

VIROTECT® ROTa ^{Ref} OD038

Rapid Latex Slide Test for the detection of Rotavirus in faecal samples.

Store at 2°C to 8°C. DO NOT FREEZE

For in-vitro diagnostic use only.

INTRODUCTION AND INTENDED USE

Rotavirus is a common cause of gastroenteritis and diarrhoea, particularly in infants and young children. This may result in dehydration and electrolyte imbalance.

Until recently, diagnosis of Rotavirus has been by electron microscopy. Latex agglutination and enzyme immunoassay have become available which are more convenient alternatives.

VIROTECT ROTa is a rapid latex agglutination test for the detection of Rotavirus in faecal samples.
For professional use only.

PRINCIPLE OF THE TEST

The latex particles are coated with rabbit antibodies raised against Rotavirus Group A.

A faecal extract is prepared, which when added to the Test Latex Reagent in the presence of Rotavirus group A antigen agglutinates the latex particles.

A Control Reagent is also included in the kit which consists of latex particles coated with normal rabbit globulins. This reagent is utilised to identify the occasional non-specific reactions which may occur. This reagent should not agglutinate even in the presence of Group A Rotavirus antigen.

CONTENTS

^{Ref}
OD038



Latex	Test
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Suspension of latex particles coated with antibodies to rota virus Group A (approximately 1%) Working Strength.

Latex	Control
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Suspension of latex particles coated with non specific rabbit antibody. (approximately 1%). Working Strength.

CONTROL	+
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0.5ml

Positive Control. Clear solution of cell culture medium containing inactivated rotavirus. Working Strength.

Buf

50ml

Phosphate Buffer with approximately 0.4% EDTA. Working Strength.

STIRRERS	100
DISPOSABLE TEST SLIDES	34
INSTRUCTION LEAFLET	1

MATERIALS REQUIRED BUT NOT PROVIDED

Screw capped tubes
Laboratory Centrifuge
Micro pipettes

PRECAUTIONS

VIROTECT ROTa reagents contain 0.095% Sodium Azide as a preservative which may be toxic if ingested. Sodium Azide may react with lead and copper plumbing to form highly explosive salts. On disposal flush with large quantities of water.

VIROTECT ROTa Reagents do not contain dangerous substances as defined by current UK Chemicals (Hazardous Information and Packaging for Supply) regulations. All reagents should, however, be treated as potential biohazards in use and disposal. Final disposal must be in accordance with local legislation. Do not ingest.

Handle all samples, antigen extracts and used test cards as potentially infectious. The buffer will not kill all the bacteria present. Dispose of contaminated items safely.

STORAGE

Reagents must be stored at temperatures between 2°C to 8°C.

The kit will perform within specification until the stated expiry date as determined from date of product manufacture and stated on kit and components. Expiry date is the last day of the month on the bottle and the kit label. Do not use reagents after the expiry date.

Exposure of reagents to excessive temperatures should be avoided. Do not expose to direct sunlight.

DO NOT FREEZE ANY OF THE REAGENTS as this will cause irreversible damage.

SPECIMEN STORAGE AND PREPARATION

If the specimen is not to be tested immediately it may be stored overnight at 2°C to 8°C or at - 20°C or below for longer periods.

Prepare an approximate 10% suspension of the faecal sample by adding 0.1ml/0.1g of sample to 1.0ml Buffer in a screw capped tube. Mix well. Stand at room temperature for 1-2 minutes. Proceed with the test protocol as detailed in the Assay Procedure section.

REAGENT PREPARATION

All reagents should be brought to room temperature (20°C to 25°C) and mixed gently to resuspend latex prior to use. Do not induce foaming.

LIMITATION OF USE

The use of samples other than faecal samples have not been validated in this test.

There is no reuse protocol for this product.

A low or suspected positive result should be re-assessed. Diagnosis should not be made solely on the findings of one clinical assay. When making an interpretation of the test it is strongly advised to take all clinical data into consideration.

Evaluate results only in conjunction with full clinical data as a positive **VIROTECT ROTa** test does not necessarily preclude the possibility of additional microbial infections.

VIROTECT ROTa is an acute phase test. Faecal samples collected after the acute phase may contain antigen concentrations below the threshold of reagent sensitivity.

ASSAY PROCEDURE

Allow test reagents to reach room temperature.

A. Routine Method

1. Centrifuge specimen (prepared as above) at approx 1000g for 10 minutes.
2. Transfer 50µl of supernatant onto each of two wells on a test slide.
3. Shake the Test Latex Reagent vigorously, then using the dropper provided, add one drop of suspension to the first circle (Test Circle).
4. Shake the Control Latex Reagent vigorously, then using the dropper provided, add one drop of suspension to the second circle (Control Circle).
5. Mix the contents of each circle using a separate disposable stirrer ensuring coverage of the test circle with the mixture.
6. Gently and evenly, rock and rotate the test slide for 2 minutes whilst examining the test slide for agglutination.

RESULTS AND INTERPRETATION

Examine the test slide under a strong light source after 2 minutes.
The positive control should produce a positive result within two minutes.
A negative result can be simulated by substituting uninnoculated buffer for faecal sample in the testing procedure.
Such a negative control should produce a negative result within two minutes.
If controls or users own samples do not give expected results, test results must be considered invalid.

TROUBLESHOOTING

Use a separate disposable tip for each sample to prevent cross contamination.

Replace caps on all reagents immediately after use.

Prior to the start of the assay bring all reagents to room temperature (20°C to 25°C). Gently mix all reagents by gentle inversion or swirling.

For use by operatives with at least a minimum of basic laboratory training.

Do not use damaged or contaminated kit components.

EVALUATION DATA

Reproducibility of Virotect Rota is 100% (+/- one double dilution).

	Virotect Rota		Totals
	+	-	
PCR +	101	3	104
PCR -	3	99	102
	104	102	206

Sensitivity 97.2%

Specificity 97.1%

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