Instructions for Use

Rheumatoid Factor Canine Rapid Screen Test

VET

REF	RAP-4811	RAP-4812
Σ	6 tests	24 tests

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Please use only the valid version of the Instructions for Use provided with the kit.
Verwenden Sie nur die jeweils gültige, im Testkit enthaltene, Gebrauchsanweisung.
Si prega di usare la versione valida delle istruzioni per l'uso a disposizione con il kit.
Por favor, se usa solo la version valida de la metodico técnico incluido aqui en el kit.
Utilisez seulement la version valide des Instructions d'utilisation fournies avec le kit.

Table of Contents

For the detection of all types of rheumatoid factors (IgG, IgA, IgM) in serum or plasma samples of dogs

1 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 lysomal 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:

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

2 INTENDED USE OF THE TESTKIT

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.

3 PRINCIPLE OF THE TEST KIT

This RF One-Step Test is based on a chromatographic test strip, a purified dog specific immunoglobulin which reacts with different subclasses. The purified dog specific immunoglobulin is 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 colour change in zone “T” indicates a positive test.

Anti-dog antibodies are also immobilized on the strip in the control zone “C”, which binds the gold conjugate to indicate that the test is working properly.

4 CONTENTS

- 6 x (or 24 x) pouches, each containing 1 test strip and 1 pipette
- 6 x (or 24 x) microtubes containing buffer
- 1 x Protocol

5 HANDLING AND STORAGE

The RF One-Step Test 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.

6 SAMPLE MATERIAL

It is advised to test fresh serum or plasma samples.

Do not use haemolytic or lipaemic serum.

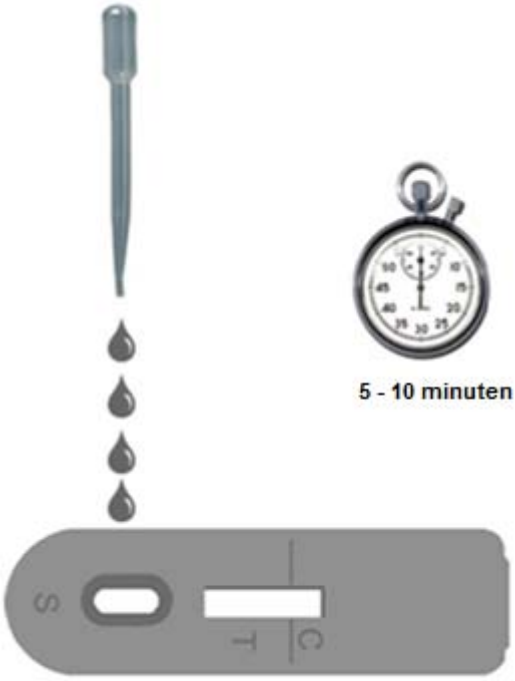
Samples may be used fresh or may be kept frozen below -20 °C before use.

7 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 fresh serum/ plasma to the micro tube (containing buffer), using the pipette (fig 1).
3. Mix well using the pipette
4. Add 4 drops of the mixture to the sample zone using the pipette (fig 3).
5. Read the results after 5 - 10 minutes.
   (See chapter 9, Validation of the test and chapter 10, Interpretation of test results.)

Figure 1

Figure 2



5 - 10 minuten

Figure 3

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 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.

9 VALIDATION OF THE TEST

To validate an RF 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.

10 INTERPRETATION OF TEST RESULTS

Positive:

Two bands are visible, zone “T” and zone “C” (fig. A). The sample contains RF antibodies.

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 of RF antibodies.

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

Negative:

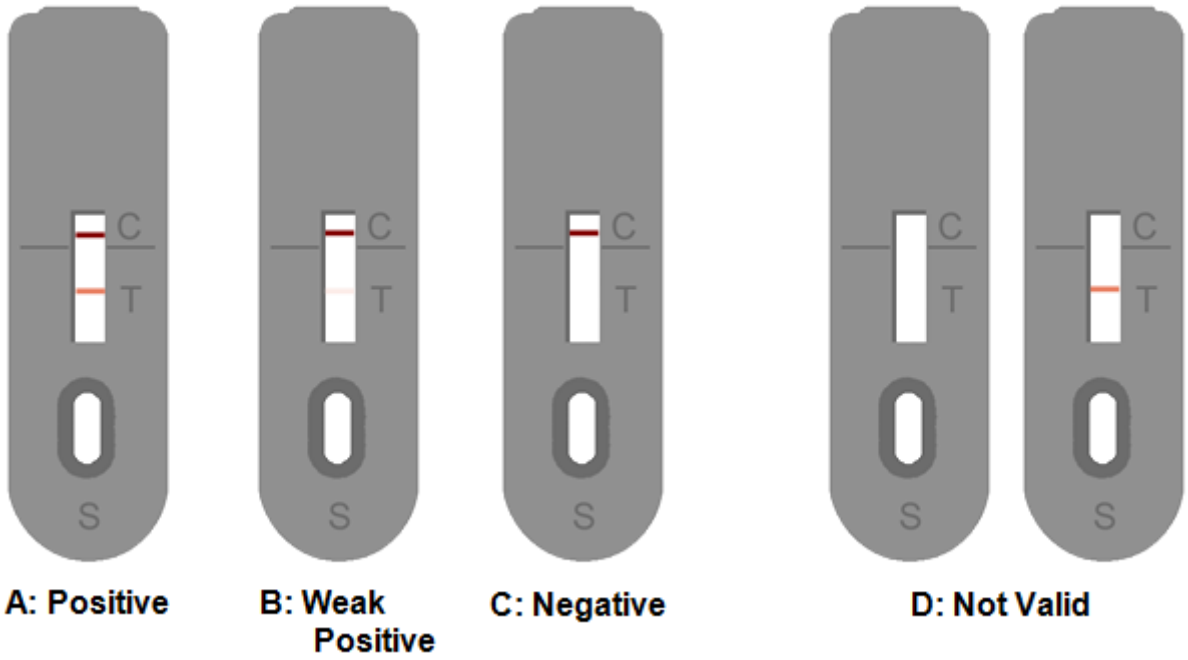
Only one band is visible in zone “C” (fig. C). The sample does not contain RF antibodies.

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.



SYMBOLS USED

Symbol	English	Deutsch	Italiano	Español	Français
CE	European Conformity	CE-Konformitäts-kennzeichnung	Conformità europea	Conformidad europea	Conformité normes européennes
	Consult instructions for use *	Gebrauchsanweisung beachten *	Consultare le istruzioni per l'uso	Consulte las instrucciones de uso	Consulter les instructions d'utilisation
IVD	*In vitro* diagnostic medical device *	*In-vitro*-Diagnostikum *	Dispositivo medico-diagnostico in vitro	Producto sanitario para diagnóstico In vitro	Dispositif médical de diagnostic in vitro
REF	Catalogue number *	Artikelnummer *	Numero di Catalogo	Nûmero de catálogo	Référence de catalogue
LOT	Batch code *	Chargencode *	Codice del lotto	Codigo de lote	Numéro de lot
	Contains sufficient for <n> tests *	Ausreichend für <n> Prüfungen *	Contenuto sufficiente per "n" saggi	Contenido suficiente para <n> ensayos	Contenu suffisant pour "n" tests
	Temperature limit *	Temperaturbegrenzung *	Temperatura di conservazione	Temperatura de conservacion	Température de conservation
	Use-by date *	Verwendbar bis *	Utilizzare prima del	Establa hasta	Utiliser jusque
	Manufacturer *	Hersteller *	Fabbricante	Fabricante	Fabricant
	Caution *	Achtung *			
VET	For veterinary use only				
Distributed by	Distributed by	Vertreiber	Distributore	Distribuidor	Distributeur
Content	Content	Inhalt	Contenuto	Contenido	Contenu
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantità	Volumen/Número	Volume/Quantité