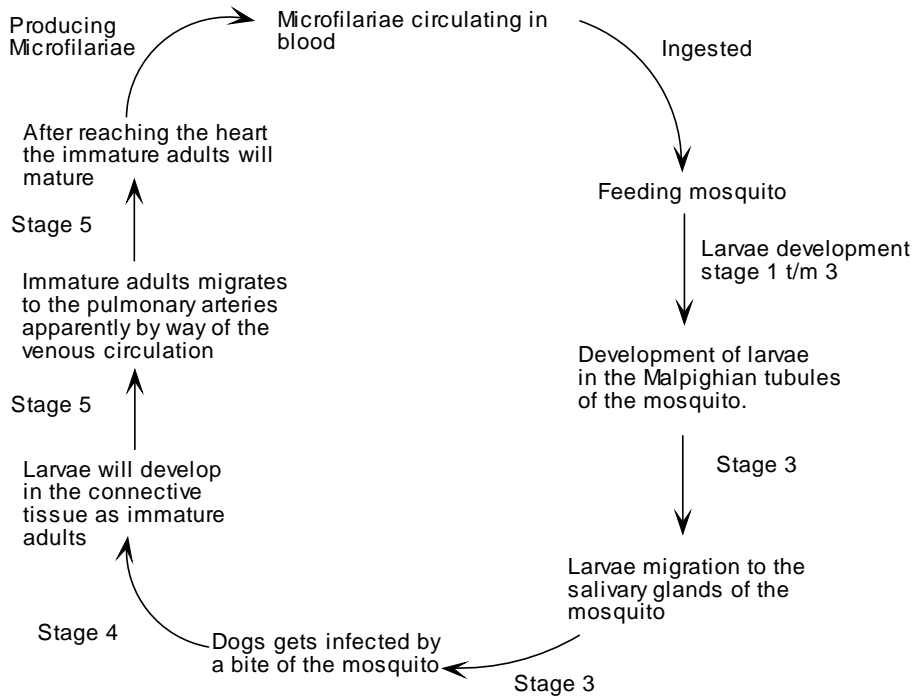


**DRG® Heartworm (Canine) Rapid Test (RAP-4802 / RAP-4803)**

Revised 6 Dec. 2011 cc (Vers. 1.1)

**For Veterinary Use Only****THIS KIT IS INTENDED FOR RESEARCH USE ONLY.****NOT FOR USE IN DIAGNOSTIC PROCEDURES.****INTRODUCTION**

*Dirofilaria immitis* (Nematode filaridae) has been to infect a variety of wild canines, foxes and felines (9% positive animals found in Australia). Prevalence of infection may vary with geographic location, habitat, densities of mosquito vectors and definitive hosts and climatic conditions. In diseased dogs *Dirofilaria Immitis* are found in heart, lungs, pulmonary arteries or thoracic vena cava. The amount of microfilariae correlates with the number of adult filariae which also correlates with the age and weight of the dog. *Dirofilaria* antigen titres correlate best with weight and worms present adjusted to female worm equivalents (four male worms equal to one female worm).

The lifecycle of *Dirofilaria Immitis*Lifecycle of *Dirofilaria Immitis* in a dog:

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Mature worms may survive and produce Microfilariae for  $\pm$  5 years in their host. Microfilariae circulate in the blood of the dog, where they may be ingested by a feeding mosquito. Larval development occurs in the Malpighian tubules. In the Malpighian tubules the Microfilariae will develop in larvae (stage 1 up to 3). When the larvae have reached his third stage he will migrate to the salivary glands of the mosquito. The third stage larvae enter the bite wound when the mosquito feeds on the dog. Within 3 days the molt from third stage to fourth stage occurs after the bite of the mosquito. Fourth stage larvae remain in the connective tissue for several months (2-3 months) to develop as immature adults (stage 5). The immature adults migrates to the pulmonary arteries apparently by way of the venous circulation. After reaching the heart, the young adults mature and start producing Microfilariae (6-9 months after infections)

**INTENDED USE**

This One- Step Test is intended to use as practical/routine screening test that can be done in a few minutes. This test kit is designed to detect *Dirofilaria Immitis* antigen by use of a Rapid Immunochromatic Assay.

**PRINCIPLE**

The Heartworm One-Step is based on a chromatographic principle in which a monoclonal antibody reacts with antigen produced by the adult worm. A monoclonal antibody is conjugated to colloidal gold particles and a monoclonal antibody is immobilized on the test strip in the test zone "T". Antigen in serum/plasma sample that is applied to the test strip at the sample zone "S", will bind to the colloidal gold particles which then migrate to zone "T". A colour change in zone "T" indicates a positive test. Colloidal gold particles are also immobilized on the test strip in the control zone "C", to indicate that the test is working properly.

**HANDLING AND STORAGE OF SPECIMENS**

The One-Step should be stored at room temperature (+/- 21 °C).

An unopened package can be used until the expiry date.

An opened package must be used immediately.

If the conditions are no longer fulfilled the test can no longer be used. Avoid freezing and heating as this will contribute to destruction of the test.

Samples may be used fresh or may be kept frozen below -20°C before use.

**CONTENTS**

- 6 / 24 x pouches, each containing 1 test strip and 1 pipette
- 6 / 24 x vials containing 500  $\mu$ L buffer
- 1 x protocol

**PRECAUTIONS**

- Handle all biological materials as though capable of transmitting infectious diseases.
- Do not pipette by mouth.

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- Do not eat, drink, smoke, prepare foods or apply cosmetics within the designated work area.
- Do not use components which passed the expiry date and do not mix components from different serial lots together.
- Optimal results will be obtained by strict adherence to this protocol. Careful pipetting and sampling throughout this procedure are necessary to maintain precision and accuracy.
- Each test strip is ultimately used as an optical reference. Therefore, do not touch the surface of the test strip and protect it from damage and dirt.

**SAMPLE MATERIAL**

It is advised to test serum or plasma samples, tissue culture samples can also be tested.

Do not use hemolytic or old blood

**TEST PROTOCOL**

1. Unpack the test strip and pipette. Only open the amount of pouches to be used. An opened package should be used immediately.
2. Add **2 drops** of serum/ plasma to the sample vial using the pipette (fig 1).
3. Mix well using the pipette (fig 2).
4. Add **4 drops** of the mixture to the sample zone using the pipette (fig 3).
5. Read the results after 5 - 20 minutes (\* see 9; Validation of the test and 10; Interpretation of test results).

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Figure 1



Figure 2

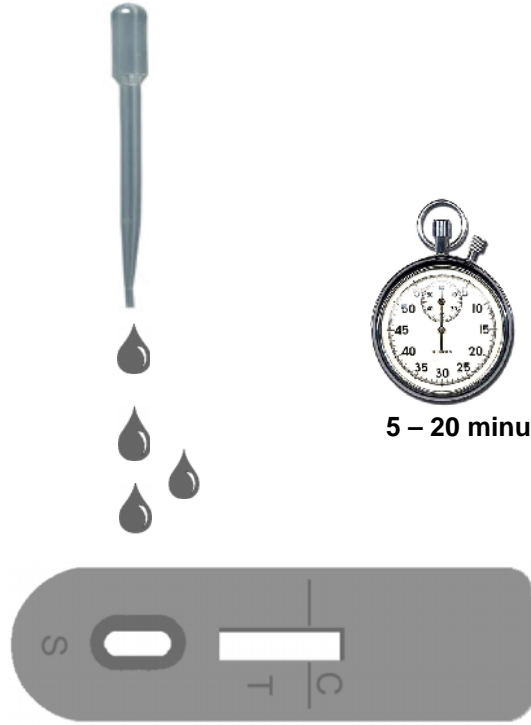


Figure 3

### VALIDATION OF THE TEST

To validate this One-Step Test a control line should always be visible at control zone “C”.

If no control line is visible the test should be considered invalid.

\* Results should be read in the given time. Results read after the given time should be considered invalid. Invalid tests should be repeated with a new test.

### INTERPRETATION OF TEST RESULTS

#### *Positive:*

Two bands are visible, zone “T” and zone “C” (fig. A). The sample contains *Dirofilaria Immitis* antigen.

Positive results may vary in optical density due to variations in antibody concentrations in the sample.

#### *Weak Positive:*

Two bands are visible; a weak band in zone “T” and a band in zone “C” (fig. B). The sample contains low concentrations *Dirofilaria Immitis* antigen.

Positive results may vary in optical density due to variations in antibody concentrations in the sample.

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**Negative:**

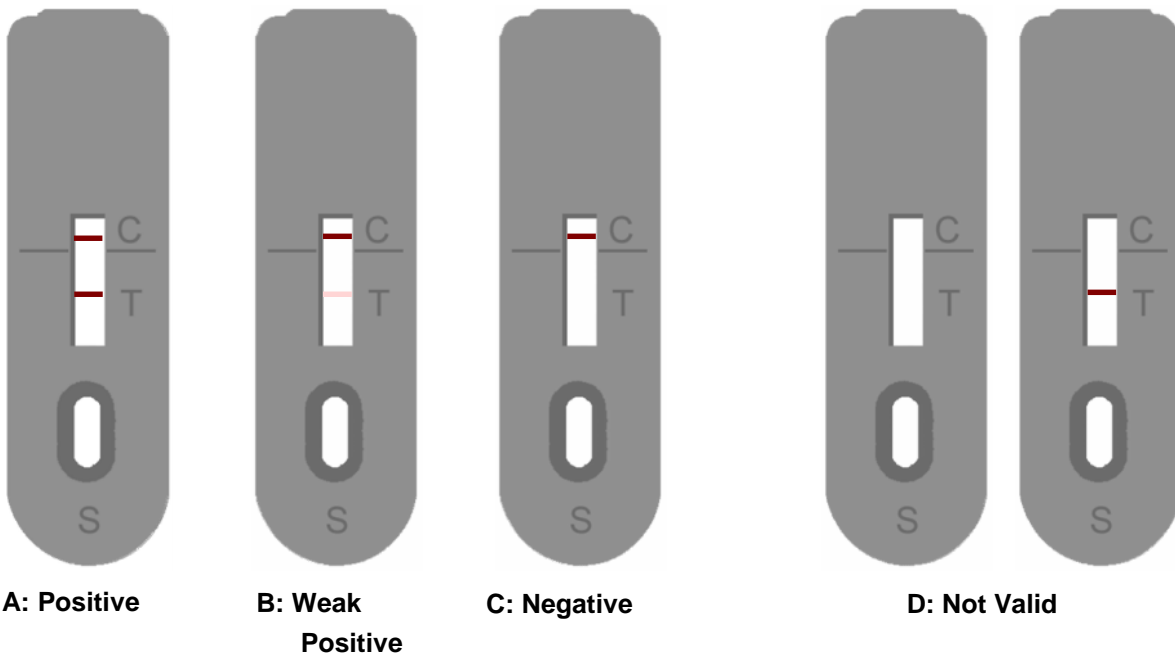
Only one band is visible in zone “C” (fig. C). The sample does not contain *Dirofilaria Immitis* antigen.

**Not valid:**

No band is visible in zone “C” (fig. D). Repeat the test procedure.

**Important**

A positive result should be confirmed by PCR or IFA. Diseased, but negative tested patients should be retested within 2-3 weeks.



*The purchaser assumes the entire risk as to the performance of these products. DRG shall not be liable for indirect, special or consequential damage of any kind resulting from use of these products.*