RAPYDTEST®

FOR THE DETECTION OF ROTAVIRUS/ADENOVIRUS IN FAECES

APACOR

Rotavirus/Adenovirus Ag
RAPYDTEST®

Intended Use

The Rotavirus/Adenovirus Ag Rapydtest® is a lateral flow immunoassay for the qualitative detection and differentiation of rotavirus and adenovirus 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 and adenovirus.

Performance Characteristics

Clinical Performance

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

Clinical Performance of rotavirus specimens: 107 faecal samples collected from subjects with symptomatic diarrhoea and non-diarrhoea symptoms were tested with the Rotavirus/Adenovirus Ag Rapydtest® and with a reference rapid test.

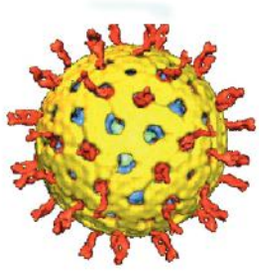
Comparison for all subjects is shown in the table.

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

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

Relative Sensitivity: 100%
Relative Specificity: 97.9%
Overall Agreement: 98.1%

	Rotavirus/Adenovirus Ag Rapydtest®		
REFERENCE TEST	POSITIVE	NEGATIVE	TOTAL
POSITIVE	10	0	10
NEGATIVE	2	95	97
TOTAL	12	95	107



VIROLOGY

SINGLE USE IN VITRO DIAGNOSTIC DEVICE

Rotavirus/Adenovirus Ag

RAPYDTEST®

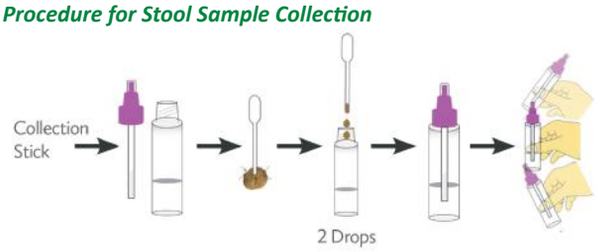
Reagents and Materials Provided

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).

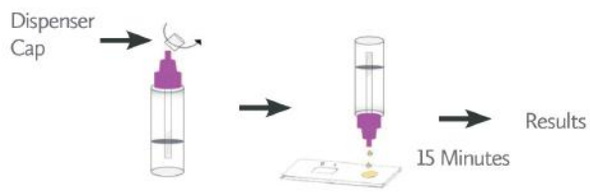
Specimen Collection and Handling

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 band is developed, the test indicates that the level of rotavirus Ag and adenovirus Ag in the specimen is undetectable. The result is negative.

2. **Positive Result:**
   In addition to the presence of the C band, if the R band is developed, the test indicates that the specimen contains rotavirus Ag. The result is rotavirus Ag positive.

   In addition to the presence of the C band, if the A band is developed, the test indicates that the specimen contains adenovirus Ag. The result is adenovirus Ag positive.

   In addition to the presence of the C band, if both the R band and the A band are developed, the result indicates the specimen contains both rotavirus Ag and adenovirus Ag. The result is both rotavirus Ag and adenovirus Ag positive.

3. **Invalid**
   If no C band is developed, the assay is invalid regardless of any colour development in the R band or A band as indicated below.
   Repeat the assay with a new device.

References

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PRODUCT	PACK SIZE	CODE
Rotavirus/Adenovirus Ag Rapydtest®	25	1640

Products can be ordered direct from Apacor or from an appointed distributor
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