

DRG[®] Rheumatoid Factor (Canine) Rapid Test (RAP-4811 / RAP-4812)

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**

Rheumatoid factor (RF) antibodies are macroglobulines which appear in the serum of dogs suffering from Rheumatoid Arthritis (RA). This is frequently characterised by chronic and progressive multi-site lameness, joint swelling and joint destruction. These macroglobulines can be of the IgM, IgA or IgG subclass (mainly the IgM class). The majority of these RF antibodies are directed against the Fc part of IgG (3) raised levels of antibodies can be found in most patients with RA (70%), but also in the other connective tissue diseases, malignancy, chronic infections and even small percentage (< 2%) in the normal population.

It is not known why patients with RA produce increased amounts of RF, but RF complexes are thought to have a role in the propagation of the RA by intra articular activation of various inflammatory factors mechanism.

This can lead to inflammation with serious destructive changes of different joints caused by lysosomal destruction.

IgA RF was found, to be significantly associated with later development of erosive bone disease; IgA and IgG RF levels increased precede clinical manifestations. The IgA and IgG RF levels also correlate better with the Erythrocyte sedimentation rate (ESR) and elevated levels of C reactive protein. IgG RF is important due to the property of self-association leading to production of complexes without bacterial/viral antigenic stimulus.

Diagnostic criteria for RA according to the American Rheumatoid Association:

- 1) Morning stiffness.
- 2) Pain on motion (at least one point).
- 3) Swelling (fluid/bone)
- 4) Symmetric joint swelling.
- 5) Subcutaneous nodules over bony prominences.
- 6) X-ray changes typical for RA.
- 7) Positive RF test, by a method which has not been positive (< 5%) of normal controls.
- 8) Pour mucin precipitate from synovial fluid.
- 9) Characteristic histologic changes in synovial membrane
- 10) Characteristic histologic changes in nodules showing granulomatous foci.

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 antibodies against Rheumatoid Factors (IgA, IgM and IgG) by use of a Rapid Immunochromatic Assay.

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This RF One-Step Test is based on a chromatographic test strip, a purified dog specific immunoglobulin which react with different subclasses. The purified dog specific immunoglobulin are conjugated to colloidal gold particles and the dog specific immunoglobulin is immobilized on the strip in the test zone "T".

RF in a sample that is applied to the strip at the sample zone "S" will bind to the gold particles which then migrate to zone "T". A color change in zone "T" indicates a positive test. Anti-Dog antibodies is also immobilized on the strip in the control zone "C", which binds the gold conjugate 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. I

f 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 x pouches or 24 x pouches
each containing 1 test strip and 1 pipette
- 1 x dropper bottle, 4 x dropper bottle
containing 2 ml buffer
- 1 x protocol

PRECAUTIONS

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

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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 zone using the pipette (fig 1).
3. Add **2 drops** of buffer from the dropper bottle to the sample zone (fig 2).
4. Read the results after 5 - 20 minutes (* see 9; Validation of the test).

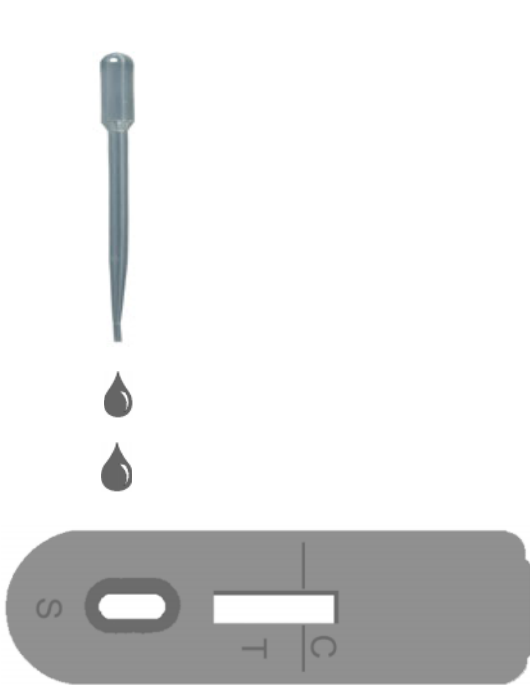


Figure 1



Figure 2

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 RF antibodies.

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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 RF antibodies.

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

Negative:

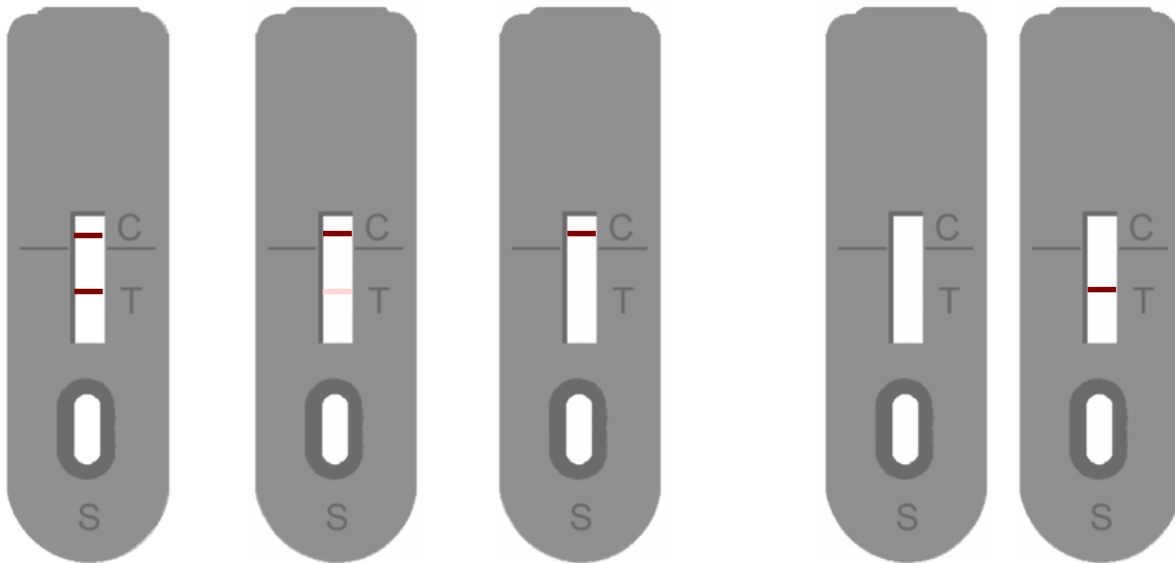
Only one band is visible in zone “C” (fig. C). The sample does not contain RF antibodies.

Not valid:

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

Important

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



A: Positive

B: Weak Positive

C: Negative

D: Not Valid

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.