Immuno Run

Antigen Detection Kit

CANINE PARVO VIRUS

Cat. No. 80CPV205/80CPV250 INSTRUCTION MANUAL

I. Intended Use

ImmunoRun CPV Antigen Detection Kit is intended for detection of Canine Parvo Virus (CPV) Antigen (Ag) in dog feces. The kit contains all components required for performing an easy and accurate test in less than 10 minutes.

II. General Information

ImmunoRun CPV Antigen Detection Kit contains individual devices intended for performing immunochromatographic assays to qualitatively detect CPV-Ag in dog feces. Each device contains 2 main windows: a round window which is the specimen application well, and a rectangular result window, marked by 2 letters: "C" for Control line and "T" for Test line. Both lines are invisible before reaction takes place. The control purple line should appear with each ongoing reaction, as it is used for validation of the test. A specific antibody to CPV is conjugated with gold particles and another specific antibody is immobilized as a band on a nitrocellulose membrane. Virus in fecal specimen binds to the gold conjugated and forms a virus-conjugate complex that migrates to the result area, where it is captured and its accumulation creates a band. A purple test line will be visible in the result window in case of enough CPV-Ag in the specimen. The specially selected anti-CPV antibodies are used in test band as both capture and detection materials. These enable CPV-Ag device to identify CPV in dog feces with a high degree of accuracy.

III. Description Of The Disease

CPV causes highly contagious infectious and fatal disease with two main manifestations: acute gastrointestinal disease or heart disease to unvaccinated dogs of any age, breed or sex. The disease is usually more severe in young dogs (6 weeks-6 months), Rottweilers and Dobermans. Parvovirus is very resistant to extremes of temperature and is unharmed by detergents, alcohol and common disinfectants. The virus can be easily spread by the most common fecal-oral transmission and indirect source of transmission (hands, shoes, clothing etc.).

The common clinical signs include vomiting, fever, appetite loss, depression and bloody diarrhea with a very foul odor. Since not all cases of bloody diarrhea with or without vomiting are caused by CPV, many sick puppies are misdiagnosed.

IV. Diagnosis Of The Disease

The ImmunoRun CPV Antigen Detection Kit is the simplest screening diagnostic method available to detect the presence of CPV. It has been validated to give 100% sensitivity and specificity. Other Immuno - diagnostic methods may be used to quantitate antibody titer, while PCR may be used to verify the presence of the virus.

V. Kit Contents

Component	5 Tests Kit (80CPV205)	50 Tests Kit (80CPV250)
CPV Ag test device	5	50
Disposable droppers	5	50
Sample collection tubes with assay diluent	5	50
Collection swabs	5	50
Instruction manual	1	1

VI. Storage And Handling

- Shipment may be performed at room temperature.
- Store at 2-30°C (room temperature or refrigerated).
 Avoid exposure to direct sunlight.

• Kit is stable for up to two years, do not use beyond expiration date stated on the package label.

Do not freeze!

Do not open or remove test kit from their individually sealed pouches until immediately before their use (do not use kit if the pouch or the device are damaged).

 Avoid touching exposed membrane in device windows.

• Components in this kit have been quality control approved as standard batch unit. Each component in the kit is for a single use only. Do not mix components from different lot numbers, and do not try to reuse a device.

 Handle and dispose of used samples, swabs, extraction buffer and used device in accordance with accepted sanitary requirements designated for bioharazardous waste.



VII. Step By Step Protocol

For best results, strict adherence to these instructions is required (see Figures 1 and 2):

Sample Preparation:

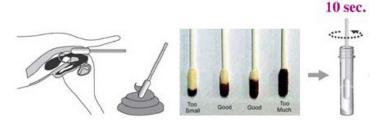
1. Collect sample from canine feces using a swab or insert swab into rectum to cover it with a thin layer of feces.

2. The specimen should be extracted immediately after collection.

3. Insert the swab into the assay diluent and agitate vigorously (~10") to assure good sample extraction.

- 4. Only Dog feces should be used with this test.
- **5.** For best results sample should be tested immediately after its extraction.

Figure 1: Use of swab with canine feces



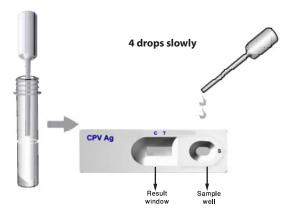
Test Protocol:

1. If stored in refrigeration, allow all kit components and specimen to reach room temperature prior to testing.

2. Remove the test cassette from its pouch and place it horizontally.

3. Using the disposable dropper, slowly apply four drops of the diluted/extracted specimen from the tube into the sample well, (drop by drop). Avoid touching membrane with the dropper.

Figure 2: Application of extracted specimen with dropper.



4. If migration through result window (purple color) does not start within a minute, apply another drop of diluent.

5. Follow the control line ("C") as it appears in the result window. In case of a positive result, a test line ("T") should appear as well.

Results should be read within 5-10 minutes from sample application. Clear positive result may be accepted earlier. Interpretation should not be based on reading accepted beyond 20 mintues.

VIII. Reading And Interpreting The Results

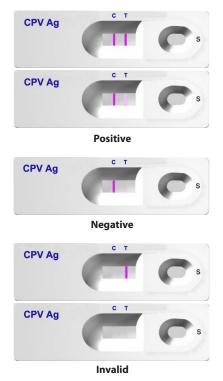
See Figure 3.

• The presence of any two visible bands: the test band (T) and the control band (C) within the result window (no matter which band appears first) indicates a **positive** result, regardless of test band intensity.

• A lack of a test band, while control band is present within the result window, indicates a **negative** result.

If the control band is not visible within the result window, the result is considered invalid (even if the test band appears).

Figure 3: CPV Ag bands interpretation



IX. Limitations And Troubleshooting

- For veterinary *in vitro* use only. Do not use internally or externally in humans or animals.
- As with all diagnostic tests, a low incidence of false results can occur. All results must be considered with other laboratory findings and clinical information available to the veterinarian.
- The test has been proved to diffrentiate disease from some vaccines, still be aware of vaccination history in order to be able to interpret the results correctly.

X. References

 MaCow DL & Hoskins JD (2006) Canine Viral Enteritis.
 In: Ifectious Diseases of the dog and cat. Greene CE, Saunders 3rd Ed.:63-73.

For further information and assistance please contact your local distributor or Biogal Galed Labs. Acs. Ltd. Directly by e-mail: info@biogal.com or by tel: 972-4-9898605 / fax: 972-4-9898690.

3