	REF	Catalog #
2°C 30°C	Store between 2-30°C	LOT	Lot Number		Consult Instructions For Use
	Do not use if package is damaged		Manufacturer		

Manufacturer: Feng Chun Yuan Medical Equipment(Shenzhen)Co.,Ltd
Address: Room.1304 & Room.1306 , No.48, Xinyu Road, Xiangshan Community Xinqiao Street, Baoan District, Shenzhen, Guangdong, China. 518 000

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