Enteroviruses directly from the fecal samples.

Enterovirus MonlabTest® provides a rapid detection of conjunctivitis, meningitis, and paralysis resembling poliomyelitis. Enteroviruses extensively but have been isolated from patients with bronchiolitis, diseases, such as myocarditis and pericarditis. Enterovirus enteroviruses (with the common cold and respiratory diseases. The numbered less infectious than other enteroviruses and are usually associated gastroenteritis but also insulin-dependent diabetes and heart diseases, such as myocarditis and pericarditis. Enterovirus 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.

Enteroviruses consist of Poliovirus, Coxsackievirus, 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 specimens to aid in the diagnosis of enterovirus.

**SYNTHESIS**

Enteroviruses consist of Poliovirus, Coxsackievirus, 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.

**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.

**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.

**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 (2-4°C) 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 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 test, 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. Open 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.

**STORAGE AND STABILITY**

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.

**MATERIALS PROVIDED**

<table>
<thead>
<tr>
<th>Materials Provided</th>
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<tbody>
<tr>
<td>- 20 Test</td>
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<tr>
<td>- Instruction for use</td>
</tr>
<tr>
<td>- 20 Specimen collection vial with buffer</td>
</tr>
<tr>
<td>- 1 Control -: negative swab + testing tube + pipette</td>
</tr>
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<td>- 1 Control +: positive swab + testing tube + pipette</td>
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4. Read the result at 10 minutes after dispensing the sample.

**Illustration 1**

Illustration 1

**Illustration 2**

Illustration 2

4 drops of the mixture “sample + buffer”
**INTERNAL PROTOCOL**

**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 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 and dispense 4 drops of the positive control liquid into the specimen well (S).

**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).

**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.

**INTERPRETATION OF RESULTS**

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<tr>
<td>T</td>
<td>S</td>
<td>C</td>
<td>T</td>
<td>C</td>
</tr>
<tr>
<td><strong>POSITIVE</strong></td>
<td>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.</td>
<td></td>
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<tr>
<td><strong>NEGATIVE</strong></td>
<td>Only one green band appears across the control line region marked with the letter C at the illustration 3 (control line).</td>
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**EXTERNAL QUALITY CONTROL**

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.

**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.

**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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**REFERENCES**


**SYMBOLS FOR IVD COMPONENTS AND REAGENTS**

- Manufacturer
- Don’t re-use
- IVD
- Contains sufficient for <n> tests
- Catalogue Code
- Keep dry
- Lot Number
- Temperature limitation
- Use by

Ref: MO-804014
Revision: May 2015

Manufacturer: Monlab SL Selva de Mar 48 08029 Barcelona Spain +34 93 433 58 60 Fax:+34 93 436 38 94 pedidos@monlab.com www.monlab.com