RAPID BIOTEC™

CE IVD

Norovirus+Rotavirus/Adenovirus+Astrovirus+Enterovirus Combo Rapid Test Device (Feces)

CATALOGUE NUMBER
D-NRAAED10

A rapid, one step test for the qualitative detection of Norovirus, Rotavirus, Adenovirus Astrovirus and Enterovirus in human feces.
For professional in vitro diagnostic use only.

INTENDED USE

The Norovirus+Rotavirus/Adenovirus+Astrovirus+Enterovirus Combo Rapid Test Device (Feces) is a rapid chromatographic immunoassay for the qualitative detection of norovirus, rotavirus, adenovirus, astrovirus and enterovirus in human fecal specimens to aid in the diagnosis of norovirus, rotavirus, adenovirus, astrovirus or enterovirus infection.

SUMMARY

The Combo Test comprises of 4 parts, viz., Norovirus, Rotavirus/ Adenovirus, Astrovirus and Enterovirus. The details for each part are given below.

The Norovirus Rapid Test (Feces) is a rapid chromatographic immunoassay for the qualitative detection of norovirus in human fecal specimen. The test utilizes antibody specific for norovirus to selectively detect norovirus in human fecal specimens.

Noroviruses (NoV) are a genetically diverse group of single stranded RNA, nonenvelopped viruses belonging to the Caliciviridae family. Initially four antigenic types of SRSV were recognized, but more recently three genogroups have been identified with the genus Norovirus. Genogroup 1 and Genogroup 2 are associated with human infections whilst Genogroup 3 is associated with bovine and porcine infection. Noroviruses are a major cause of acute gastroenteritis worldwide, often causing explosive outbreaks in institutions. They are highly contagious, with an inoculum of as few as ten particles being able to cause infection. Transmission occurs through ingesting contaminated food and water and by person-to-person spread. Transmission is predominantly faecal-oral but may be airborne due to aerosolisation of vomitus, which typically contains abundant infectious virus particles. Outbreaks may involve several routes of transmission. The illness is acute, usually mild, although it has caused fatalities among the frail elderly, and self-limiting and follows an incubation period of 24-48 hours although cases can occur within 12 hours of exposure.

The symptoms of Norovirus illness usually include nausea, vomiting, diarrhea, and some stomach cramping. Sometimes people additionally have a low-grade fever, chills, headache, muscle aches, and a general sense of tiredness. The illness often begins suddenly, and the infected person may feel very sick. In most people the illness is self-limiting with symptoms lasting for about 1 or 2 days.

The Rotavirus and Adenovirus Combo Rapid Test (Feces) is a rapid chromatographic immunoassay for the qualitative detection of rotavirus and adenovirus in human fecal specimen, providing results in 10 minutes. The test utilizes antibody specific for rotavirus and adenovirus to selectively detect rotavirus and adenovirus from human fecal specimens.

Acute diarrheal disease in young children is a major cause of morbidity worldwide and is a leading cause of mortality in developing countries.[1] Rotavirus is the most common agent responsible for acute gastroenteritis, mainly in young children.[2] Its discovery in 1973 and its association with infantile gastroenteritis represented a very important advancement in the study of gastroenteritis not caused by acute bacterial infection. Rotavirus is transmitted by oral-fecal route with an incubation period of 1-3 days. Although specimen collections taken within the second and fifth day of the illness are ideal for antigen detection, the rotavirus may still be found while diarrhea continues. Rotaviral gastroenteritis may result in mortality for populations at risk such as infants, the elderly and immunocompromised patients.[3] In temperate climates, rotavirus infections occur mainly in the winter months. Endemics as well as epidemics affecting some thousand people have been reported.[4] With hospitalized children suffering from acute enteric disease up to 50% of the analyzed specimen were positive for rotavirus.[5] The viruses replicate in the cell nucleus and tend to be host species specific producing a characteristic cytopathic effect (CPE).

Research has shown that enteric adenoviruses, primarily Ad40 and Ad41, are a leading cause of diarrhea in many of these children, second only to the rotaviruses.[6,7,8,9] These viral pathogens have been isolated throughout the world, and can cause diarrhea in children year round. Infections are most frequently seen in children less than two years of age, but have been found in patients of all ages. Further studies indicate that adenoviruses are associated with 4 - 15% of all hospitalized cases of viral gastroenteritis.[5,6,7,8,9] Rapid and accurate diagnosis of gastroenteritis due to adenovirus is helpful in establishing the etiology of gastroenteritis and related patient management.

The Astrovirus Rapid Test (Feces) is a rapid chromatographic immunoassay for the qualitative detection of astrovirus in human fecal specimen. The test utilizes antibody specific for astrovirus to selectively detect astrovirus from human fecal specimens.

Astrovirus is a type of virus that was first discovered in 1975 using electron microscopes following an outbreak of diarrhea in humans.[10] Astroviruses are 28–35 nm diameter, icosahedral viruses that have a characteristic five- or sixpointed star-like surface structure when viewed by electron microscopy. Along with the Picornaviridae and the Caliciviridae, the Astroviridae comprise a third family of nonenveloped viruses whose genome is composed of plus-sense, single-stranded RNA. [11] Astrovirus has a non-segmented, single stranded, positive sense RNA genome within a non-enveloped icosahedral capsid.[12] Human astroviruses have been shown in numerous studies to be an important cause of gastroenteritis in young children worldwide.[11]

The Enterovirus Antigen Rapid Test (Feces) is a rapid chromatographic immunoassay for the qualitative detection of *Enterovirus* in human feces

Pathogenic enteroviruses include poliovirus, Coxsackie virus, and orphan virus (ECHO virus), which causes cytopathic changes in the human gut. In 1970, the International Committee on Virus Nomenclature assigned these viruses to the genus Enterovirus of the Picornavirridae family. The enteroviruses found after the 67 types of the three named enteroviruses are named according to the enterovirus Ordinal Numbers, that is, enteroviruses 68, 69, 70, 71, 72, etc.[13]

Poliovirus (types 1 to 3), coxsackie virus A (types 1 to 22, 24), coxsackie virus B (types 1 to 6), echovirus (types 1 to 9, 11 to 27,29 to 33) and the later recognized enteroviruses (types 68 to 72) together form the 68 known human members of the genus Enterovirus of the family of Picornaviridae (Matthews, 1982). Enterovirus 72 is the cause of acute infectious hepatitis.[14]

Other signs and symptoms associated with (groups of) enteroviruses are vesicular disease, exan-thems,myalgia, myo- and pericarditis, respiratory disease, and enteritis. A special position is taken by enterovirus 70 and coxsackievirus A24. Both caused huge epidemics of acute hemorrhagic conjunctivitis throughout the world.[14]

PRINCIPLE

The Combo Test comprises of four parts and details of each part are given herewith.

The Norovirus Rapid Test (Feces) is a qualitative, lateral flow immunoassay for the detection of Norovirus in human fecal specimens. The assay uses Genogroup 1 and Genogroup 2 specific monoclonal antibodies coated on the test membrane. During testing, the fecal specimen reacts with the conjugated antibodies. The mixture migrates upward on the membrane by capillary action to react with Genogroup 1 and 2 antibodies on the membrane and generates a colored line at the T1 and T2 zone respectively. The presence of a colored line in T1 region indicates a positive result for Genogroup 1 and in T2 region for Genogroup 2 respectively, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control reaction zone (C) indicating that proper volume of specimen has been added and membrane wicking has occurred.

The Rotavirus and Adenovirus Combo Rapid Test (Feces) is a qualitative, lateral flow immunoassay for the detection of rotavirus and adenovirus in human fecal specimen.

In this test, the membrane is pre-coated with anti-rotavirus antibody on the T2 test line region of the test and anti-adenovirus antibody on the T1 test line region of the test. During testing, the specimen reacts with the particle coated with anti-rotavirus antibody and anti-adenovirus antibody. The mixture migrates upward on the membrane by capillary action to react with anti-rotavirus antibody and anti-adenovirus antibody on the membrane and generate a colored line. The presence of these colored lines in test line region indicates a positive result, while their absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

The Astrovirus Rapid Test (Feces) is a qualitative, lateral flow immunoassay for the detection of astrovirus in human fecal specimens. In this test, the membrane is pre-coated with anti-astrovirus antibody on the test line region of the test. During testing, the specimen reacts with the particle coated with anti-astrovirus antibody. The mixture migrates upward on the membrane by capillary action to react with anti-astrovirus antibody on the membrane and generate a colored line in the test line region. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

The Enterovirus Antigen Rapid Test (Feces) is a qualitative, lateral flow immunoassay for the detection of Enterovirus in human feces. The membrane is precoated with Enterovirus antibody on the test line region of the test. During testing, Enterovirus, if present in the specimen reacts with Enterovirus antibody conjugated with colored particle. The mixture migrates upward on the membrane by capillary action to react with Enterovirus antibody on the membrane and generate a colored line. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The Combo Test comprises of three parts and details of each part are given herewith.

The Norovirus rapid test contains Norovirus Genogroup 1 and Genogroup 2 monoclonal antibody coated particles and Norovirus Genogroup 1 and Genogroup 2 monoclonal antibodies coated on the membrane.

The Rotavirus rapid test contains anti-rotavirus antibody coated particles and anti-rotavirus antibody coated on the membrane.The Adenovirus rapid test contains anti-adenovirus antibody coated particles and anti-adenovirus antibody coated on the membrane.

The Astrovirus rapid test contains anti-astrovirus antibody coated particles and anti-astrovirus antibody coated on the membrane.

The Enterovirus rapid test contains Enterovirus antibody particles and Enterovirus antibody coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test Devcie should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouches either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch containing desiccant until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- Viral detection is improved by collecting the specimens at the onset of the symptoms. It has been reported that the maximum excretion of norovirus in the feces of patients with gastroenteritis occurs 3-13 days after onset of symptoms. If the specimens are collected long after the onset of diarrheic symptoms, the quantity of antigen may not be sufficient to obtain a positive reaction or the antigens detected may not be linked to the diarrheic episode.
- Viral detection is improved by collecting the specimens at the onset of the symptoms. It has been reported that the maximum excretion of rotavirus, adenovirus and astrovirus,*enterovirus* in the feces of patients with gastroenteritis occurs 3-5 days after onset of symptoms. If the specimens are collected long after the onset of diarrheic symptoms, the quantity of antigen may not be sufficient to obtain a positive reaction or the antigens detected may not be linked to the diarrheic episode.
- The fecal specimen must be collected in clean, dry, waterproof container containing no detergents, preservatives or transport media.
- Bring the necessary reagents to room temperature before use.

MATERIALS

Materials Provided

- Test Devcies
- Specimen Collection Tubes with Extraction Buffer
- Positive control(Adenovirus/Rotavirus)
- Negative control
- Package Insert
- Droppers
- Positive control(Norovirus/ Astrovirus/Enterovirus)

Materials Required But Not Provided

- Specimen Collection Containers
- Centrifuge and Pipette to Dispense 80 µL if required
- Timer

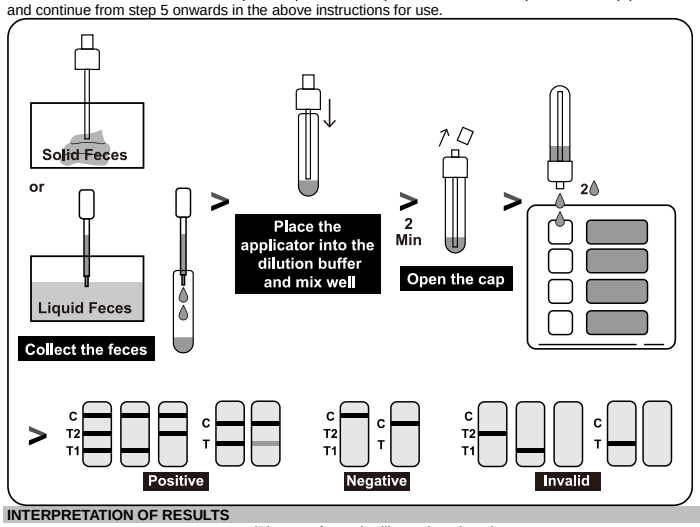
DIRECTIONS FOR USE

Allow the test Devcie, specimen and buffer to reach room temperature (15-30°C) prior to testing.

1. To collect fecal specimens:
   Collect sufficient quantity of feces (1-2 ml or 1-2 g) in a clean, dry specimen collection container to obtain enough virus particles. Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8°C if not tested within 6 hours. For long-term storage, specimens should be kept below -20°C.
2. To process fecal specimens:
   - For **Solid Specimens**:
     Unscrew the cap of the specimen collection tube，then randomly **stab the specimen collection applicator into the fecal specimen in at least 3 different sites** to collect approximately **50 mg of feces** (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.
   - For **Liquid Specimens**:
     Hold the dropper vertically, aspirate fecal specimens, and then transfer **2 drops of the liquid specimen (approximately 80 µL)** into the specimen collection tube containing the extraction buffer.

   Tighten the cap onto the specimen collection tube, then **shake the specimen collection tube vigorously** to mix the specimen and the extraction buffer. Leave the collection tube for **reaction for 2 minutes**.
3. Bring the pouch to room temperature before opening it. Remove the test Devcie from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
4. Hold the specimen collection tube upright and unscrew the small cap of the specimen collection tube. Invert the specimen collection tube and **transfer 2 full drops of the extracted specimen (approximately 80 µL)** to each specimen well (S) of the test Devcie, then start the timer. Avoid trapping air bubbles in the specimen well (S). See illustration below.
5. **Read the results at 15 minutes** after dispensing the specimen. Do not read results after 20 minutes.

Note: If the specimen does not migrate (presence of particles), centrifuge the extracted specimen contained in the extraction buffer vial. Collect 80 µL of supernatant, dispense into the each specimen well (S). Start the timer and continue from step 5 onwards in the above instructions for use.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

All the Test interpretations must be carried out as per the windows classified for each type.

Norovirus:

T1 and T2 POSITIVE:* Three colored lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the Genogroup 1 region (T1) and/ or Genogroup 2 region (T2).

T1 POSITIVE:* Two colored lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the Genogroup 1 region (T1).

T2 POSITIVE:* Two colored lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the Genogroup 2 region (T2).

Rotavirus and Adenovirus Combo:

Rotavirus Positive: * A colored line appears in the control line region (C) and another colored line appears in the T2 line region.

Adenovirus Positive: * A colored line appears in the control line region (C) and another colored line appears in the T1 line region.

Rotavirus and Adenovirus Positive: * A colored line appears in the control line region (C) and two other colored lines appear in T1 line region and T2 line region respectively.

Astrovirus/ Entervirus:

POSITIVE:* Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T).

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T).
***NOTE:** For all the five windows, the intensity of the color in the test line region (T) will vary depending on the concentration of viral antigens present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.
INVALID: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Devcie. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal Quality Control

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Quality Control

External Controls are included in this kit. In compliance with Good Laboratory Practice (GLP) positive/negative controls are recommended.

Procedure for External Quality Control Testing

1.Remove the test cassette from the sealed pouch and use it within one hour.
2.Place the cassette on a clean and level surface, then open the cap of POSITIVE CONTROL or NEGATIVE CONTROL tube.
3.Use a pipette or a dropper to transfer 2 drops of dissolved POSITIVE CONTROL or NEGATIVE CONTROL (approximately 80 μL) to the specimen well(S) of the test cassette, then start the timer.
4.Wait for the colored line(s) to appear. Read test results at the designated read time specified in the package insert of specified product.

***NOTE:** The control could be stored at room temperature or refrigerated (2-30℃) . If the powder was dissolved, keep the control solution storing at 2-8℃ for 1 day.

If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

LIMITATIONS

1. The Norovirus+Rotavirus/Adenovirus+Astrovirus+Enterovirus Combo Rapid Test Device (Feces) is for *in vitro* diagnostic use only. The test should be used for the detection of human norovirus, rotavirus, adenovirus and astrovirus,enterovirus in fecal specimens only. Neither the quantitative value nor the rate of increase in human norovirus, rotavirus, adenovirus and astrovirus,enterovirus concentration can be determined by this qualitative test.
2. The Norovirus+Rotavirus/Adenovirus+Astrovirus+Enterovirus Combo Rapid Test Device (Feces) will only indicate the presence of norovirus, rotavirus, adenovirus and astrovirus,enterovirus in the specimen and should not be used as the sole criteria for the conforming norovirus, rotavirus, adenovirus and astrovirus,enterovirus to be etiological agent for diarrhea.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of norovirus, rotavirus, adenovirus and astrovirus,enterovirus infection with low concentration of virus particles.
5. For Norovirus test: fecal specimen from infant under one year old can produce a false positive result.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

1. Norovirus

The performance of the Norovirus Rapid Test Devcie has been evaluated with 136 clinical specimens. The results were tabulated as below.

Method		Other Rapid Test		Total Results
Norovirus Rapid Test	Results	Positive	Negative	
	Positive	33	2	35
	Negative	0	101	101
Total Results		33	103	136

Relative Sensitivity: ＞99.9% (95%CI:*89.4%-99.9%) *Confidence Intervals
Relative Specificity: 98.1% (95%CI:*93.2%-99.8%)
Relative Accuracy: 98.5% (95%CI:*94.8%-99.8%)

2. Rotavirus

The performance of the Rotavirus Rapid Test Devcie has been evaluated with 501 clinical specimens collected from children and young adults in comparison with latex agglutination method. The results were tabulated as below.

Method		Latex Agglutination		Total Results
Rotavirus Rapid Test	Results	Positive	Negative	
	Positive	251	7	258
	Negative	7	236	243
Total Results		258	243	501

Relative Sensitivity: 97.3% (95%CI:*94.5%-98.9%) *Confidence Intervals
Relative Specificity: 97.1% (95%CI:*94.2%-98.8%)
Relative Accuracy: 97.2% (95%CI:*95.4%-98.5%)

3. Adenovirus

The performance of the Adenovirus Rapid Test Devcie has been evaluated with 381 clinical specimens collected from children and young adults in comparison with latex agglutination method. The results were tabulated as below.

Method		Latex Agglutination		Total Results
Adenovirus Rapid Test	Results	Positive	Negative	
	Positive	118	6	124
	Negative	6	251	257
Total Results		124	257	381

Relative Sensitivity: 95.2% (95%CI:*89.8%-98.2%) *Confidence Intervals
Relative Specificity: 97.7% (95%CI:*95.0%-99.1%)
Relative Accuracy: 96.8% (95%CI:*94.6%-98.4%)

4. Astrovirus

The performance of the Astrovirus Rapid Test Devcie has been evaluated with 105 clinical specimens collected from children in comparison with Other Astrovirus Rapid test. The results were tabulated as below.

Method		Other Astrovirus Rapid test		Total Results
Astrovirus Rapid Test	Results	Positive	Negative	
	Positive	33	2	35
	Negative	1	69	70
Total Results		34	71	105

Relative Sensitivity: 97.0% (95%CI:*84.7%-99.9%) *Confidence Intervals
Relative Specificity: 97.2% (95%CI:*90.2%-99.6%)
Overall Accuracy: 97.1% (95%CI:*91.9%-99.4%)

5. Enterovirus

The performance of the Enterovirus Antigen Rapid Test Devcie has been evaluated with 160 clinical specimens. The results were tabulated as below.

Method		Other Test		Total Results
Enterovirus Antigen Rapid Test (Feces)	Results	Positive	Negative	
	Positive	59	1	60
	Negative	1	99	100
Total Results		60	100	160

Relative Sensitivity: 98.3% (95%CI*: 91.1%->99.9%) *Confidence Intervals
Relative Specificity: 99.0% (95%CI*: 94.6%->99.9%)
Overall Accuracy: 98.8% (95%CI*: 95.6%-99.9%)

Precision

Intra-Assay

Within-run precision has been determined by using 3 replicates of five different specimens containing different concentrations of norovirus, rotavirus, adenovirus and astrovirus,enterovirus antigen. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same five different specimens containing different concentrations of norovirus, rotavirus, adenovirus and astrovirus,enterovirus antigen. Three different lots of the Norovirus+Rotavirus/Adenovirus+Astrovirus+Enterovirus Combo Rapid Test Device have been tested over a 3-month period using above negative and positive specimens. The specimens were correctly identified >99% of the time.

Cross-Reactivity

Cross reactivity with following organisms has been studied at 1.0 x 10^7organisms/mL. The following organisms were found negative when tested with the Norovirus+Rotavirus/Adenovirus+Astrovirus+Enterovirus Combo Rapid Test Device (Feces).

Corynebacterium diphtheria	*Neisseria gonorrhea*	*Shigella sonnei*
Pseudomonas aeruginosa	*Shigella flexneri*	*Clostridium difficile*
Enterococcus faecalis	*Proteus vulgaris*	*Gardnerella vaginalis*
Shigella dysenteriae	*Enterococcus faecium*	*Helicobacter pylori*
Candida albicans	*Proteus mirabilis*	*E.coli*

BIBLIOGRAPHY

1.Wadell, G. Laboratory Diagnosis of Infectious Diseases: Principles and Practices. New York: Springer-Verlag, Volume II, 1988: 284-300.
2.WILHELMI I, ROMAN E, SANCHEZ-FAUQUIER A. Viruses causing gastroenteritis. Clin Microbiol Infect. April. 2003, vol.9:247-262
3.Cubitt, WD (1982) Rotavirus Infection: An Unexpected Hazard in Units Caring for the Elderly. Geriatric Medicine Today 1: 33-38
4.Hung, T et al (1984) Waterborne outbreak of Rotavirus Diarrhoea in Adults in China caused by a Novel Rotavirus. Lancet, May 26;1(8387): 1139-1142
5.Cukor, G; Perron, DM; Hudson, R and Blacklow, NR (1984) Detection of Rotavirus in Human Stools by Using Monoclonal Antibody. J. Clin. Microl. 19: 888-892
6.Wood, D. J. and A. S. Bailey. Detection of Adenovirus Types 40 and 41 in Stool Specimens by Immune Electron Microscopy. Journal of Medical Virology, 1987; 21: 191-199.
7.Nishio, Osamu, M. Ooseto, K. Takagi, Y. Yamasita, Y. Ishihara, and S. Isomura. Enzyme-Linked Immunosorbent Assay Employing Monoclonal Antibodies for Direct Identification of Enteric Adenoviruses (Ad40, 41) in Feces. Microbiol. Immunol. 1990; 34(10): 871-877.
8.Wood, D. J., K. Bijlsma, J. C. de Jong, and C. Tonkin. Evaluation of a Commercial Monoclonal Antibody-Based Enzyme Immunoassay for Detection of Adenovirus Types 40 and 41 in Stool Specimens. Journal of Clinical Microbiology, June 1989; 27(6): 1155-1158.
9.Thomas, Eva. E., D. Roscoe, L. Book, B. Bone, L. Browne, and V. Mah. The Utility of Latex Agglutination Assays in the Diagnosis of Pediatric Viral Gastroenteritis. Am. J. Clin. Pathol. 1994; 101:742-746.
10.Madeley CR, Cosgrove BP (1975). "Letter: 28 nm particles in faeces in infantile gastroenteritis". Lancet. 2 (7932): 451–2.
11.Brown DW, Gunning KB, Henry DM, et al. (January 2008). "A DNA Oligonucleotide Microarray for Detecting Human Astrovirus Serotypes". Journal of Virological Methods. 147 (1): 86–92.
12.Matsui SM, Kiang D, Ginzton N, Chew T, Geigenmüller-Gnirke U (2001). "Molecular biology of astroviruses: selected highlights". Novartis Found. Symp. Novartis Foundation Symposia. 238: 219–33; discussion 233–6.
13.Christensen A ,Svein Arne Nordbø.[Enterovirus infections diagnosed in middle Norway during the period 1992-2001].[J].Tidsskrift for Den Norske Lgeforening Tidsskrift for Praktisk Medicin Ny Rkke, 2003, 123(22):3180-3.
14.Kapsenberg J G .Picornaviridae: The Enteroviruses (Polioviruses, Coxsackieviruses, Echoviruses)[J].Springer New York, 1988.DOI:10.1007/978-1-4612-3900-0_36.

Index of Symbols

	Consult instructions for use		Contains sufficient for <*n*> test	EU REP	Authorized representative in the European Community/European Union
IVD	*In vitro* diagnostic medical device		Use-by date		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Batch code	REF	Catalogue number
	Do not use if package is damaged and consult instructions for use		Manufacturer		Date of manufacture

EU REP **VidaQuick Biotech S.L.**
No.132, Rosello Street, Barcelona,
Barcelona Province, 08036, Spain
E-mail: info@vidaquick.com

Rapid Labs Ltd
Unit 2 & 2A Hall Farm Business
Centre Church Road Little Bentley Colchester
Essex CO7 8SD
United Kingdom

Revision 1 03/02/2026