

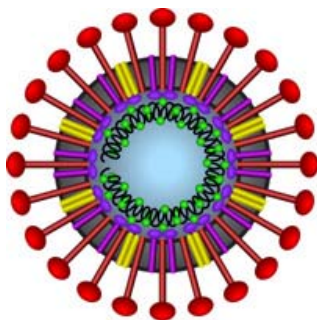
DRG® Corona Virus Ag Rapid Test (Bovine) (RAP-4797 / RAP-4798)**As of 3 Apr. 2009 (Vers. 1.0)****For Veterinary Use Only****INTRODUCTION**

Bovine Coronavirus BCV was first associated with diarrhoea in newborn calves and later with winter dysentery in adult cattle. It is now considered an important pathogen causing enteric disease, often in combination with respiratory clinical signs. Fatal respiratory disease caused by BCV has been reported in young stock. BCV infections often result in high morbidity but usually in low mortality. The same virus strain can cause disease in both calves and adults, and the animal often sheds virus in both nasal secretions and feces.

The typical syndrome in calves from a few days to a few weeks of age is usually associated with infections such as rotavirus (34%), Coronavirus (23%) and cryptosporidium (18%).

Bovine Coronavirus is a group 2 member of the genus Coronavirus in the family Coronaviridae.

The BCV virion is enveloped and spherical in shape. The genome is a single-stranded, positive-sense RNA molecule of 27 to 32 kb.

**Coronavirus structure**

Infected animals exceed enormous number of viral particles, and therefore contaminating the environment. Together with the Rota Clinic One Step Test the veterinarian is now able to detect the cause of diarrhea in about 60% of all cases.

This rapid, sensitive and easy to perform diagnostic test will enable hygienic, therapeutic and prophylactic measures to be put in place to protect the other calves in the herd in order to keep the number of infected animals as low as possible.

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 Bovine Corona virus antigen by use of a Rapid Immunochromatic Assay.

PRINCIPLE

The Bovine Corona Virus Ag One-Step Test is based on a chromatographic principle in which a monoclonal antibody with reacts with epitopes of the Coronavirus. A monoclonal antibody is conjugated to colloidal gold particles and a monoclonal antibody is immobilized on the test strip in the test zone "T". Bovine Coronavirus in the faeces 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.

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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, 1 pipette and 1 cotton swab
- 6 / 24 x vials containing 600 µl 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 feces or rectal swab samples, tissue culture samples can also be tested.

It is advised to test samples as concentrated as possible (see Test protocol).

TEST PROTOCOL

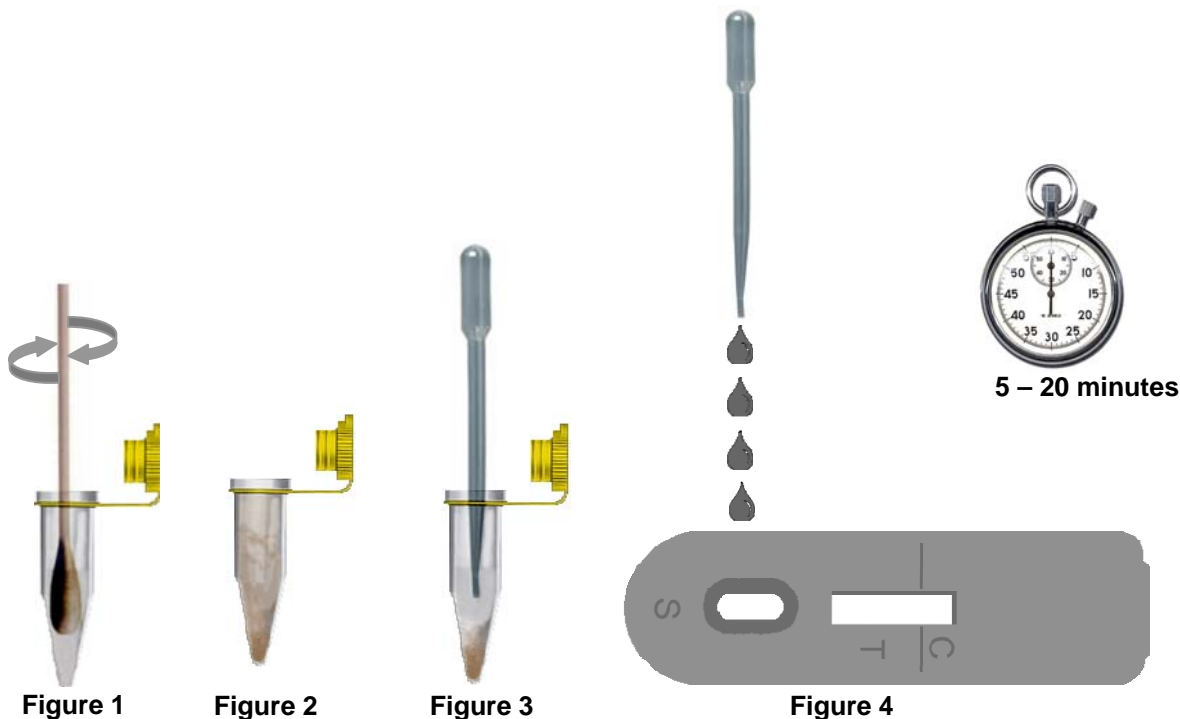
1. Unpack the test strip, swab and pipette. Only open the amount of pouches to be used. An opened package should be used immediately.
2. Take a small sample of faeces or a rectal swab using the included swab.
3. Vigorously wash the swab in the buffer vial (fig. 1).
4. Let particles, if present, sink to the bottom (fig. 2). If necessary centrifuge the sample.
5. Add 4 drops of the supernatant (fig. 3), with the included pipette, of the sample solution to the sample zone “S” (fig. 4).

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6. Read the results after 5 - 20 minutes (* see 9; Validation of the test and 10; Interpretation of test results).



VALIDATION OF THE TEST

To validate this 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.

INTERPRETATION OF TEST RESULTS

Positive:

Two bands are visible, zone “T” and zone “C” (fig. A). The sample contains Bovine Corona virus antigen.

Positive results may vary in optical density due to variations in viral 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 Bovine Corona virus antigen.

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

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Negative:

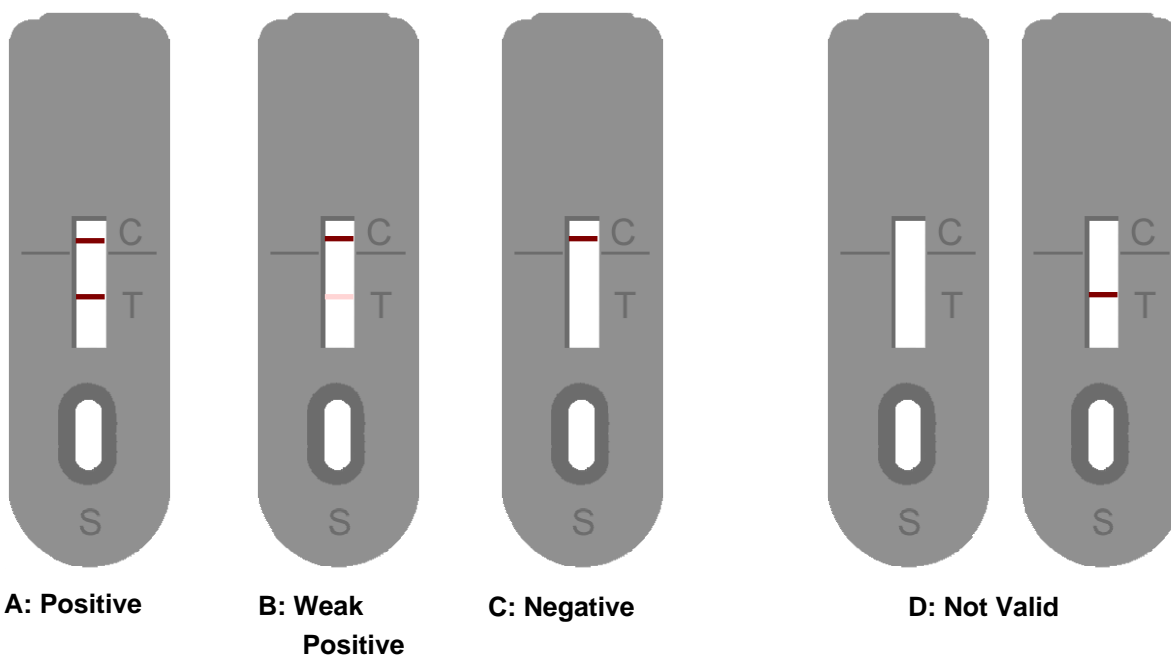
Only one band is visible in zone “C” (fig. C). The sample does not contain Bovine Corona virus antigen.

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 virus isolation. 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.

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SYMBOLS USED WITH DRG ASSAYS

Symbol	English	Deutsch	Français	Español	Italiano
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
	European Conformity	CE-Konformitätskennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Número de lote	Numero di lotto
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungstemperatur	Température de conservation	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributore
Content	Content	Inhalt	Conditionnement	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantité	Volumen/Número	Volume/Quantità
Symbol	Portugues	Dansk	Svenska	Ελληνικά	
	Consulte as instruções de utilização	Se brugsanvisning	Se bruksanvisningen	Εγχειρίδιο χρήστη	
	Conformidade com as normas europeias	Europæisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή Συμμόρφωση	
	Diagnóstico in vitro	In vitro diagnostik	Diagnostik in vitro	in vitro διαγνωστικό	
					
	Catálogo n.º	Katalognummer	Katalog nummer	Αριθμός καταλόγου	
	No do lote	Lot nummer	Batch-nummer	Αριθμός Παρτίδος	
		Indeholder tilstrækkeligt til "n" test	Innehåller tillräckligt till "n" tester	Περιεχόμενο επαρκές για «n» εξετάσεις	
	Temperatura de conservação	Opbevarings-temperatur	Förvaringstemperatur	Θερμοκρασία αποθήκευσης	
	Prazo de validade	Udløbsdato	Bäst före datum	Ημερομηνία λήξης	
	Fabricante	Producent	Tillverkare	Κατασκευαστής	
Distributed by					
Content	Conteúdo	Indhold	Innehåll	Περιεχόμενο	
Volume/No.	Volume/Número	Volumen/antal	Volym/antal	Όγκος/αριθ.	