ImmunoRun

Antibody Detection Kit

CANINE ANAPLASMA

Cat. No. 85CAP105/85CAP150

INSTRUCTION MANUAL

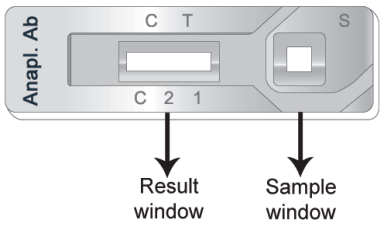
I. Intended Use of the Kit

ImmunoRun Anaplasma Ab detection kit is intended for detection of *Anaplasma phagocytophilum* and *Anaplasma platys* antibodies (Ab) in canine serum, plasma or whole blood. The kit contains all components required to perform the test.

II. General Information

ImmunoRun Canine Anaplasma Ab Detection kit contains individual devices intended for performing immunochromatographic assay to qualitatively detect antibodies against *Anaplasma phagocytophilum* and *Anaplasma platys* in canine serum, plasma or whole blood. Each device contains 2 main windows. A sample window (marked S) which is the specimen application well and a square 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 Anaplasma spp. antigen is used in the test band as a capture material. These enable the ImmunoRun Canine Anaplasma detection kit to identify antibody against *Anaplasma phagocytophilum* and *Anaplasma platys* in canine serum, plasma or whole blood with a high degree of accuracy.

Fig. 1: Anaplasma Ab. device



III. Description of the Disease

Anaplasma phagocytophylum Infection in dogs (Canine Granulocytotropic Anaplasmosis) is caused by *Anaplasma phagocytophylum*, an obligate intracellular parasite, which preferentially infects cells of myeloid lineage of bone marrow, predominantly neutrophils. This is a tick borne disease, which manifested in acute disease with nonspecific signs of illness such as fever, lethargy or depression, anorexia, musculoskeletal pain or discomfort and in fewer cases joint pain.

Anaplasma platys Infection in dogs (Thrombocytotropic Anaplasmosis) is caused by *Anaplasma platys*, a small rickettsial parasite of platelets. Severity of disease may vary from slight fever and some splenomegaly to fever, lethargy, pale mucous membrane, petechial hemorrhages of skin and oral mucous etc. The possibility of co-infections (e.g. *E. canis*) cannot be eliminated as a contributor to the symptoms.

IV. Diagnosis of the Disease

ImmunoRun Canine Anaplasma Ab detection kit is the simplest screening diagnostic method available to detect the presence of antibodies to Anaplasma spp. For best results strict adherence to the following step by step protocol is required.

V. Kit Contents

Component	5 Tests Kit (85CAP105)	50 Tests Kit (85CAP150)
CAP 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 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.
- **Do not freeze!**
- The test kit is stable through the expiration date marked on the package label, do not use beyond expiration date.
- 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.

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VII. Step by Step Protocol

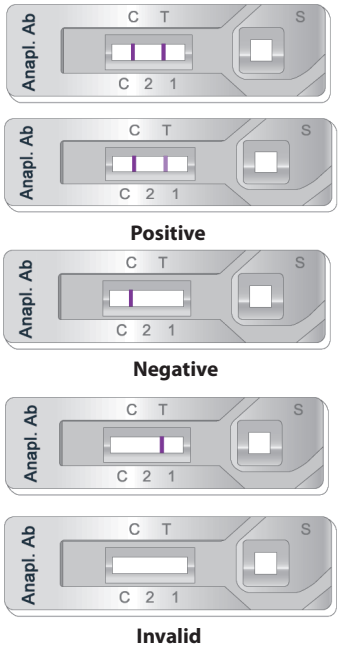
For best results, strict adherence to these instructions is required.

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 cassete horizontally on a dry surface.
7. Using a capillary tube insert **10 µl** of blood/serum/plasma sample into the sample well. Using the dropper bottle, apply **3 drops** of **Diluting Buffer** into the sample well . If migration through result window (purple color) does not start within a minute, apply another drop of 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 **10 minutes** of sample application.

VIII. Reading and Interpreting the Results

- See Fig. 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: Anaplasma 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 laboratory findings and other clinical information available to the veterinarian.
- This is a screening test. Additional follow-up testing using other laboratory methods is recommended.

X. References

- Craig E. Greene (2012)
Greene Infectious Diseases of the Dog and Cat
26:244-258

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

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