VET Diagnostix

TRM Ag

Rabbit Trichomonas Antigen



INTENDED USE

The RA.TRM Ag Test is a lateral flow immunochromatographic assay for the qualitative detection of the Rabbit Trichomonas Antigen (RA.TRM Ag) in rabbit's feces. The RA.TRM Ag Test can be applied to FIC-Q100N Dry Immunoassay Analyzer for result reading.

Assay Time: 5-10 minutes

Specimen: Rabbits' feces

PRINCIPLE

The RA. TRM Ag 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 well 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 TRM antigen in the specimen, a visible T line will appear, it can also be recognized by the FIC-Q100N Dry Immunoassay Analyzer. 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 TRM antigen in the specimen.

MATERIALS PROVIDED

Contents	5T	1T
RA. TRM Ag Test device	5	1
Assay buffer tube	6	1
Sterile swab	5	1
Measuring spoon	5	1
Instruction for use	1	1

MATERIALS REQUIRED BUT NOT PROVID

1. FIC-Q100N Dry Immunoassay Analyzer
2. Timer

STORAGE AND STABILITY

The kit can be stored at room temperature (2-30℃). The test kit is stable through the expiration date (18 months) marked on the package label. DO NOT FREEZE. Do not store the test kit in direct sunlight.

PRECAUTIONS

1. All materials, including specimen and test device, should be recovered to 15-25℃ for at least 10 minutes before running the assay.
2. Do not use the test beyond its expiration date.
3. Do not use the test if the foil pouch is broken.
4. Do not remove the test card from its pouch until immediately before use.
5. Do not tough the membrane from the window. Dirty spots would bring wrong result readings if the tests are applied to the FIC-Q100N Dry Immunoassay Analyzer.
6. The components in this kit have been strictly checked by quality control procedures. Do not mix components from different lot numbers.
7. The QR code inside the box should not be applied to RA.TRM Ag tests from different lot numbers.
8. All specimens should be considered as potential infectious. It is suggested to wear gloves and take protection actions when testing. All materials should be strictly treated according to local rules and regulations.

SAMPLE PREPARATION

1. Specimen should be obtained and treated as below.

- Solid feces: mash up and take one flat spoonful.

- Liquid feces: use the sterile swab to collect. (Note: Too much sampling will affect the stability of the colloidal gold particles and easily

cause false positives. The sample size should cover 1/3 to 2/3 of the sterile swab head.).

2. Insert the swab into the provided assay buffer tube. Agitates it sufficiently to get extraction.

TEST PROCEDURES

A. Direct Use

1. Take out the test card from the foil pouch and place it horizontally onto a worktable.
2. Suck the treated sample extraction from the assay buffer tube and place 4 drops into the sample well “S” of the test card. Start the timer.

Note: If the liquid will not flow through the surface of the test strip in 30 seconds, please add another drop of the treated sample extraction.

3. Waiting for 5 to 10 minutes to interpret the test result.

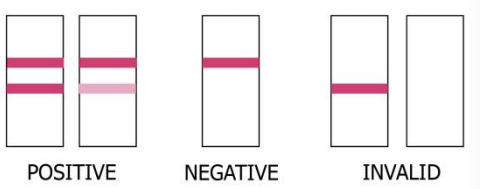
B. Applied to FIC-Q100N

1. Turn on the FIC-Q100N dry immunoassay analyzer and and check the status.
2. Use the scanner that comes with the analyzer to scan the QR code inside the box to apply the calibration curve into the analyzer.
3. Take out the test card from the foil pouch and insert it into the test card slot of the analyzer. Keep the specimen well of the test card facing up and leave the specimen well outside.
4. Suck the treated sample extraction from the assay buffer tube and place 4 drops into the sample well “S” of the test card. Start the timer.Then insert it into the bottom of the test card slot.
5. Press [STANDARD TEST] on the screen to start the testing. Result would be displayed on the screen in 10 minutes. In the case of direct use way, [QUICK TEST] could also be applied if using a timer to record the time. *Results read by the Dry Immunoassay Analyzer.



INTERPRETATION OF RESULTS

A. Direct Use



Positive (+): The presence of both “C” line and zone “T” line, no matter T line is clear or vague.

Negative(-): Only clear C line appear. No T line.

Invalid: No colored line appears in C zone. No matter if T line appears.

B. Applied to FIC-Q100N

Within the help of FIC-Q100N dry immunoassay analyzer, the test result could be defined into 5 phases: negative, suspicious (grey zone), weak positive, positive and strong positive. It brings better judgement and objective interpretation than visual judgement, especially in case of low TRM loading. The symbols in below table represent the different result and interpretation.

Symbol	Result	Interpretation
-	Negative	Unlikely TRM infection.
+/-	Suspicious	Could not be determined. It is suggested to repeat the test with once another sampling.
+	Weak positive	Low TRM loading.
++	Positive	Infection confirmed.
+++	Strong positive	Severe infection.

LIMITATIONS

1. The RA.TRM Ag Test is for *in vitro* veterinary diagnosis use only. All result should be considered with other clinical information available with veterinarian. It is suggested to apply a further confirmatory method when positive result was observed.
2. The FIC-Q100N dry immunoassay analyzer is based on visible light spectrum. Cases like stain background and dirty spot on the membrane may cause unexpected result compared to the visual reading. It is strongly suggested to repeat the testing if such conflict happens between visual judgement and machine judgement.
3. For lateral flow immunoassay, the most stable result could be observed around 8-12 minutes after running the assay. The calibration curve was generated strictly at 10 minutes point. It is strongly suggested to adhere to the exact test reading time in the Instructions for Use.

Version:20240416A109Q