Enterovirus MonlabTest®

MO-804014 20 TESTS

One step test to detect Enterovirus antigens in human feces

A rapid, one step test for the qualitative detection of Enterovirus antigens (VP1 peptide) in human feces.
Only for professional *in vitro* diagnostic use.

INTENDED USE

Enterovirus MonlabTest® is a rapid chromatographic immunoassay for the qualitative detection of VP1 peptide of Enterovirus antigens in human feces specimens to aid in the diagnosis of enterovirus.

SYNTHESIS

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. *Echovirus* is 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 MonlabTest® provides a rapid detection of Enteroviruses directly from the fecal samples.

PRINCIPLE

Enterovirus MonlabTest® is a qualitative immunoassay for the detection of VP1 peptide of Enterovirus antigens in human feces samples. The membrane is pre-coated with antibodies against Enterovirus antigens on the test line region. During testing, the sample reacts with the particle coated with anti-VP1 peptide, antibodies which were pre-dried on the test strip. The mixture 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 conjugates and generate one or two coloured lines. A green coloured band always appears in the control line (third line) and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- 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 in the 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.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/36-86ºF). 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.

MATERIALS PROVIDED	MATERIALS REQUIRED BUT NO PROVIDED
- 20 Test - Instruction for use - 20 Specimen collection vial with buffer - 1 Control -: negative swab + testing tube + pipette - 1 Control +: positive swab + testing tube + pipette	- Specimen collection container - Disposable gloves - Timer

SPECIMEN COLLECTION AND PREPARATION

Collect sufficient quantity of feces (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 (2-4ºC) for 1-2 days prior to testing. For longer storage the specimen must be kept frozen at -20ºC/-4ºF. In this case, the sample will be totally thawed, and brought to room temperature before testing.

PROCEDURES

To process the collected stool samples (see illustration 1):
Use a separate specimen collection vial for each sample with 1 mL of the buffer. Unscrew the cap of the vial and introduce the stick two times into the faecal specimen to pick up a little of sample (125 mg). Close the vial with the buffer and stool sample. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the faecal specimen with a dropper and add 125µL into the specimen collection 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 pouches until ready to perform the assay.
1. Remove the Enterovirus MonlabTest® from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the tip 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 at **10 minutes** after dispensing the sample.

Illustration 1

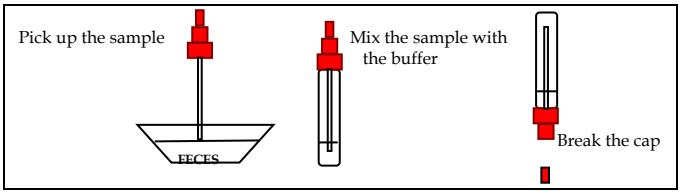
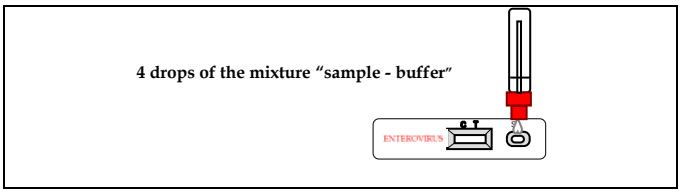


Illustration 2



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INTERPRETATION OF RESULTS

Illustration 3

POSITIVE: Two lines appears across the central window. In the result line region, a **red** test line marked in the illustration 3 with the letter T, and in the control line region, a **green** control line marked in the illustration 3 with the letter C.
NEGATIVE: Only one **green** band appears across the control line region marked with the letter C at the illustration 3 (control line).
INVALID: Total absence of the **green** control coloured band regardless the appearance or not of the **red** test line. See illustration 3. 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 your local distributor.

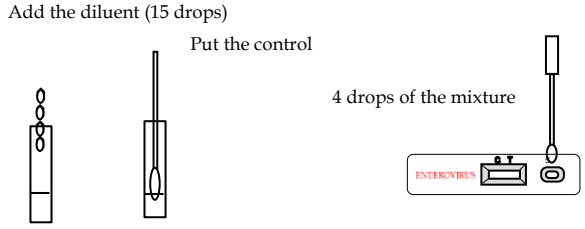
NOTES ON THE INTERPRETATION OF RESULTS

The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of antigens in the specimen. However, neither the quantitative value, nor the rate of increase in antigens can be determined by this qualitative test.

QUALITY CONTROL

Internal procedural controls are included in the test:
- A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

External Quality Control
Each kit contains a positive and negative control material. Use the control swabs to check that the extraction reagents and the test are working properly. Also use the controls to test that you are able to correctly perform the test procedure.
Quality Control Procedure:
Enterovirus Positive control: Remove the *Enterovirus* positive control from its sealed pouch. Add the diluent (15 drops) in a testing tube. Put the *Enterovirus* positive control swab, mix 60 seconds and extract as much liquid possible from the swab. Discard the swab. Remove the test from its sealed pouch and dispense 4 drops of the positive control liquid into the specimen well (S).
Result: *Enterovirus* positive (see interpretation of results).
Enterovirus Negative control: Repeat the procedure for Negative Swab Control using the Reagent Control (-) instead the Reagent Control (+)
Result: *Enterovirus* negative (see interpretation of results).



LIMITATIONS

1. The test must be carried out within 2 hours of opening the sealed bag.
2. An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
3. After one month of infection, the number of viruses in feces 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* infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician.
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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.

PERFORMANCE CHARACTERISTICS

Sensitivity and specificity

It was performed an evaluation 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.

Cross-Reactivity

It was performed an evaluation to determine the cross reactivity of Enterovirus MonlabTest®. There is not cross reactivity with common intestinal parasites occasionally present in feces: Rotavirus, Adenovirus, Astrovirus, Hepatitis A.

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.

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

	Manufacturer	IVD	For *in vitro* diagnostic use only
	Don't re-use		Consult instructions for use
Σ n	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by

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