

RAPYDTEST®

FOR THE DETECTION OF ROTAVIRUS/ADENOVIRUS IN FAECES

APACOR

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

REFERENCE TEST	Rotavirus/Adenovirus Ag Rapydtest®		TOTAL
	POSITIVE	NEGATIVE	
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.

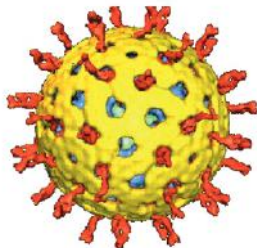
Comparison for all subjects is shown in the table.

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%

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



VIROLOGY

SINGLE USE IN VITRO DIAGNOSTIC DEVICE

Rotavirus/Adenovirus Ag
RAPYDTEST®



Rotavirus/Adenovirus Ag RAPYDTEST®

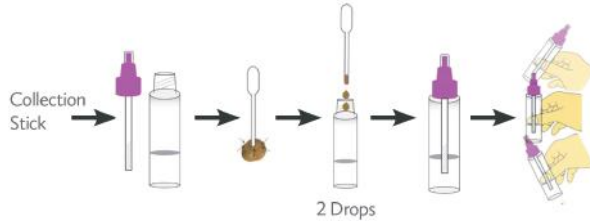
Reagents and Materials Provided

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).

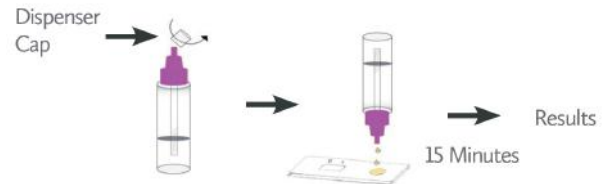
Specimen Collection and Handling

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

Procedure for Stool Sample Collection



Test Procedure

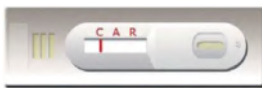


Do not read results after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

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.

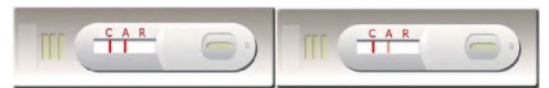


2. Positive Result:

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

1. Diarrhoeal Diseases (updated February 2009) [http://www.who.int/vaccine_research/diseases/diarrhoeal/en/index4.html]
2. Parashar, U, Gibson CJ, Bresee JS, et al. Rotavirus and severe childhood diarrhoea. *Emerg Infect Dis* (2005) 12:304-306.
3. Parashar UD, Bresee JS, Gentsch JR, et al. Rotavirus. *Emerg Infect Dis* (1998) 4(4):561-570.
4. Shinozaki, T, et al. Epidemiology of enteric adenoviruses 40 and 41 in acute gastroenteritis in infants and young children in the Tokyo area. *Scand J Infect Dis* (1991) 23:543-547.
5. Uhnou, J, Wadell, G, Svensson, L, et al. Importance of enteric adenoviruses 40 and 41 in acute gastroenteritis in infants and young children. *J Clin Microbiol* (1984) 20:365-372.
6. Parashar UD, Hummelman EG, Breese JS, et al. Global illness and deaths caused by rotavirus disease in children. *Emerg Infect Dis* 2003, 9(5):565-572.
7. Levy, K, Hubbard, AE and Eisenberg, JN. Seasonality of rotavirus disease in the tropics: a systematic review and meta-analysis. *Int J Epidemiol* (2009) 38:1487-1496.
8. Cook, SM, Glass, RI, et al. Global seasonality of rotavirus infections. *Bull WHO*. (1990) 68:171-177.
9. Farkas T and Jiang XI. Rotaviruses, Caliciviruses, Astroviruses, Enteric adenoviruses and Other Diarrheic Viruses. In *Manual of Clinical Microbiology* 9th edition. Edited by: Murray PR, Baron EJ, Jorgensen JH, Landry ML, Pfaller MA. Washington DC:ASM Press; 2007:1453-69.
10. Brandt, CD, Kim HW, Rodriguez WJ et al. Adenoviruses and pediatric gastroenteritis. *J Infect Dis* (1985) 151:437-443.
11. Dey, R.S., Ghosh, S., Chawla-Sarkar, M., et al. Circulation of a Novel Pattern of Infections by Enteric Adenovirus Serotype 41 among Children below 5 Years of Age in Kolkata, India. *J Clin Microbiol* (2011) 49:500-505.
12. David O: Matson. Rotavirus, Enteric adenoviruses, Caliciviruses, Astroviruses and other viruses causing gastroenteritis. In *Clinical Virology Manual* 3rd edition. Edited by: Steven Specter, Richard L Hodinka, Stephen A Young. ASM Pres; 2000:275-77.
13. Dennehy, P.H., D.R. Gauntlett, and S.E. Spangenberg. Choice of reference assay for the detection of rotavirus in fecal specimens: electron Microscopy versus enzyme immunoassay. *J Clin Microbiol* (1990) 6:1280-1283.
14. Lipson, S.M., and K.A. Zelinsky. Comparison of four latex agglutination (LA) and three enzymelinked immunosorbant assays (ELISA) for the detection of rotavirus in fecal specimens. *Am J Clin Path* (1989) 92:637-643.

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

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: orders@apacor.com

APACOR
 UNIT 5 SAPPHIRE CENTRE
 FISHPONDS ROAD, WOKINGHAM
 BERKSHIRE, RG41 2QL, UK
 TEL: +44 (0)118 979 5566
 FAX: +44 (0)118 979 5186



EC REP
 MDSS GmbH
 Schiffaraben 41
 30175 Hanover
 Germany