Enterovirus Rapid Test

Cat. No.:DTS608
Pkg.Size:

Intended use

The Enterovirus Device is a rapid chromatographic immunoassay for the qualitative detection ofEnterovirus antigens (VP1 peptide) in faecal samples to aid in the diagnosis of Enterovirus infection.

General Description

Enteroviruses consist of Poliovirus, Coxsakievirus, Echovirus, and numbered Enterovirus. Enteroviruses are single-stranded RNA viruses. Enteroviruses can cause a wide spectrum of diseases in humans. All enteroviruses are transmitted by the fecal-oral route, but clinical outcomes may go beyond gastroenteritis, as some viruses travel from the intestinal tract to other organs.Poliovirus usually infects their host by attacking the central nervous system and cause paralysis in victims (poliomyelitis). Coxsackievirus has been associated with not only respiratory system infections and gastroenteritis but also insulin-dependent diabetes and heart diseases, such as myocarditis and pericarditis. Echovirusis generally less infectious than other enteroviruses and are usually associated with the common cold and respiratory diseases. The numbered enteroviruses (Enterovirus types 68 to 71) have not been studied extensively but have been isolated from patients with bronchiolitis, conjunctivitis, meningitis, and paralysis resembling poliomyelitis. Enterovirus Device provides a rapid detection of Enteroviruses directly from the faecal samples.

Principle Of The Test

The Enterovirus Device is a qualitative immunoassay for the detection of VP1 peptide of Enterovirus in faecal samples. The membrane is precoated with mouse monoclonal antibodies against Enterovirus antigen on the test line region. During testing, the sample is allowed to react with the particle conjugate coated with anti-VP1 peptide virus antibodies which was pre-dried on the test strip. The mixture then moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate a coloured line. The mixture continues to move across the membrane to the immobilized antibody placed in the controlband region, a GREEN coloured band always appears. The presence of this GREEN band serves as verification that sufficient volume is added,that proper flow is obtained and as an internal control for the reagents.

Reagents And Materials Provided

Devices
Instructions for use
Specimen collection vial with buffer

Materials Required But Not Supplied

Specimen collection container
Disposable gloves
Timer

Storage

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Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C/36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

Specimen Collection And Preparation

Collect sufficient quantity of faeces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-4°C/36-40°F) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at –20°C/4°F. In this case, the sample will be totally thawed, and brought to room temperature and mix as thoroughly as possible before testing.

Assay Procedure

To process the collected stool samples (see illustration 1):
Use a separate vial for each sample.Unscrew the cap of the vial and introduce the stickin different parts of the faecal specimen to pick up the sample (approx. 150mg) and put into the vial with buffer. Shake the vial inorder to assure good sample dispersion. For liquid stool samples, aspirate the faecal specimen with a dropper and add 150µL into the vial with buffer.
Test Procedure (see illustration 2)
Allow the tests, stool samples and buffer to reach to room temperature (15-30°C/59-86°F) prior to testing. Do not open thepouch until ready to perform the assay.
1. Remove theEnterovirus Device from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure a good sample dispersion.Break off the cap of the vial.
3. Use a separate device for each sample. Dispense exactly 4 drops into the specimen well (S). Start the timer.
4. Read the result at10 minutes after dispensing the sample.

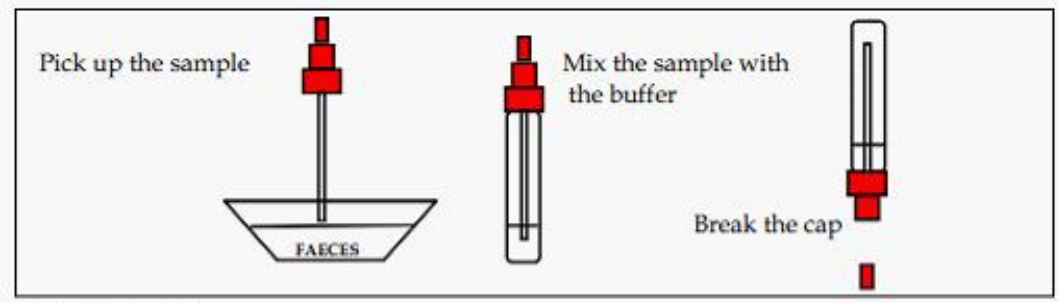
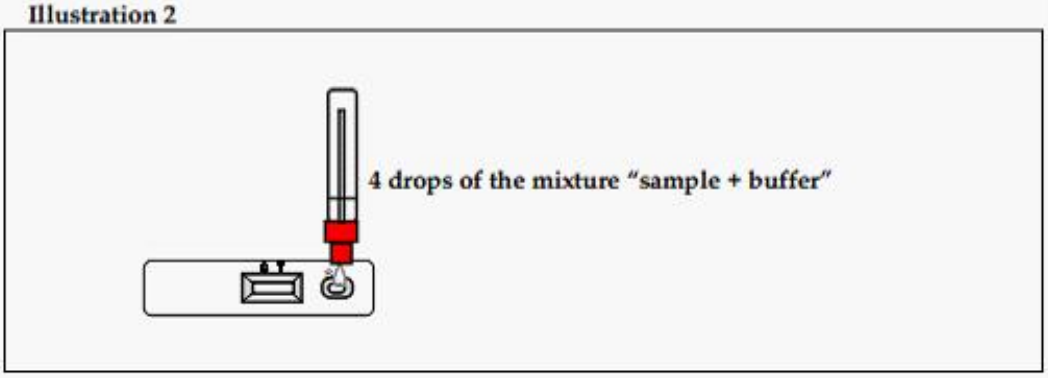


Illustration 2



Quality Control

Internal procedural controls are included in the test: A green line appearing in the control line region (C). It confirms sufficient

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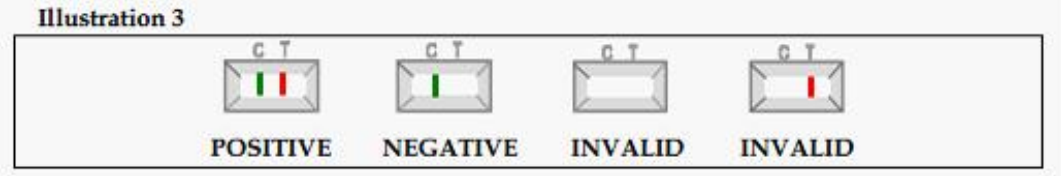
specimen volume and correct procedural technique.

Interpretation of Results

POSITIVE: Two lines appears across the central window in the result line region, ared test line marked with the letter T and in the control line region, a green control line markedwith the letter C.
NEGATIVE: Only one green band appears across the control line region marked with the letter C.
INVALID: A total absence of the green control coloured band regardless the appearance or not of the red test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact you local distributor.
The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of viralantigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.



Expected Values

Enteroviral infections are more prevalent in children than in adults.Enteroviral infections in humans are reported to peak in summer and early autumn, which also coincides with increased water recreational activities and water contact.

Sensitivity

It was studied 35 stool samples using Enterovirus Device and all of them were confirmed by IDEIA Enterovirus assay (Dako)and IMAGEN Enterovirus (Oxoid). The results showed >99% of sensitivity.

Specificity

It was studied 35 stool samples using Enterovirus Device and all of them were confirmed by IDEIA Enterovirus assay (Dako)and IMAGEN Enterovirus (Oxoid). The results showed >99% of sensitivity and >99% of specificity.
The antibodies used to elaborate this test recognise Enterovirus epitopes found in stool patients. This preliminary values has to be taken with precaution until more evaluation data will be available.

Precautions

Do not use after expiration date.
The test should remain in the sealed pouch until use.
Do not use the test if pouch is damaged.
Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke inthe area.
All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
The test should be discarded in a proper biohazard container after testing.
The test must be carried out within 2 hours of opening the sealed bag.

Limitations

1. The test must be carried out within 2 hours of opening the sealed bag.

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2. An excess of stool sample could cause wrong results (brown bands appear).

3. After one month ofinfection, the number of viruses in faeces is decreasing, making the sample less reactive. Stool samples could be collected previously to the onset of symptoms or also at 24-48 hours.

4. This test provides a presumptive diagnosis for Enterovirus group infections. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated and should be determine the serotype of Enterovirus to established the type of disease.

5. If the patient has been recently vaccinated (for example against Poliovirus), it could appear a positive result.

REFERENCES

1. FONG, T. et al. “Enteric Viruses of Humans and Animals in Aquatic Environments: Health Risks, Detection, and Potential Water Quality Assessment Tools”.Microbiology and Molecular Biology Reviews, June 2005, Vol. 69, No. 2: p. 357-371.
2. AFFFI, S. et al. “Isolation and Identification of Non-Polio Enteroviruses from Children in Different Egyptian Governorates”, Australian Journal of Basic and Applied Sciences, 2009, Vol. 3, No. 4: pp. 3230-3238.

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