CALCULATOR KIT

HANGZHOU EVEGEN BIOTECH CO., LTD.





VET Diagnostix

CANINE

AJ.VD01E-2403s6

PRODUCT ITEM

VD003Q	Canine Heartworm (Dirofilaria immitis) Antigen Test
VD004Q	Ehrlichia canis Antibody Test
VD005Q	Babesia canis Antibody Test
VD006Q	Babesia gibsoni Antibody Test
VD010Q	Borrelia burgdorferi (Lyme Disease) Antibody Test
VD028Q	Canine Leishmania canis Antibody Test
VD031Q	Canine Anaplamsa Antibody Test
VD105Q	Babesia Antibody Test

Free combination

SPECIMEN:

dog's serum, plasma

ASSAYTIME:

5-10minutes

STORAGE AND STABILITY

The kit can be stored at room temperature (2-30°C). 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 the 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.

SPECIMEN PREPARATION

Collect the whole blood for the patient dog, centrifuge it to get the serum, or place the whole blood into a tube which contains anticoagulants to get plasma.



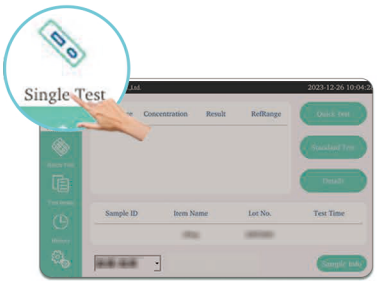


TEST PROCEDURE

1

Turn on the FIC-Q100N dry immunoassay analyzer and check the status.

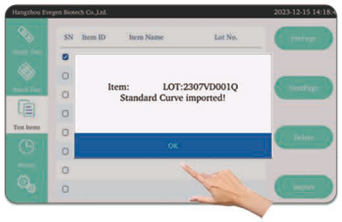




2

Use the scanner that comes with the analyzer to scan the QR code to apply the calibration curve into the analyzer.





3

Use the pipettor to place 10μL of the prepared specimen into the sample well “S” of the test card. Then drop 90μL of the assay buffer into the sample well.







4

Insert the test device into the test card slot of the analyzer. Keep the specimen well of the test card facing up and leave the specimen well outside.

Click “Quick Test” and wait for the test result.



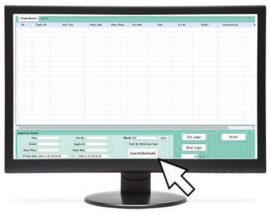


If there are other test devices to be tested at the same time, please repeat steps 1 to 4.

5

Double-click to open a program named “Cloud Printing Client(International)” on the computer.
Click “Search(Refresh)” and select the appropriate test record to print.





INTERPRETATION OF RESULTS

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 antibody titer or low antigen concentration. The symbols in below table represent the different result and interpretation.

Symbol	Result	Interpretation
-	Negative	Unlikely infection.
+/-	Suspicious	Could not be determined. It is suggested to repeat the test with once another sampling.
+	Weak positive	Low antibody titer, in the stage of current infection or previous infection./ Low concentration of antigen
++	Positive	Medium antibody titer, in the stage of current infection or previous infection./ Infection confirmed.
+++	Strong positive	High antibody titer, in the stage of current infection or previous infection./ Severe infection.

LIMITATIONS

1. The 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 antibodies applied in the assay were monoclonal antibodies. In case of some new variant strains, it might not be applicable to be detected out by the rapid test.

3. 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 the such conflict happens between visual judgement and machine judgement.

4. 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.

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