

Antigen Detection Kit CANINE HEARTWORM

Cat. No. 80CDI205/80CDI250
INSTRUCTION MANUAL

I. Intended Use

ImmunoRun CDI (Heartworm) Antigen Detection Kit is intended for detection of Canine *Dirofilaria immitis* (CDI) Antigen (Ag) in dog whole blood/serum/plasma. The kit contains all components required for performing an easy and accurate test in less than 10 minutes.

II. General Information

ImmunoRun CDI Antigen Detection Kit contains individual devices intended for performing immuno-chromatographic assays to qualitatively detect CDI-Ag in dog blood/serum/plasma specimens. Each device contains 2 main windows. A round window 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 CDI is conjugated with gold particles and another specific antibody is immobilized as a band on a nitrocellulose membrane. Virus in 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 CDI-Ag in the specimen. The specially selected anti-CDI antibodies are used in test band as both capture and detector materials. These enable CDI-Ag device to identify CDI with a high degree of accuracy.

III. Description Of The Disease

Canine heartworm disease is a serious and potentially fatal disease. The cause of the disease is a parasitic round white worm called *Dirofilaria immitis*, inhabiting the right side of the heart in the adjacent large blood vessels. Heartworm infection is spread by mosquitoes which carry infective larvae. After biting, the infective larva migrate through the tissues of the body and via blood vessels enter the heart, where during several months, they grow up to adult size. Large accumulations of adult worms in the heart impair the circulation of blood, resulting in serious damage to the dog's heart, lungs, liver and kidneys. Usually, a dog can lead a nearly normal life with a few heartworms in its system. But symptoms, such as difficult breathing, cough, tire easily, weight loss and fainting, will appear in advanced stages. If not controlled, death may follow .

IV. Diagnosis Of The Disease

The ImmunoRun CDI Antigen Test Kit is the simplest screening diagnostic method available to detect the presence of CDI. Different studies with ImmunoRun CDI Antigen Detection Kit have yielded specificity of 100% and sensitivity of 94.4%-100%. 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 (80CDI205)	50 Tests Kit (80CDI250)
CDI Ag test device	5	50
Disposable droppers	5	50
Instruction manual	1	1

VI. Essentials Not Included

- Syringes or vacutainers for blood collection.
- Centrifuge for serum/plasma separation.
- Anticoagulant or reaction tubes.

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):

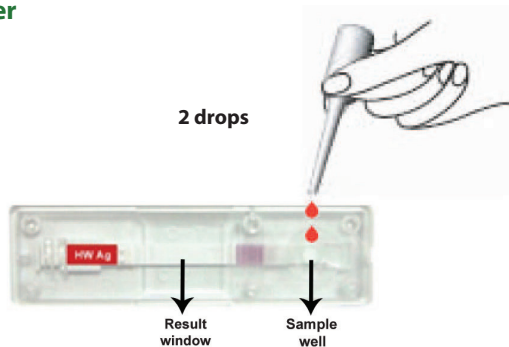
Sample Preparation:

1. Only dog specimen should be used with this test.
2. Collect blood from a dog. When using whole blood, storage is not recommended. Perform the test immediately after sample collection.
3. Serum or plasma specimens may be stored at 2-8°C up to 48 hours. A temperature of -10°C or below should be used for longer storage.
4. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified by centrifugation prior to assaying.

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 and place it horizontally on a dry surface.
3. Using the disposable dropper apply **2 drops** of the specimen into the sample well. Avoid touching membrane with the dropper.

Figure 1: Application of specimen with disposable dropper



4. If migration through result window (purple color) does not start within a minute apply another drop into the sample well.
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.



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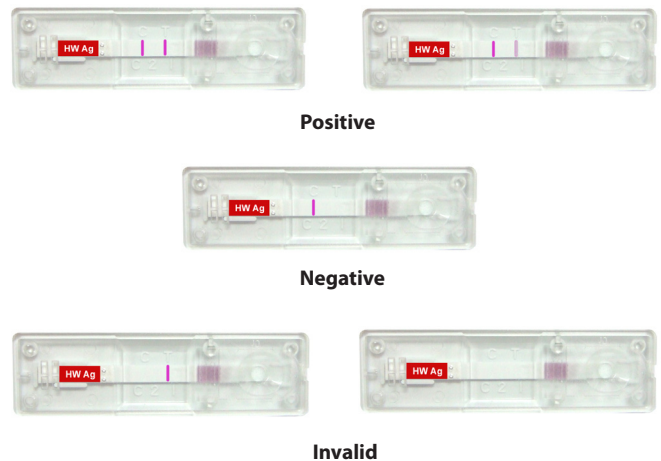
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IX. Reading And Interpreting The Results

- See Figure 2
- 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.
- The presence of only one band marked as "C" indicates a **negative** result.
- If the control band "C" is not visible within the result window, the result is considered **invalid** (even if the test band "T" appears).

Figure 2: CDI (HW)-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 CDI derived from vaccination. Be aware of vaccination history in order to be able to interpret the results correctly.

XI. References

- American Heartworm Society. 2005 Guidelines for Diagnosis, Prevention and Management of Heartworm (*Dirophilaria immitis*) infection in Dogs. Batavia, IL, 2005.
- Charles H et al. (1990) Cornell: Evaluation of heartworm immunodiagnostic test. JAVMA 197(6):724-729.
- Hoch H & Strickland K (2008) Canine and feline dirofilariasis: Life cycle, pathophysiology and diagnosis. Compendium: Continuing Education for Veterinarians. 30(5):133-141.

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.