

RAPYDTEST®

FOR THE DETECTION OF ROTAVIRUS IN FAECES

APACOR

Rotavirus Ag
RAPYDTEST®

Intended Use

The Rotavirus Ag Rapydtest® is a lateral flow immunoassay for the qualitative detection of rotavirus antigens in faecal specimens.

This device is intended to be used as a screening test and as an aid in the diagnosis of infection with rotavirus.



Performance Characteristics

Serotype Detection

The Rotavirus Ag Rapydtest® detects Group A rotavirus.

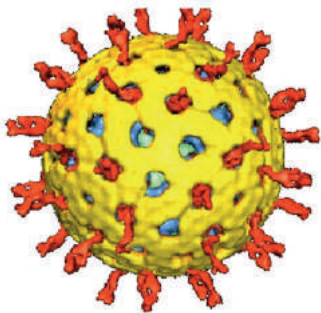
Cross-Reactivity

The cross-reactivity of the Rotavirus Ag Rapydtest® was assessed by testing faecal specimens collected from patients with other gastro-intestinal infectious diseases. No cross-reactivity was observed.

Clinical Performance

Clinical Performance of rotavirus specimens: 107 faecal samples collected from subjects with symptomatic diarrhoea and non-diarrhoea symptoms were tested with the Rotavirus Ag Rapydtest® and with a reference rapid test. Comparison for all subjects is shown in the table.

Relative Sensitivity: 100%
Relative Specificity: 97.2%
Overall Agreement: 98.1%

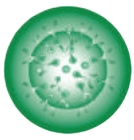


	Rotavirus Ag Rapydtest®		
REFERENCE TEST	POSITIVE	NEGATIVE	TOTAL
POSITIVE	36	0	36
NEGATIVE	2	69	71
TOTAL	38	69	107



VIROLOGY

SINGLE USE IN VITRO DIAGNOSTIC DEVICE



Rotavirus Ag RAPYDTEST®

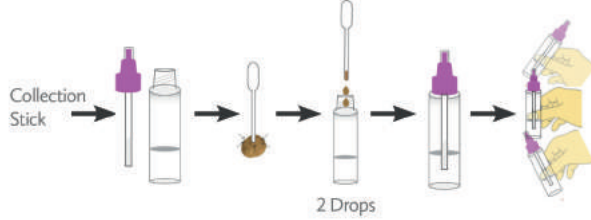
Reagents and Materials Provided

1. Individually sealed foil pouches containing:
 - a. One cassette test device.
 - b. One desiccant.
2. Stool collection devices, each containing 2ml of extraction buffer.
3. Plastic droppers for transferring watery stool.
4. One package insert (instruction for use).

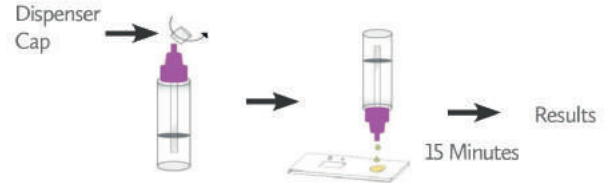
Specimen Collection and Handling

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Procedure for Stool Sample Collection



Test Procedure



Do not read results after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

Interpretation of Assay Result

1. Negative Result:
If only the C line is developed, the test indicates that the level of rotavirus Ag in the specimen is undetectable.
The result is negative.
2. Positive Result:
If both the C line and the T line are developed, the test indicates that the specimen contains rotavirus Ag.
The result is positive.
3. Invalid:
If no C line is developed, the assay is invalid regardless of colour development on the T line as indicated below.
Repeat the assay with a new device.



References

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PRODUCT	PACK SIZE	CODE
Rotavirus Ag Rapydtest®	25	1641

Products can be ordered direct from Apacor or from an appointed distributor
Visit our website for all the latest information www.apacor.com or email on: sales@apacor.com



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