

DRG[®] CRP (Canine) Rapid Test (RAP-4799 / RAP-4800)

Revised 1 Dec. 2011 cc (Vers. 1.1)

For Veterinary Use Only**THIS KIT IS INTENDED FOR RESEARCH USE ONLY.
NOT FOR USE IN DIAGNOSTIC PROCEDURES.****1 INTRODUCTION**

C-Reactive Protein is an acute-phase protein produced by the liver during conditions of inflammation, bacterial infection, or tissue trauma. Quantitation of CRP can be useful for the determination of inflammatory conditions that would be otherwise difficult to detect and monitor.

CRP is considered to be the best indicator of the presence and extent of inflammatory process. CRP concentration increases rapidly with the onset of acute inflammation or tissue destruction.

The most important role of CRP is its interaction with the complement system, which is one of the body's immunologic defence mechanisms.

CRP is an alpha globulin with a mass of 110,000 to 140,000 Daltons, and composed of five identical subunits, which are non-covalently assembled as a cyclic pentamer. It is synthesized in the hepatocyte cells of the liver and is normally present as a trace constituent of serum. It has been reported that in healthy dogs the CRP concentration is low (<4 mg/L) in normal serum.

The levels in serum rise quickly following acute tissue damage and can reach levels 1000-fold within 24 to 48 hours and also falls very rapidly once the stimulus is removed.

A positive CRP may indicate a number of things, including:

- Rheumatoid arthritis
- Rheumatic fever
- Cancer
- Tuberculosis
- Pneumococcal pneumonia
- Myocardial infarction
- Connective tissue disease
- Bacterial, viral, fungal, or parasitic infection
- Other causes of ongoing inflammation

2 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 C-Reactive Protein by use of a Rapid Immunochromatic Assay.

3 PRINCIPLE

This CRP One-Step Test is based on a chromatographic test strip, a purified dog specific immunoglobulin which react with CRP. 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". CRP 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.

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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.

5 CONTENTS

RAP-4800	RAP-4799
6 x pouches, each containing 1 test strip and 1 pipette	24 x pouches, each containing 1 test strip and 1 pipette
6 x vials containing 1.5 mL buffer	24 x vials containing 1.5 mL buffer
1 x dropper bottle containing 2 ml buffer	4 x dropper bottle containing 2 ml buffer
1 x protocol	1 x protocol

6 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.

7 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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8 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 **1 drop** of serum/ plasma to the sample vial using the pipette (fig 1).
3. Mix well using the pipette
4. Add **1 drop** of the mixture to the sample zone using the pipette (fig 2).
5. Add **2 drops** of buffer from the dropper bottle to the sample zone (fig 3).
6. Read the results after 5 - 15 minutes (* see 9; Validation of the test).

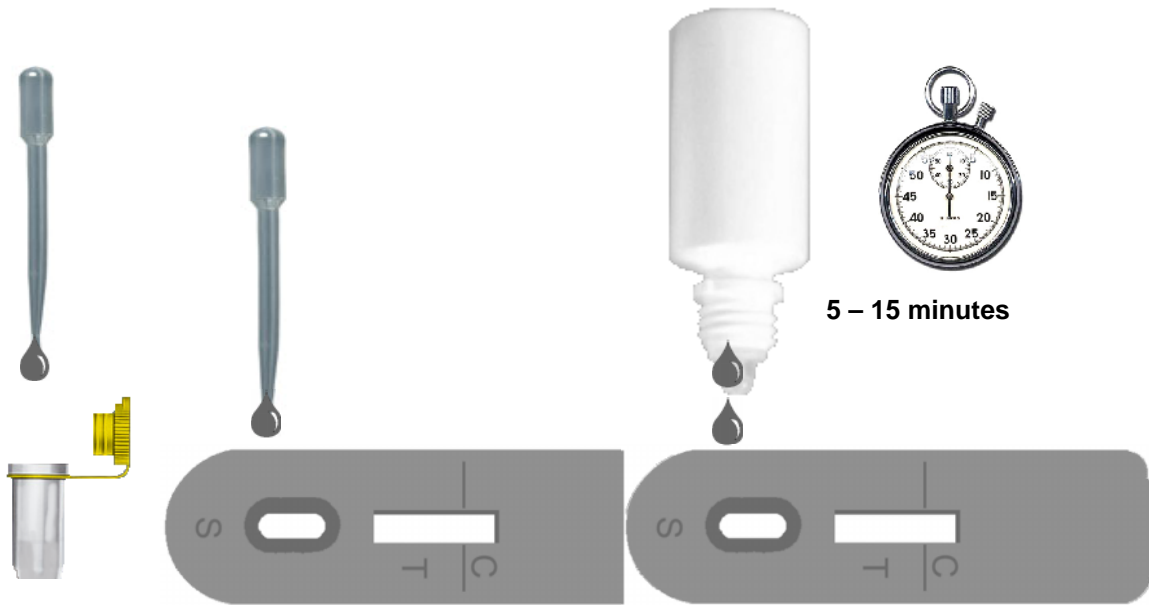


Figure 1

Figure 2

Figure 3

9 VALIDATION OF THE TEST

To validate the 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.

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10 INTERPRETATION OF TEST RESULTS

Positive:

Two bands are visible in zone “T” and zone “C” (fig. A). The sample contains CRP concentration > 5 mg/L. Positive results may vary in optical density due to variations in CRP 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 CRP concentration 3 - 5 mg/L.

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

Negative:

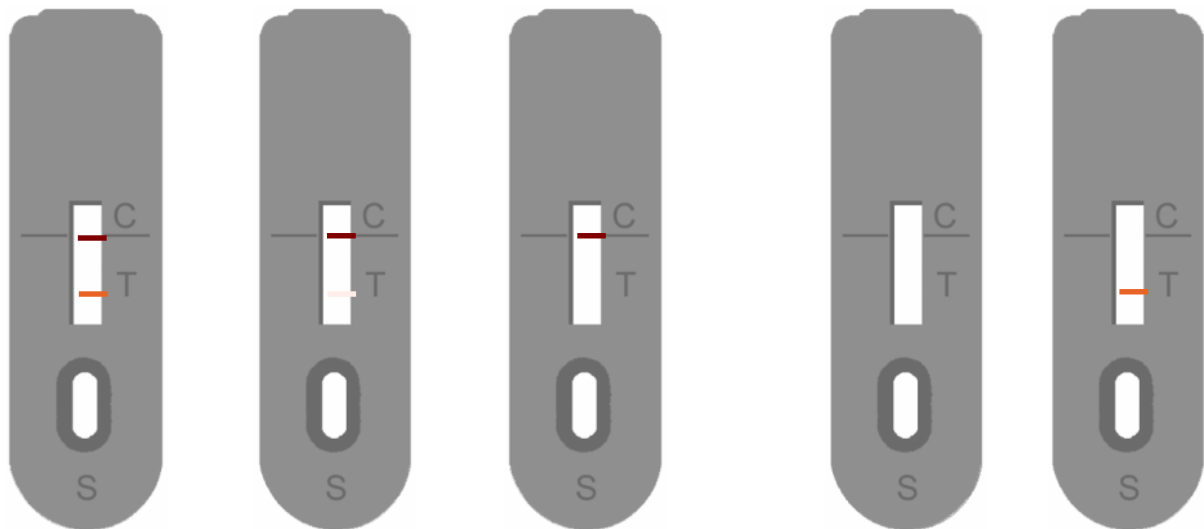
Only one band is visible in zone “C” (fig. C). The sample contains CRP concentration < 3 mg/L.

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.