Healvet®

Canine Parvovirus antigen（CPV Ag）Rapid Quantitative Test

INTENDED USE

The Healvet™ canine parvovirus antigen Rapid Quantitative Test is a fluorescence immunoassay used along with Healvet™ FIA 3000 for quantitative determination of CPV Ag concentration in canine feces.

For *in vitro* diagnostic use only. For professional use only.

TEST PRINCIPLE

1.This test employs a quantitative Double antibody sandwich fluorescence immunoassay technique.

2.The fluorescent signal intensity reflects the amount of CPV Ag captured and is processed in Healvet™ FIA 3000. The CPV concentration is expressed in ng/mL.

WARNINGS AND PRECAUTIONS

1.This kit is for in vitro diagnostic use only. Do not swallow.

2.Lot Number of all the test components (test device, ID chip and buffer) must match each other. Do not mix components from different kit lots.

3.Inspect the packaging and labels before use. Do not use if the pouch is broken, torn or not well sealed, or the vial looks damaged or leaked.

4.Carefully follow the instructions and procedures described in this insert.

5.Do not use the test device beyond the expiration date. The test device must remain in its original sealed pouch until ready to use. Do not use if the pouch or the device itself is damaged, torn or not fully sealed.

6.A buffer tube should be used for processing one sample only.

7.The operation shall be conducted away from vibration and magnetic field. Healvet™ FIA 3000 may generate minute vibration during use, which should be regarded as normal.

8.One pipette tip should be used for one specimen only.

9.Do not touch the test area of the test device

10.All specimens and used test materials are considered as potentially infectious. The used pipette tips, buffer tubes, test devices and specimens must be handled carefully and disposed of in accordance with local regulations and procedures.

MATERIAL

Material Provided

Each box contains:

1.10 individual sealed pouches, each containing:

■ a test Device

■ a desiccant pouch

2.One Test Device ID Chip

3.Instructions for Use

4.10 swab sticks

5.10 Pipette Tips

6.10 tubes of PBS buffer

Material Required But Not Provided

1.Healvet™ FIA 3000

2.Transfer Pipette

3.Timer

STORAGE AND STABILITY

1.Store the test kit at 4～30℃ up to the expiration date.

2.Once the pouch is opened, the test should be performed within an hour.

3.If removed from refrigerator, allow the test for 30 minutes to attain room temperature before testing.

SPECIMEN COLLECTION AND PREPARATION

Specimen of this canine fecal material (stool). And, It should be obtained and handled by standard methods for the sample collection. The stool specimen must be tested as soon as they are prepared. If necessary, they may be stored at 2~8℃ for up to 48 hours. If longer storage is required, the sample may be frozen at -20℃.

Bring all materials to room temperature before use. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.

TEST PROCEDURE

Refer to Healvet™ FIA 3000 Operation Manual for complete instructions for use of the Test device.

1.Set a Test Device on a clean, level horizontal place.

2.Make sure that the Test Device lot No. matches with ID Chip No. Insert ID Chip into the meter. Be aware not to touch the insertion tip of the ID chip.

3.Collect the stool specimens at 4 different points or directly take the specimens from the canine colon. Insert and mix the swab with assay solution in a tube until the specimens has been dissolved .

4.Pipette 75μl of mixed sample to add into the sample of the test device. Avoid forming bubbles.

5.Please refer to the Section V Operation in Operation Manual for details.

a) **Quick Test mode:** start the timer right after adding the sample mixture to the sample well. Leave the Test Device at room temperature for 10 minutes. Then insert test device immediately onto the holder of the meter and click Test. The instrument will scan the Test Device automatically and show the test result.

b) **Standard Test mode:** insert the Test Device into the device holder of the Meter right after adding the sample to the sample well, click Test. The meter will start to countdown and read the test result automatically.

6.Results are displayed on the main screen or be printed by click Print.

INTERPRETATION OF RESULTS

1.The Healvet™ FIA 3000 calculates CPV Ag test results automatically and displays the concentration of CPV antigen on the screen right after correctly adding the sample to the sample well for 10 minutes. For further information, refer to the Operation Manual for the Healvet™ FIA 3000.

2.Healvet™ FIA 3000 will prompt " Abnormal C-line" when insufficient sample volume or liquid is not fully crawled across the test line, then recommends adding sample again.

QUALITY CONTROL

Each Healvet™ CPV Ag Rapid Quantitative Test contains an internal control for routine quality control requirements. This internal quality control is performed each time a patient sample is tested, If an invalid result from the internal control occurs, the meter will display an error message, indicating that another test should be conducted.

LIMITATIONS OF PROCEDURE

1.This test should be used for the detection of CPV in feces specimen.

2.The results of Healvet™ CPV Ag Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If test results do not agree with the clinical evaluation, additional tests should be performed accordingly.

3.Canine parvovirus quantitative products can detect the presence of CPV antigen in the sample, but should not be used as the sole criterion for the diagnosis of canine parvovirus infection.

4.As with all diagnostic tests, all results must be considered along with other clinical information available to the physician.

5.If the test results are negative and clinical symptoms persist, other clinical methods are recommended for subsequent testing. Negative results at any time cannot rule out the possibility of canine parvovirus virus infection.

INTERPRETATION

Detection range and reference value of canine parvovirus (CPV) Ag:

1.Detection range : 16-8000 ng/mL

2.Reference

Reference	Signification
<60ng/mL	Normal
60-300 ng/mL	Suspected canine parvovirus virus
>300 ng/mL	Contracted canine parvovirus virus

Each Laboratory should establish a reference range that is representative of the population to be evaluated. The diagnosis must be made in conjunction with other clinical symptoms and tests.

MANUFACTURED BY

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