DRG® Rotavirus Ag Rapid Test (RAP-4809 / RAP-4810)

As of 5 Apr. 2009 (Vers. 1.0) **For Veterinary Use Only**

INTRODUCTION

Rotaviruses have been diagnosed as causing diarrhea in nearly every mammalian species.

Rotaviruses are important causes of severe gastroenteritis in many new born animals, especially in intensively reared farm animals. Rotaviral gastroenteritis may result in mortality for populations at risk such as infants, the elderly, and immunocompromised patients. In temperate climates, Rotavirus infections occur mainly in the winter months.

Rotavirus is one of the factors in "Neonatal disease complex", 27% of death cases were caused by rotavirus (Animal Pharm, April 1997). Infected animals exceed enormous numbers of Rota viral particles, and usually are detectable up to 1 week after infection or for more than 30 days in immunocompromised patients, thus contaminating the environment. The risk of getting a herd outbreak of neonatal diarrhea is particularly high during the parturition season because of rapid spread of the virus.

Rotavirus is transmitted by the fecal-oral route; clinical as well as subclinical infections are common. Symptoms are diarrhea, vomiting, dehydration and apathy.

Since rotavirus is resistant to many disinfectants and is not inactivated by either extreme temperature nor pH, the source of infections may persist on a farm for many months. A built-up of contamination can also depend on shedding of rotavirus by subclinically infected adult animals.

Rotavirus can also cross species barriers. Human rotavirus can infect animals and vice-versa, with canine and feline-like viruses found in humans. Given these circumstances there is a high need for a rapid and simple test to diagnose rotavirus infections.

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 Rota virus antigen by use of a Rapid Immunochromatic Assay.

PRINCIPLE

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

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.

DRG International Inc., USA

Fax: (908) 233-0758 • E-mail: corp@drg-international.com • **Web:** www.drg-international.com

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

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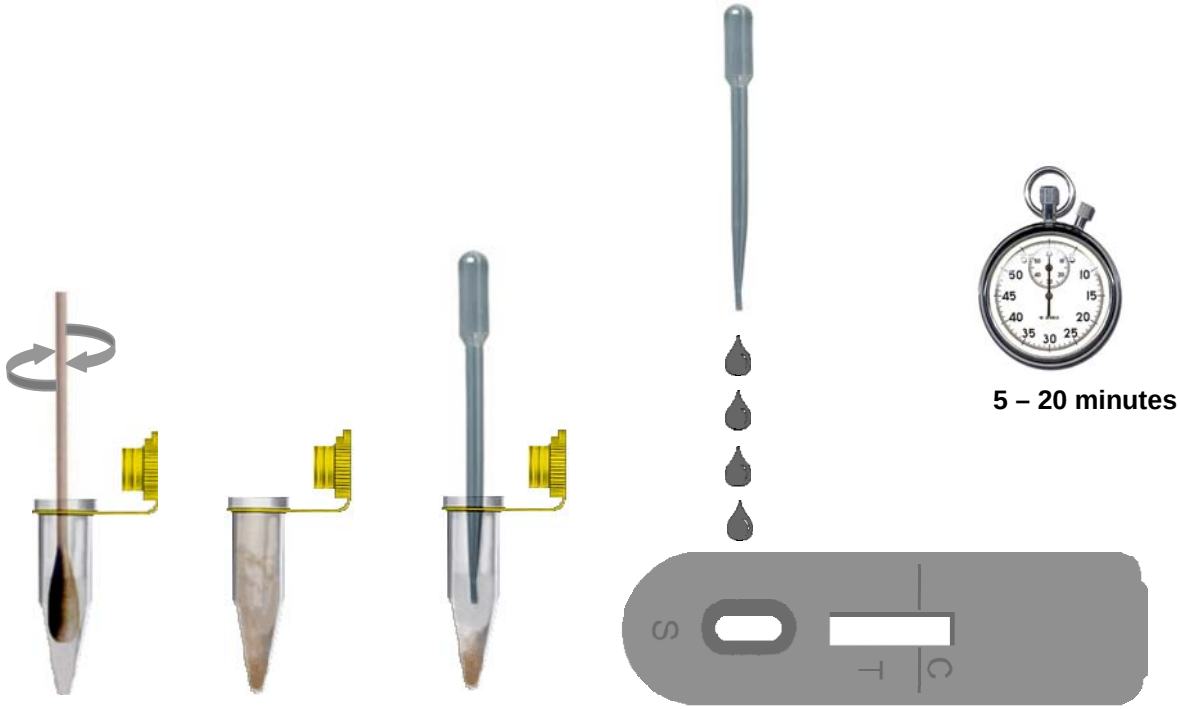


Figure 1 Figure 2 Figure 3 Figure 4

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 Rota 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 Rota virus antigen.

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

Negative:

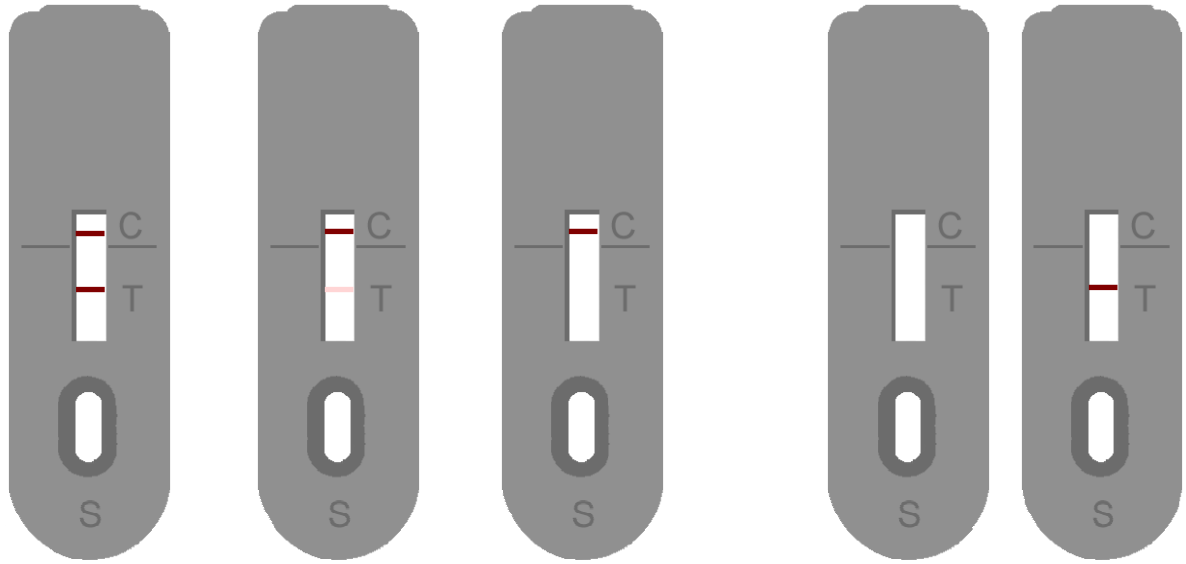
Only one band is visible in zone "C" (fig. C). The sample does not contain Rotavirus antigen.

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.



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.

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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
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
LOT	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
CE	Conformidade com as normas europeias	Europaeisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή Συμμόρφωση
IVD	Diagnóstico in vitro	In vitro diagnostik	Diagnostik in vitro	in vitro διαγνωστικό
REF	Catálogo n.º	Katalognummer	Katalog nummer	Αριθμός καταλόγου
LOT	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	Förvaringstempratur	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..