Key Code TSMX7596C
www.oxoid.com/ifu

Europe +800 135 79 135 US 1 855 236 0910

CA 1 855 805 8539 ROW +31 20 794 7071

# ProSpecT
# Rotavirus Microplate Assay

REF R240396 .....96 Tests

## 1 INTENDED USE

The ProSpecT™ Rotavirus test is a qualitative enzyme immunoassay for the detection of rotavirus (Group A) in human faecal samples, as an aid in the diagnosis of acute gastroenteritis caused by Group A rotavirus.

## 2 SUMMARY

Rotaviruses are non-enveloped RNA viruses of icosahedral symmetry consisting of a spherical inner core and two outer capsid shells[1]. At least seven serogroups (A-G) within the genus Rotavirus have been identified[1,2].

Human serotypes of Group A rotavirus are a major cause of gastroenteritis in young children throughout the world[3,4,5,6,7]. Rotavirus gastroenteritis also occurs in older children and elderly populations[8,9,10]. The virus is commonly associated with nosocomial infections in paediatric wards and neonatal nurseries. Outbreaks can result in prolonged hospitalisation and treatment of infected children[11,12,13]. Rotavirus gastroenteritis may be severe, even life threatening, in undernourished or immunocompromised infants[8,9,10].

The laboratory diagnosis of rotavirus infections plays an important role in patient management and enables effective management and control of outbreaks. At present human serotypes of rotavirus do not grow readily in cell culture systems, hence they are difficult to isolate from clinical specimens[14]. Therefore, the laboratory diagnosis of rotavirus infections relies on direct detection of the virus or viral antigens in faecal specimens. This can be performed using electron microscopy to detect the virus or viral antigens, or polyacrylamide gel electrophoresis to detect RNA of the rotavirus genome[3,15,16,17]. These procedures are technically demanding and require specialised equipment which limits their application[14].

Enzyme immunoassays, latex agglutination tests, and immunochromatographic tests using specific monoclonal or polyclonal antibodies, have been described for the direct detection of rotavirus in clinical specimens[18,19,20,21]. These tests offer a rapid, sensitive and specific method for the detection of rotavirus in faecal specimens. Strains may be further characterised by reverse transcriptase polymerase chain reaction, but such testing is not commonly done[22].

The ProSpecT Rotavirus test is an immunoassay for the detection of Group A rotaviruses in faecal specimens. The test utilises a polyclonal antibody to detect group specific proteins, including the major inner capsid protein (VP6), present in Group A rotaviruses.

## 3 PRINCIPLE OF THE TEST

The ProSpecT Rotavirus test utilises a polyclonal antibody in a solid phase sandwich enzyme immunoassay to detect group specific antigen present in Group A rotaviruses. Break-apart microwells are coated with a rotavirus specific polyclonal antibody. Faecal suspension or control sample is added to the microwell and incubated simultaneously with a rotavirus specific polyclonal antibody conjugated to horseradish peroxidase. Rotavirus antigen present in the sample is captured between antibody on the solid phase and the enzyme conjugated antibody. After 60 minutes incubation at room temperature, the microwells are washed with working strength Wash Buffer to remove excess specimen and any unbound enzyme labelled antibody. A chromogen is added to the microwells and incubated for 10 minutes at room temperature. The presence of specifically bound enzyme labelled antibody in the microwells results in a colour change, which is stopped by the addition of acid. Colour intensity significantly above background levels is indicative of the presence of rotavirus antigen in the specimen or control.

## 4 SYMBOL DEFINITIONS

| | |
|---|---|
| REF | Catalogue Number |
| IVD | In Vitro Diagnostic Medical Device |
| Σ | Contains sufficient for <n> tests |
| | Consult Instructions for Use (IFU) |
| | Temperature Limitation (Storage Temp.) |
| LOT | Batch Code (Lot Number) |
| | Use By (Expiration Date) |
| | Manufacturer |
| DILUTED SAMPLE | Diluted Sample |

## 5 KIT CONTENTS, PREPARATION FOR USE AND STORAGE

The ProSpecT Rotavirus Microplate Assay includes sufficient reagents to perform Σ 96 tests.
See also **Precautions,** section **6**.

The expiration date of each kit is stated on the package label.

Store all components at 2 to 8°C.

Before use, bring all reagents to room temperature (20 - 25°C) and mix gently. Return the unused reagents to the refrigerator after use.

All reagents, except the Wash Buffer, are supplied at working strength. Reagents can be dispensed directly from the dropper bottles or poured out for use with multichannel pipettes. If excess reagent has been poured, the excess should be discarded. Do not pour excess reagent back into the bottle.

**Instructions for Use**
**Transfer pipettes**
**Microplate Strip Holder and Cover**
**Certificate of Contents**
**Procedure Card**

MICROTITRATION PLATE

**Microplate* (**8 wells / strip)
12 strips (8 microwell break-apart strips) coated with a rotavirus specific rabbit polyclonal antibody. A resealable foil pouch containing desiccant is provided for storage of unused microwells. Microwells may be used for up to 16 weeks after initial opening, provided they are stored correctly in the pouch.

CONJUGATE

**Enzyme Conjugate***
One dropper bottle containing 12 ml of rotavirus specific rabbit polyclonal antibody conjugated to horseradish peroxidase in a buffered protein solution containing antimicrobial agent and blue dye.

CONTROL +

**Positive Control***
One dropper bottle containing 4 ml of inactivated bovine rotavirus in buffer containing antimicrobial agent.

CONTROL –

**Negative Control***
One dropper bottle containing 4 ml of a tris buffered saline solution, antimicrobial agent and red dye.

SAMPLE DILUENT

**Specimen Dilution Buffer**
One bottle containing 120 ml of a tris buffered saline solution, antimicrobial agent and red dye.

WASH BUFFER (x10)

**Wash Buffer**
One bottle containing 120 ml of a (x10) concentrated phosphate buffered solution containing antimicrobial agent and detergent.

Dilute (x10) Wash Buffer concentrate to (x1) by adding 1 part concentrate to 9 parts distilled or deionised water. Diluted Wash Buffer is stable for up to 30 days when stored at 2 to 8°C.

SUBSTRATE TMB

**Colour Substrate**
One dropper bottle containing 12 ml of 3,3',5,5'-tetramethylbenzidine (TMB) in buffer.

The Colour Substrate should be stored in and used from the light protected bottle in which it is provided. If an aliquot is removed from the original bottle for any reason, do not return unused Colour Substrate to the original bottle.

STOP SOLUTION

**Stop Solution**
One dropper bottle containing 12 ml of 0.46 mol/L sulphuric acid.

***Note:** Do not interchange reagents between kits with different lot numbers.

## 6 PRECAUTIONS

IVD

The reagents are for *in vitro* diagnostic use only.

For professional use only.

Please refer to the Material Safety Data Sheet (MSDS) and product labelling for information on potentially hazardous components.

### HEALTH AND SAFETY INFORMATION

6.1 The Positive Control contains inactivated bovine rotavirus which has been shown to be non-infectious in cell culture. However, the control must be handled and disposed of as though potentially infectious.

6.2 Wash Buffer contains potential skin sensitiser (<1% v/v). Avoid skin contact. Wear disposable vinyl or nitrile gloves.

6.3 Do not eat, drink, smoke, store or prepare foods, or apply cosmetics within the designated work area.

6.4 Do not pipette materials by mouth.

6.5 Wear disposable gloves while handling clinical specimens and reagents. Always wash hands after working with infectious materials.

6.6 Dispose of all clinical specimens in accordance with local legislation.

6.7 ProSpecT Rotavirus reagents contain a proprietary anti-microbial agent which presents no hazard to the user if normal laboratory safety precautions are followed.

### ANALYTICAL PRECAUTIONS

6.8 Components must not be used after the expiry date printed on the labels. Do not mix or interchange the following reagents as performance may be compromised:- Plate, Conjugate and Controls.

6.9 The following common reagents may be used across the ProSpecT product range:- Wash Buffer, TMB Substrate and Stop Solution.

6.10 Avoid contamination of reagents.

6.11 When using the dropper bottle method ensure all controls and reagents are added in the same way. (Performance of the kit may be adversely affected if a combination of pipette and dropper methods are used).

6.12 Use separate disposable pipettes or pipette tips for each sample, control or reagent (if not using dropper bottles) in order to avoid cross contamination of either samples, controls or reagents which could cause erroneous results.

6.13 Store deionised or distilled water for dilution of concentrated reagent in clean containers to prevent microbial contamination.

6.14 Avoid contamination with metal ions and oxidising agents.

6.15 Colour Substrate is sensitive to light exposure. If the reagent is exposed to light and develops colour, the reagent must be discarded.

6.16 Microwells cannot be reused.

6.17 Unused working strength Wash Buffer can be stored for up to 30 days at 2-8°C for subsequent use. When not in use Wash Buffer reservoirs should be rinsed in deionised or distilled water and left to dry.

6.18 Manual or automated washing equipment must be free of microbial contamination, be correctly calibrated and maintained according to the manufacturer's instructions.

6.19 When using reagent dropper bottles, hold the bottles vertically with the nozzle approximately 5 mm above the microwell. Squeeze the bottle **gently** and ensure that the drops fall freely into the microwells without touching the sides of the well. Avoid contamination of all the dropper nozzles.

## 7 COLLECTION OF FAECAL SPECIMENS

Faecal specimens should be collected as soon as possible following the onset of symptoms.

Peak excretion of rotavirus in faeces from patients with gastroenteritis is reported to occur 3-5 days after the onset of symptoms[5].

Faecal specimens for direct testing should be collected into containers that do not contain media, preservatives, animal sera metal ions, oxidising agents or detergents, as all of these additives may interfere with the ProSpecT Rotavirus test.

If rectal swabs are collected they must contain sufficient faecal material to obtain a 10% suspension of faeces (see **Section 8**).

Specimens may be stored for 8 days at 2-8°C prior to testing. For long- term storage of faecal specimens, store at -20°C.

## 8 PROCEDURE

### REQUIRED MATERIALS PROVIDED

See **Kit Contents**, section **5**

### MATERIALS REQUIRED BUT NOT PROVIDED

Faecal specimen collection containers
Clean screw-capped disposable containers (minimum 3 ml capacity) for preparation of faecal specimen
Clean absorbent paper (onto which microwells can be tapped dry)
Precision micropipettes and disposable tips to deliver 50 µl, 100 µl and 1000 µl
Waste discard container with suitable fresh disinfectant
Timer
Wash bottle for Wash Buffer
Distilled or deionised water
Microplate reader capable of reading 450 nm (with 620-650 nm reference optional)

### OPTIONAL MATERIALS NOT PROVIDED

Vortex mixer with plate adapter or plate shaker incubator
Automated plate washer or suitable equipment for washing 8 microwell strips

### PROCEDURE

8.1 Open the foil pouch, remove the required number of microplate strips and place into a microplate strip holder. Use one well for the Negative Control and one well for the Positive Control. If using less than 8 wells break off

RESEAL POUCH TIGHTLY TO EXCLUDE MOISTURE AND RETURN TO STORAGE AT 2-8°C.

### DILUTON OF FAECAL SAMPLES

Add 1ml of Sample Diluent to a suitable labelled container and use to prepare a 10% suspension or dilution of faecal specimen by addition of approximately 0.1 g of solid faeces (small pea-sized portion) or approximately 100 µl of liquid faeces using transfer pipettes. Mix thoroughly and leave transfer pipette in container for later use.

Rotate rectal swabs in 1 ml of Sample Diluent whilst squeezing swab against the side of the container to release faecal material. Mix thoroughly.

Faecal suspensions previously preserved in formalin should be further diluted in ProSpecT Rotavirus Sample Diluent to prepare a 10% suspension of faeces before testing.

Specimens diluted in ProSpecT Rotavirus Sample Diluent may be stored at 2-8°C for up to 8 days prior to testing.

**NOTE: Faecal specimens prepared in ProSpecT Astrovirus, ProSpecT Adenovirus and ProSpecT Norovirus Sample Diluent can also be tested in the ProSpecT Rotavirus test. Alternative Sample Diluents have not been validated for use.**

8.2 Add 2 drops (or 100 µl) of each diluted specimen, Negative Control or Positive Control to the separate microwells. At least one Negative Control and one Positive Control should be included in each batch of tests.

8.3 After addition of all specimens and controls, add 2 drops (or 100 µl) of Conjugate to each microwell.

8.4 Cover the plate and incubate the microwells at 20-30°C for 60 ± 5 minutes.

8.5 Shake out or aspirate the contents of the wells. Wash by completely filling each well with diluted Wash Buffer (~350-400 µl per well). Shake out or aspirate all fluid from wells after each wash. Wash a total of 5 times. After the last wash remove contents and strike plate on clean paper towels or aspirate. If using an automated washer, this should be programmed to complete 5 wash cycles. Washers must be correctly calibrated to ensure complete filling and emptying of microwells between each wash. After the final wash, the plate should be inverted and tapped on absorbent paper to remove the last traces of wash buffer.

8.6 Add 2 drops (or 100 µl) of Substrate to each microwell.

8.7 Cover the plate and incubate the microwells at 20-30°C for 10 minutes.

8.8 Stop the Substrate reaction by adding 2 drops (or 100 µl) of Stop Solution to each microwell. Ensure thorough mixing of the microwells before reading the results. The coloured product is stable for up to 30 minutes after addition of Stop Solution.

8.9 Read spectrophotometrically at 450 nm (see sections **9** and **10**).

## 9 QUALITY CONTROL

At least one Positive and one Negative Control must be included each time the test is performed.

### SPECTROPHOTOMETRIC DETERMINATION

The Negative Control value, or mean of the Negative Control values, should be less than 0.150 absorbance units.

The Positive Control value must be greater than 0.500 absorbance units.

## 10 RESULTS

### SPECTROPHOTOMETRIC DETERMINATION

10.1 The microwells should be read photometrically within 30 minutes of addition of the Stop Solution.

10.2 Mix the contents of the microwells and read the absorbance of each microwell using a spectrophotometer set at 450 nm. Ensure the bottoms of the microwells are clean before reading. The reader should be blanked on air before the plate is scanned.

10.3 If the spectrophotometer allows for the use of a reference wavelength (at 620 to 650 nm), dual wavelength reading should be performed.

10.4 Calculate the cut-off value by adding 0.200 absorbance units to the Negative Control value, or mean value when more than one Negative Control is included.

10.5 Interpret the test results:

| | |
|---|---|
| Positive: | clinical sample absorbance value > the cut-off value. |
| Negative: | clinical sample absorbance value < the cut-off value. |
| Equivocal: | clinical sample absorbance value within 0.010 absorbance units of the cut-off value. These samples should be retested or the patient resampled. |

## 11 PERFORMANCE LIMITATIONS

11.1 The validity of results with the ProSpecT Rotavirus Microplate Assay depends on the control reactions performing as expected. See **Quality Control** section **9**.

11.2 A negative result does not exclude the possibility of rotavirus infection in the patient. Failure to detect rotavirus may be a result of factors such as collection of specimen at an improper time in the disease when too few virions are present, improper sampling and/or handling of the specimen.

11.3 ProSpecT Rotavirus test detects group specific viral proteins present in human serotypes of Group A rotavirus. The test cannot be used to differentiate between serotypes of Group A rotavirus, or to detect other rotavirus serogroups (B-G).

11.4 All reagents are provided at fixed working concentrations. Test performance may be adversely affected if reagents are modified or incorrectly stored under conditions other than those detailed in section **5**.

11.5 The use of ProSpecT Rotavirus Microplate Assay for directtesting of specimens other than faecal specimens is not recommended as either the presence of insufficient antigen or inadequate specimen collection may cause misleading negative results. A positive result in faecal specimens, in association with diarrhoea, is highly suggestive of rotavirus gastroenteritis.

11.6 A positive result does not preclude the presence of other enteric pathogens. Whilst the relationship between rotavirus and gastroenteritis is well established, concurrent infection with other microbial pathogens is possible.

11.7 Meconium samples have not been validated for use with ProSpecT Rotavirus test.

11.8 Test results should be interpreted in conjunction with information available from epidemiological studies, clinical assessment of the patient and other diagnostic procedures.

## 12 EXPECTED VALUES

Positivity rates may vary according to the prevalence of rotavirus in different populations, geographical location, specimen collection, handling, storage, transportation of specimens and the general health environment of the patient population under study[11,12,13,21].

Rotavirus is the most common cause of gastroenteritis in children between the ages of 6 months and 3 years and is responsible for 30-50% of diarrhoeal illness in hospitalised infants and young children. Rotavirus is also associated with outbreaks of diarrhoea in geriatric populations or in institutions[20].

## 13 PERFORMANCE CHARACTERISTICS

### CLINICAL STUDIES

ProSpecT Rotavirus test was evaluated in clinical studies performed at three centres in the UK. Studies were conducted on faecal specimens taken from patients presenting with gastroenteritis. The results of the ProSpecT Rotavirus test were compared with Electron Microscopy (EM) and a commercial enzyme immunoassay (EIA) for the direct detection of rotavirus in faecal specimens.

A total of 201 faecal specimens were tested. The results of these studies are shown in Table 13.1.

### CLINICAL PERFORMANCE

The ProSpecT Rotavirus test, when read photometrically, showed a correlation of 99.5% (200/201) with Electron Microscopy and 99.0% (199/201) with a commercial EIA. The overall sensitivity and specificity of the ProSpecT Rotavirus test, when compared to EM, was 100% (77/77) and 99.2% (123/124) respectively. The relative sensitivity and relative specificity when compared to the commercial EIA was 98.7% (77/78) and 99.2% (122/123) respectively (see Table 13.1). The same specimens were also interpreted visually and the data is presented in Table 13.2.

**Table 13.1 Comparison of ProSpecT Rotavirus (photometric determination) with Electron Microscopy and EIA**

| METHOD | | EM | | EIA | |
|---|---|---|---|---|---|
| | | + | - | + | - |
| ProSpecT Rotavirus | + | 77 | 1 | 77 | 1 |
| | - | 0 | 123 | 1 | 122 |
| Sensitivity | | 100% | | 98.7% | |
| 95% Confidence intervals | | (95%-100%) | | (93%-100%) | |
| Specificity | | 99.2% | | 99.2% | |
| 95% Confidence intervals | | (96%-100%) | | (96%-100%) | |
| Correlation | | 99.5% | | 99.0% | |
| 95% Confidence intervals | | (97%-100%) | | (96%-100%) | |

**Table 13.2 Comparison of ProSpecT Rotavirus (visual interpretation) with Electron Microscopy and EIA**

| METHOD | | EM | | EIA | |
|---|---|---|---|---|---|
| | | + | - | + | - |
| ProSpecT Rotavirus | + | 77 | 2 | 77 | 2 |
| | - | 0 | 122 | 1 | 121 |
| Sensitivity | | 100% | | 98.7% | |
| 95% Confidence intervals | | (95%-100%) | | (93%-100%) | |
| Specificity | | 98.4% | | 98.4% | |
| 95% Confidence intervals | | (94%-100%) | | (94%-100%) | |
| Correlation | | 99.0% | | 98.5% | |
| 95% Confidence intervals | | (96%-100%) | | (96%-100%) | |

### PRECISION

**Intra-assay precision**

The intra-assay precision was assessed using the positive and negative controls and three faecal specimens. Each control and specimen was tested in a single assay 32 times and the mean and coefficient of variation determined (n=32).

**Table 13.4 Intra-assay precision of the ProSpecT Rotavirus test**

| Specimen status | Mean Au | %CV |
|---|---|---|
| Negative Control | 0.06 | 4.8 |
| Positive Control | 1.67 | 4.9 |
| Negative faecal specimen | 0.05 | 4.8 |
| Positive faecal specimen | 0.39 | 6.0 |
| Positive faecal specimen | 1.04 | 7.3 |

**Inter-assay precision**

The inter-assay precision was assessed using the positive and negative controls and three faecal specimens. Each control and specimen was tested individually in 38 different assays performed by three operators and the mean absorbance values and coefficient of variation determined (n=38).

**Table 13.5 Inter-assay precision of the ProSpecT Rotavirus test**

| Specimen status | Mean Au | %CV |
|---|---|---|
| Negative Control | 0.06 | 5.6 |
| Positive Control | 1.43 | 9.9 |
| Negative faecal specimen | 0.06 | 7.8 |
| Positive faecal specimen | 0.41 | 8.1 |
| Positive faecal specimen | 1.10 | 8.5 |

### CROSS-REACTIVITY

The following micro-organisms were tested and shown to be negative in the ProSpecT Rotavirus test. Cross-reactivity tests were performed either on clinical specimens for which the microbial status had been determined, or on laboratory cultures of known organisms, containing approximately $10^7$-$10^8$ viable organisms/ml. The source of micro-organisms is referenced in the key below:

**Viruses**

Adenovirus 1, 2, 3, 5, 40, 41[a]
Astrovirus[a]
Coronavirus[a]
Coxsackie virus B2, B3, B4, B5[a]
Echovirus 9, 11, 18, 22, 32[a]
Enterovirus[a]
Picornavirus[a]
Polio virus types 1, 2, 3[a] (vaccine strains)
Small round structured viruses[a] (including Calici virus)

**Bacteria**

*Aeromonas sp*
*Bacillus cereus*
*Campylobacter spp*[d]
*Clostridium difficile (toxin)*
*Clostridium perfringens (toxin)*[a]
*Clostridium spp*[c]
*Corynebacterium sp*
*Escherichia coli*
*Enteropathogenic E. coli*
*Enterotoxigenic E. coli*
*Lactobacillus spp*
*Legionella spp*[c]
*Listeria monocytogenes*
*Plesiomonas shigelloides*
*Pseudomonas aeruginosa*
*Salmonella agona*
*Salmonella enteritidis*
*Salmonella typhimurium*
*Salmonella virchow*[a]
*Shigella dysenteriae*
*Shigella flexneri*[a]
*Shigella sonnei*[d]
*Staphylococcus aureus*
(protein A producing Cowan strain)
*Streptococcus group A*
*Vibrio alginolyticus*
*Vibrio cholerae*
*Vibrio haemolyticus*

**Protozoa**

*Cryptosporidium sp*[a]
*Entamoeba histolytica*[a]
*Giardia lamblia*[a]

**Other micro-organisms**

*Candida albicans*[c]
*Pneumocystis carinii*[b]
*Trichuris trichiura*[a]

**Key:**

[a] micro-organisms present and tested in faeces
[b] biopsy material
[c] micro-organisms grown on solid culture media
[d] micro-organisms tested both in faeces and in broth culture

All other micro-organisms were tested in broth culture

## 14 BIBLIOGRAPHY


1. **van Regenmortel M.H.V., Fauquet C.M., Bishop D.H.L., Carstens E.B., Estes M.K., Lemon S.M., Maniloff J., Mayo M.A., McGeoch D.J., Pringle C.R. and Wickner R.b., (2000)**
Virus Taxonomy. Seventh Report of the International Committee on Taxonomy of Viruses. pp 421-433

2. **Estes M.K. and Cohen J. (1989)**
Rotavirus Gene Structure and Function
Microbiological Reviews 53: 410-419

3. **Bishop R.F., Davidson G.P., Holmes I.H. and Ruck B.J, (1974)**
Detection of a new virus by electron microscopy of faecal extracts from children with acute gastroenteritis
Lancet i: 149-151

4. **Kapikian A.Z., Yolken R.H., Greenberg H.B., Wyatt R.G., Kalica A.R., Chanock R.M. and Kim H.W. (1980)**
Gastroenteritis viruses. In Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections. 5th Ed., Lennette E.H., Schmidt N.J., Eds. Amer Pub. Health Assoc., Washington D.C. pp 927-996

5. **Flewett T.H. and Woode G.N. (1978)**
The Rotaviruses
Archives of Virology, 57: 1-23

6. **Steinhoff M.C. (1980)**
Rotavirus: The first five years
Journal of Pediatrics, 96: 611-622

7. **Blacklow N.R. and Cukor G. (1981)**
Viral Gastroenteritis.
New England Journal of Medicine, 304: 397-406

8. **Wenman W.M., Hinde D., Feltham S. and Gurwith M. (1979)**
Rotavirus infection in Adults: Results of a Prospective Study
New England Journal of Medicine, 301: 303-306

9. **Cubitt W.D. (1982)**
Rotavirus infection: An Unexpected Hazard in Units caring for the Elderly Geriatric Medicine Today, 1: 33-88

10. **Marrie T.J., Spencer H.S., Faulkner R.S., Ethier J. and Young C.H. (1982)**
Rotavirus Infection in a Geriatric population.
Archives of Internal Medicine, 142: 313-316

11. **Brandt C.D., Kim H.W., Rodriguez W.J et al. (1983)**
Paediatric viral gastroenteritis during eight years of study
Journal of Clinical Microbiology, 18: 71-78

12. **Brandt C.D., Parrot R.H., Kim H.W. and Rodriguez W.J. (1984)**
Diarrhoea viruses: detection, specific identification, and epidemiology
In Medical Virology III (eds. I. de la Maza and E. Peterson) Elsevier New York pp 35-68

13. **Kapikian A.Z. and Chanock R.M. (1985)**
Rotaviruses. In Virology (eds B.N. Fields et al)
Raven Press New York pp 863-906

14. **Martin A.L. and Follet A.C. (1987)**
An assessment of the sensitivity of three methods for the detection of rotavirus
Journal of Virological Methods, 16: 39-44

15. **Kalica A.R., Purcell R.H., Sereno M.M. et al (1977)**
A microtitre solid phase radioimmunoassay for detection of human reovirus like agent in stools
Journal of Immunology, 118: 1275-1279

16. **Herring A.J., Inglis N.F., Ojeh C. et al (1982)**
Rapid diagnosis of rotavirus infection by direct detection of viral nucleic acid in silverstained polyacrylamide gels
Journal of Clinical Microbiology, 16: 473-477

17. **Pyndiah N., Beguin R., Richard J., Charles M., Rey A. and Bonifas V. (1988)**
Accuracy of rotavirus diagnosis: Modified genome electrophoresis versus electron microscopy
Journal of Virological Methods, 20: 39-44

18. **Grauballe P.C., Vestergaard B.F., Meyling A. and Genner J. (1981)**
Optimised enzyme-linked immunosorbent assay for the detection of human and bovine rotavirus in stools: comparison with electron microscopy, immunoelectrophoresis, and fluorescent antibody techniques
Journal of Medical Virology, 7: 29-40

19. **Coulson B.S. and Holmes I.H. (1984)**
An Improved Enzyme Linked Immunosorbent Assay for the Detection of Rotavirus in Faeces of Neonates
Journal of Virolology Methods, 8: 165-179

20. **Cukor G., Perron D.M., Hudson R. and Blacklow N.R. (1984)**
Detection of Rotavirus in Human Stools by Using Monoclonal Antibody.
Journal of Clinical Microbiology, 19: 888-892

21. **Herrmann J.E., Blacklow N.R., Perron D.M., Cukor G., Krause P.J., Hyams J.S., Barrett H.J. and Ogra P.L. (1985)**
Monoclonal Antibody Enzyme Immunoassay for Detection of Rotavirus in Stool Specimens
Journal of Infectious Disease, 152: 830-832

22. **Centres for Disease Control and Prevention (2007)**
Rotavirus (Cause of Diarrhea)




CE

Oxoid Ltd Wade Road Basingstoke Hants, RG24 8PW UK

For technical assistance please contact your local distributor.

IFU X7596C, Revised April 2012 Printed in the UK