Canine Parvovirus Antibody（CPV-Ab）Rapid Quantitative Test

INTENDED USE

The canine parvovirus antibody （ CPV-Ab ） Rapid Quantitative Test is a fluorescence immunoassay used along with FIA 680 for quantitative determination of CPV-Ab concentration in canine serum or plasma specimen. The test is used as an aid to Infection inspection, The inflammatory response.

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

TEST PRINCIPLE

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

2.The fluorescent signal intensity reflects the amount of CPV-Ab captured and is processed in FIA 680. The CPV-Ab concentration is expressed in Tu/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. FIA 680 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 tubes of Tris-HCl buffer

Material Required But Not Provided

1. FIA 680

2.Transfer Pipette

3.Timer

4.Centrifuge

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

The test can be performed with either serum or plasma.

1.Collect whole blood specimen into the collection tube (containing anticoagulants such as EDTA, heparin and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen of supematant.

2.Collect whole blood specimen into a collection tube (Not containing anticoagulants such as EDTA, heparin and sodium citrate) by venipuncture. Leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supematant.

3.Separate serum or plasma from blood within 2 hours after blood collection. If a specimen appears to be severely hemolyzed, another specimen should be obtained and tested.

3.Optimally, the test should be performed immediately after the specimen collection. If the test cannot be performed within 2 hour after blood collection, store the specimen at 2℃～8℃ for no longer than 48 hours. For long-term storage, specimens shall be kept below -20℃.

TEST PROCEDURE

Refer to FIA 680 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.Pipette 20μl of prepared sample into the buffer, gently mix well. Vigorous agitation and foaming should be avoided.

4.Pipette 100 μl 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 FIA 680 calculates CPV-Ab test results automatically and displays the concentration of CPV-Ab 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 FIA 680.

2.FIA 680 will prompt "No Sample or sample volume insufficient!" when insufficient sample volume or liquid is not fully crawled across the test line, then recommends adding sample again.

QUALITY CONTROL

Each CPV-Ab 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 is developed for testing canine serum or plasma specimen.

2.The results of CPV-Ab 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.The false positive results include cross-reactions with some components of the blood from individual to antibodies; and non-specific adhesion of some components in blood. that have similar epitopes to capture and detector protein. In the case of false negative results, the most common factors are: non-responsiveness of antigen protein to the antibodies by that certain unknown components are masking its epitope, such that antigen protein cannot be seen by the antibodies; instability of CPV-Ab protein, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The performance of the test is highly sensitive to the storage and handling conditions of kits and sample specimens at optimal conditions.

4.There is the possibility that factors such as technical or procedural errors, as well as additional substances in rectum or fecal specimens that are not listed in the Cross-Reactivity section, may interfere the test and cause erroneous results.

INTERPRETATION

Reference range of CPV-Ab in canine rectum or fecal.

1.Detection range: 10-300 Tu/ml

2.Reference: 10 Tu/ml

Each Laboratory should establish a reference range that is representative of the population to be evaluated.

MANUFACTURED BY

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