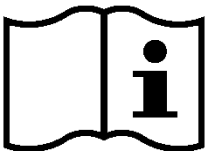
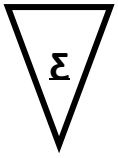


Useŕs Manual

Canine C-Reactive Protein One-Step

For the detection of C-reactive protein in dog serum or plasma samples

REF D1011-PR01



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January 2022

Please use only the valid version of the package insert provided with the kit.

1. Table of Contents

2. Introduction

C-Reactive Protein (CRP) is an acute-phase protein produced by the liver during conditions of inflammation, bacterial infection, or tissue trauma. Quantitation of C-reactive protein can be useful for the determination of inflammatory conditions that would be otherwise difficult to detect and monitor. C-reactive protein is considered to be the best indicator of the presence and extent of inflammatory process. CRP concentrations increases rapidly with the onset of acute inflammation or tissue destruction. The most important role of C-reactive protein 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 of 1000-fold within 24-48 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

3. Intended use of the test kit

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.

4. Principle of the test kit

This CRP One-Step test is based on a chromatographic test strip, a purified specific immunoglobulin which react with CRP. Polyclonal CRP antibody is conjugated to colloidal gold particles and the dog specific CRP 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". No colour change is zone "T" indicates a positive test. Labelled colloidal gold particles are also immobilized on the test strip in the control zone "C", to indicate that the test is working properly.

5. Contents

- 6 x Pouches, each containing 1 test strip and 1 pipette
- 6 x Buffer vial
- 1 x Protocol

6. 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.

7. Sample material

It is advised to test fresh serum or plasma samples. Do not use haemolytic or lipemic serum.

8. 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 serials 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.

9. Test protocol

1. Unpack the test strip, swab and pipette. Only open the amount of pouches to be used. An opened package should be used immediately.
2. Add **2 drops** of serum or plasma sample to the buffer vial using the pipette (Figure 1).
3. Mix well using the pipette (Figure 2).
4. Add **4 drops** of the buffer vial containing the sample, with the included pipette ***slowly*** to the sample zone "S" (Figure 3).
5. Read the result after 35 - 45 minutes (for the interpretation of the test result see chapter 10 and chapter 11).

Figure 1

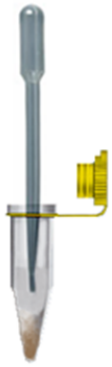

Figure 2

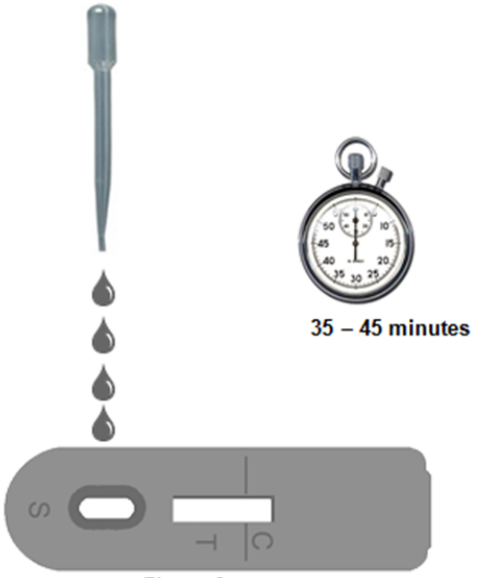

Figure 3

35 – 45 minutes

10. Validation of the test

To validate an EVL One-Step 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.

11. Interpretation of the test results

Positive:
Only one line is visible in zone "C" (Figure A). The sample contains CRP.

Weak positive:
Two lines are visible, a weak line in zone "T" and a line in zone "C" (Figure B). The sample contains low concentrations CRP.
Positive results may vary in optical density due to variations of CRP concentrations in the sample

Negative:
Two lines are visible in zone "T" and in zone "C" (Figure A). The sample does not contain CRP.

Not valid:
No line is visible in zone "C" (Figure D). Repeat the test procedure with a new test cassette.

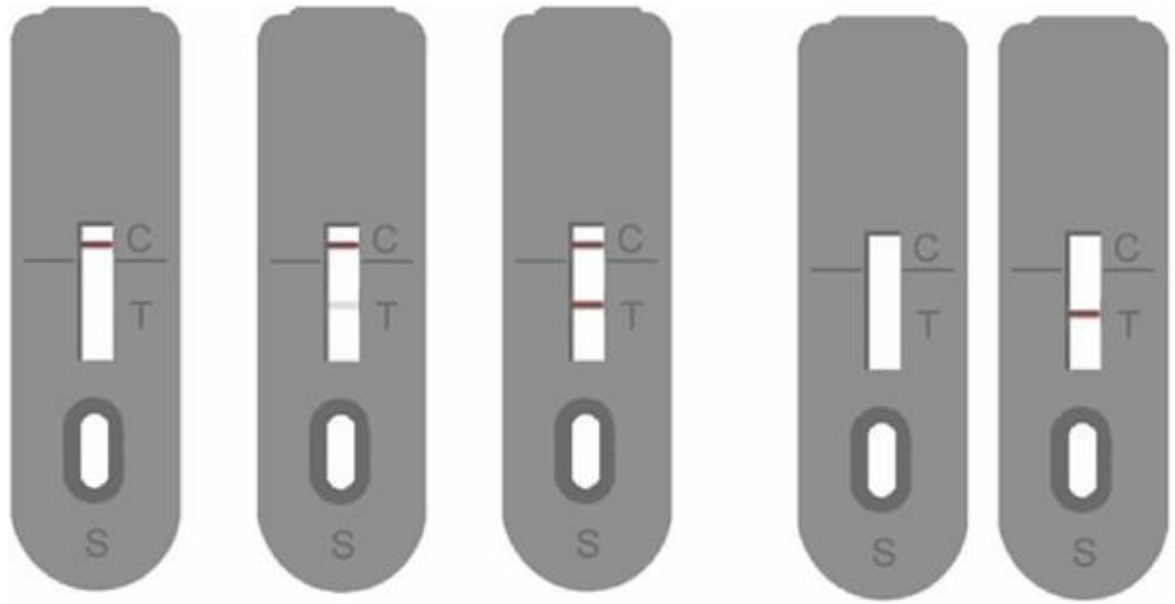

Figure A: Positive

Figure B: Weak positive

Figure C: Negative

Figure D: Not Valid

Note:
A positive result should be confirmed by ELISA. Diseased, but negative tested patients should be retested within 1 - 2 days.

12. Symbols used with EVL ASSAYS

Symbol	English
	Consult instructions for use
	European Conformity
IVD	In vitro diagnostic device
RUO	For research use only
REF	Catalogue number
LOT	Lot/ No. / Batch code
	Contains sufficient for <n> tests
	Storage Temperature
	Expiration Date
	Legal Manufacturer
Distributed by	Distributor
Content	Content
Volume/No.	Volume / No.

The entire risk as to the performance of these products is assumed by the purchaser. EVL shall not be liable for indirect, special or consequential damages of any kind resulting from use of the products. In case of problems or questions contact EVL.