

Antigen Detection Kit CANINE DISTEMPER VIRUS

Cat. No. 80CDV205/80CDV250
INSTRUCTION MANUAL

I. Intended Use

ImmunoRun CDV Antigen Detection Kit is intended for detection of Canine Distemper Virus (CDV) Antigen (Ag) in dog conjunctiva (eye mucus), nasal discharges, saliva, urine, serum or plasma samples. The kit contains all components required for performing an easy and accurate test in less than 10 minutes.

II. General Information

ImmunoRun CDV Antigen Detection Kit contains individual devices intended for performing immuno-chromatographic assays to qualitatively detect CDV-Ag in dog specimens (see above). Each device contains 2 main windows: a round window, which is the specimen application well and a square 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 CDV is conjugated with gold particles and another specific antibody is immobilized as a band on a nitrocellulose membrane. Virus in the 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. These enable CDV-Ag device to identify CDV with a high degree of accuracy. A purple test line will be visible in the result window in case of enough CDV-Ag in the specimen.

III. Description Of The Disease

Canine distemper is a worldwide highly contagious disease caused by Canine Distemper Virus (CDV), that can affect respiratory, gastrointestinal and central nervous system of dogs and other carnivores. Non-immunized pups and dogs are susceptible to infection and disease. Infected dogs shed the virus through body secretions. The first symptom of distemper is eye discharge that appear watery to pus-like. Subsequently, dogs develop fever, nasal discharge, coughing, lethargy, reduced appetite, vomiting and diarrhea. In later stages, the virus may attack the nervous system, leading to seizures and partial or complete paralysis. Occasionally, the virus may cause footpads to harden. Distemper is often fatal; early diagnosis and supportive care may prevent fatal outcome.

IV. Diagnosis Of The Disease

The ImmunoRun CDV Antigen Detection Kit is the simplest screening diagnostic method available to detect the presence of CDV. Studies have shown sensitivity and specificity higher than 97.5%, best results obtained when conjunctiva was used. 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 (80CDV205)	50 Tests Kit (80CDV250)
CDV Ag test device	5	50
Disposable droppers	5	50
Sample collection tubes with assay diluent	5	50
Collection swabs	5	50
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VI. Essentials Not Included

- Saline.
- Syringes or vacutainers for blood collection.
- Centrifuge for serum separation.
- Reaction tubes for serum.

VII. 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 biohazardous waste.

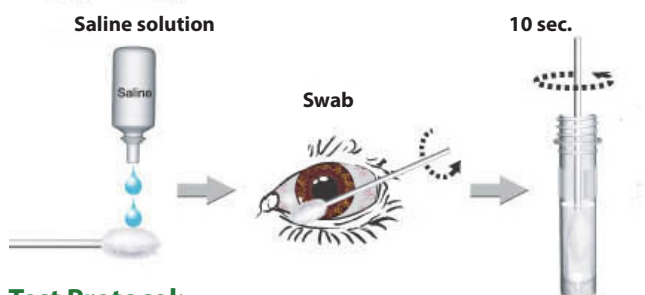
VIII. Step By Step Protocol

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

Sample Preparation:

1. Only dog specimen should be used with this test.
2. Any specimen should be processed immediately after collection.
3. Collect canine conjunctival discharges, epithelial cells from nasal cavities, saliva or urine using the collection swab pre-wetted with saline solution.
4. Insert the swab with the collected specimen into the diluent buffer and agitate vigorously to assure good sample extraction. (Figure1).
5. If blood is used, apply only the serum/plasma fraction, use the disposable dropper to apply 2-3 drops into the assay diluent tube and mix it.
6. Applying specimens of two sources (conjunctiva and nasal discharges/serum and swabs) into the same diluent at the same time is possible and may improve sensitivity.
7. Sample should be tested immediately after its extraction/dilution. If not, they should be stored for up to 48 hours at 2-8°C for extended period.

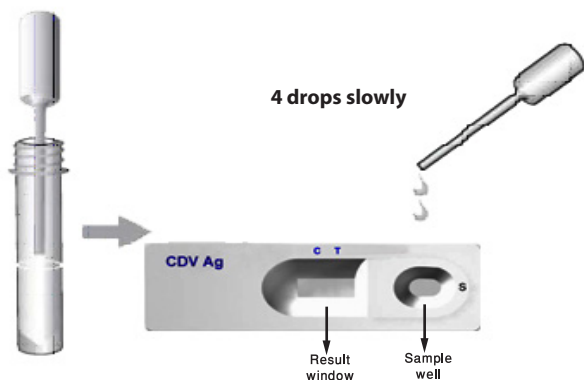
Figure 1: Collection swab application



Test Protocol:

1. If stored refrigerated, allow all kit components and specimen to reach room temperature prior to testing.
2. Remove the test cassette from the foil pouch prior to use. Place it horizontally on a dry surface.
3. Using the disposable dropper, slowly apply 4 drops of the diluted/extracted sample into the sample well, 1 drop at a time.

Fig 2: Application of extracted/diluted sample with a disposable dropper.



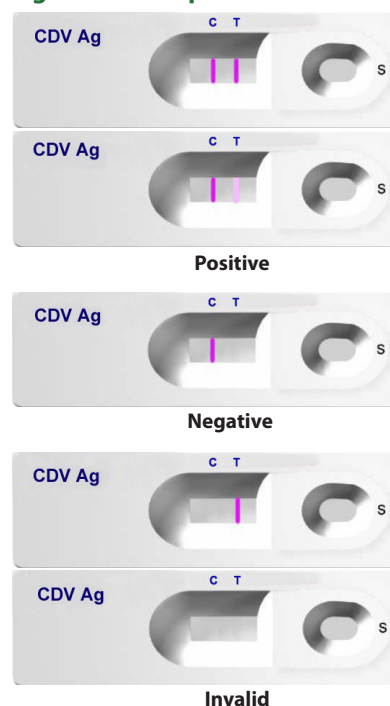
4. If migration through result window (purple color) does not start within a minute, apply another drop of the mixed specimen.
5. Follow the control line as it appears in the result window. In case of a positive result, a test line should appear as well.

Results should be read within **10 minutes** from sample application. Clear positive result may be accepted earlier. Interpretation should not be based on reading accepted beyond that time.

IX. 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).

Fig. 3: CDV Ag bands interpretation



X. 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 is not selective and may detect post CDV derived from vaccination. Be aware of vaccination history in order to be able to interpret the results correctly.

XI. References

- Greene CE & Apple MJ (2006) Canine Distemper In: Infectious Diseases of the dog and cat. Greene CE, Saunders, 3rd Ed.:25-41.
- Soma T et al. (2003) Detection of canine distemper virus antigen in canine serum and its application to diagnosis. Vet Records 18:499-501.

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.



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