ImmunoRun

Antibody Detection Kit

CANINE LEISHMANIA

Cat. No. 85CLI105/85CLI150
INSTRUCTION MANUAL

I. Intended Use

ImmunoRun CLI Antigen Detection Kit is intended for detection of Canine *Leishmania infantum* (CLI) Antibodies (Ab) 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 CLI Antibody Detection Kit contains individual devices intended for performing immuno-chromatographic assays to qualitatively detect CLI-Ab in dog whole blood/serum/plasma specimens. Each device contains 2 windows. A small round window marked with **"S"** is the specimen application well, where the assay diluent is also applied and a rectangular result window marked by 2 letters: **"T"** marks the test line and **"C"** marks the control line (See Fig. 1). 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. The specially selected CLI antigen is used as both capture and detection reagents. Antibodies anti-CLI in specimen bind to the gold conjugated CLI antigen and form a complex that migrates to the area where it is captured, and its accumulation creates a band - a purple test line. These enable CLI Ab device to identify CLI antibodies in canine blood/plasma/serum with a high degree of accuracy.

Fig. 1: CLI-Ab device.

III. Description Of The Disease

Leishmania infantum is the causative agent of visceral leishmaniasis in the Mediterranean, parts of Asia and Africa and in Latin America. It is a well known cause for leishmaniasis in human in these areas. It may also cause cutaneous leishmaniasis, which is a zoonosis in most of the cases. Visceral Leishmania is much more serious (and common) than cutaneous Leishmania, since it means that parasites have reached vital internal organs of the dog. Wild canids and domestic dogs are the natural reservoir of this intracellular flagellate protozoan parasite, transmitted from dog to dog and by a sand fly vector. CLI has been also found in dogs that had traveled to endemic areas and returned to an area known to be free. The signs of the disease are very variable; common symptoms include anorexia, diarrhea, fatigue, weight loss, hair loss and fever. Unfortunately, CLI is difficult to treat. In many dogs, relapses usually occur and symptoms re-appear as soon as treatment is stopped.

IV. Diagnosis Of The Disease

In case of suspicion, the parasite can be observed through a microscope by sampling from an injury, a lymphatic node or the bone marrow. Serologic tests are recommended to detect circulating antibodies in the dog bloodstream. The ImmunoRun CLI Antibody Detection Kit is the simplest screening diagnostic method available to detect the presence of antibodies against CLI. For best results strict adherence to the following step by step protocol is required. Comparison to IFA as a reference test, gave 95.6% sensitivity and 98.0% specificity. Other Immuno-diagnostic methods may be used to quantitate antibody titer, while PCR may be used to verify the presence of the protozoa.

V. Kit Contents

Component	5 Tests Kit (85CLI105)	50 Tests Kit (85CLI150)
CLI Ab test device	5	50
Dropping bottle containing assay diluent	1	5
Disposable capillary tube with a 10µl marked line (See Fig. 2)	5	50
Instruction manual	1	1

Fig. 2: 10µl marked line on a disposable capillary tube.

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 biohazardous waste.

89CLI155 24.08.2020

VII. Step By Step Protocol

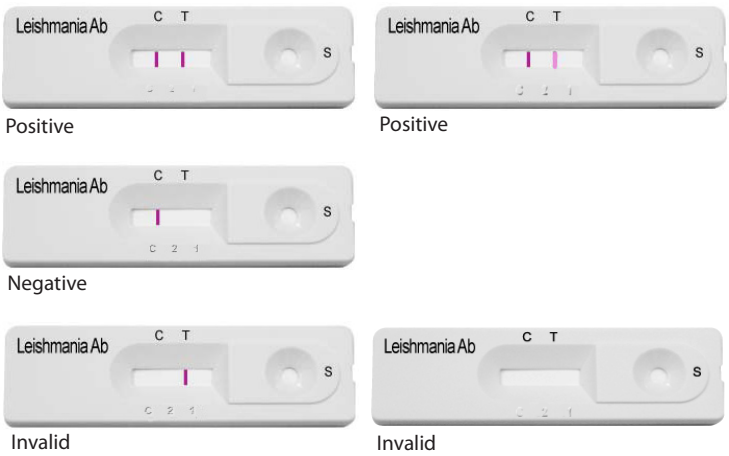
For best results, strict adherence to these instructions is required.

1. Collect blood from a dog. If any anticoagulant is used, blood sample should be tested within 24 hours.
2. If the test is delayed, centrifuge sample in order to separate plasma/serum from other blood components and store refrigerated (2-8°C) for up to 72 hours, or freeze (below -20°C) for a longer period.
3. Specimens containing precipitate may yield inconsistent results. Such specimens must be clarified by centrifugation prior to assaying.
4. Allow all kit components and specimen to reach room temperature prior to testing.
5. Remove the test cassete from the foil pouch prior to use.
6. Place the test cassette horizontally on a dry surface.
7. Using a capillary tube insert 10µl of **whole blood/ serum/plasma** sample into the sample well (**"S"**), then add 2 drops (~80µl) of **Assay Diluent.** If migration through result window (purple color) does not start within a minute, apply another drop of **Assay Diluent**.
8. 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.
9. Reading test results must be done within **5-20 minutes** of sample application. **Do not read results after 20 minutes!**

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.
- 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).

Fig. 3: CLI-Ab 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.
- This is a screening test. Additional follow-up testing using other laboratory methods is recommended.

X. References

- Baneth et al (2008) Canine leishmanensis – new concepts and inlights on an expanding zoonosis: part 1. Trends Parasitol. 24(7)324-330.

- Miro et al. (2008) Canine leishmanensis – new concepts and inlights on an expanding zoonosis: part 2. Trends Parasitol. 24(8)371-377.

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.

Biogal – Galed Labs. Acs. Ltd.
Tel: 972-4-9898605 | Fax: 972-4-9898690
E-mail: info@biogal.com | Site: www.biogal.com