ENTEROVIRUS

For *in Vitro* diagnostic use only

Immunochromatographic test for the qualitative detection of *Enterovirus* antigens in human faeces

I. INTENDED USE

Enterovirus group includes *Poliovirus*, *Coxsackievirus*, *Echovirus* and *Enterovirus*. Enteroviruses cause a wide spectrum of diseases in humans, such as febrile syndrome, sore throat, meningitis and myocarditis. They are transmitted by fecal-oral route.
Enterovirus Mascia Brunelli is an immunochromatographic rapid test for the qualitative detection of Enterovirus antigens (VP1 peptide) in human faecal samples.

II. PRINCIPLE OF THE TEST

The ENTEROVIRUS is a sandwich immunochromatographic assay that uses monoclonal antibodies conjugated with latex, specific against enterovirus antigens, and monoclonal antibodies coated for the direct determination of Enteroviruses in faeces, with high sensitivity and specificity.
During testing, the sample is allowed to react with the coloured conjugate which was pre-dried on the test strip. If Enterovirus are present in the sample, they will be captured by the coloured conjugate, producing a red band in "T" area. The mixture continues to move across the membrane by capillary action to the immobilized antibody placed in the control band region and a green coloured band always appears. The presence of this green band serves as verification that the reagents work correctly.

III. REAGENTS AND MATERIALS

Each kit contains:
1. Enterovirus card (25 devices): the devices are in a sealed pouch containing a desiccant.
2. Extraction buffer-Diluent (25 x 1,0 mL).
3. Plastic dropper (6 items).
4. Instruction for use (1)

Required materials (not supplied)

Specimen collection container, disposable gloves and Timer.

IV. SPECIAL PRECAUTIONS

- The kit is for professional use and for in vitro diagnostic use only.
- Do not use after expiration date. Do not use the test if the pouch is damaged.
- The test should remain in the sealed pouch until use.
- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.
- 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.

V. 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.

VI. SPECIMENS COLLECTION

Collect the samples as soon as possible after the appearance of specific symptoms. Do not use preservatives or animal serum, detergent or transport medium that may interfere with the test.
If testing cannot be performed immediately, specimens should be stored at 2-8℃ for 1-2 days or frozen immediately at -20℃ for longer storage. In this case, the sample will need to be totally thawed, and brought to room temperature before testing.
Unscrew the cap of an extraction tube. Collect the stool sample with the tip of the collection device by dipping in three different places of the same stool specimen. Transfer a small portion (approximately 6 mm diameter) of stool. Put the collection device back into the tube. Shake the extraction tube in order to get an homogeneous suspension. Wait at least 3 minutes. Repeat the procedure in order to obtain a dark yellow-brown solution, if necessary.
The transfer of too little stool, or failure to mix and completely suspend the stool in the extraction tube may result in a false negative test result. Care should be taken to transfer not less and not more than the indicated amount. The sample should be thoroughly mixed with a vortex before testing. The addition of an excessive amount of stool may cause invalid results due to limited sample flow.

VII. PROCEDURE

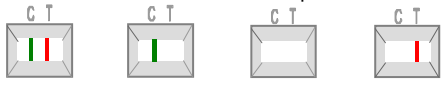
1. Allow the tests, stool samples and diluents to reach room temperature. Remove the device card from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial.
3. Breack the cap of the vial with sample and dispense 4 drops or 150uL into the specimen well.
4. Wait **10 minutes** after dispensing the sample and observe the appearance of the coloured bands "T" and "C"..

VIII. INTERPRETING THE RESULTS

Negative test: Only one GREEN control band appears across the central window in the site marked with the letter C (control line). The sample is negative for Enterovirus.

Positive test: In addition to the GREEN control band across the central window in the site marked with the letter C (control line), a RED band (test line) also appears in the site marked with the letter T (result region). The sample contains Enterovirus.

Invalid: A total absence of the control coloured band. Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are likely the reasons for control line failure. Review the procedure and repeat the tests using a new test.



Positive Negative Invalid

IX. PERFORMANCE

A. EXPECTED VALUES

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

B. SENSITIVITY AND SPECIFICITY

More than 99% correlation between ENTEROVIRUS Mascia Brunelli, IDEA Enterovirus assay (Dako) and IMAGEN Enterovirus (Oxoid). 35 positive samples and 30 negative samples were tested.

C. INTERFERENCES

There is no cross reactivity with Adenovirus, Rotavirus, HAV A, Astrovirus and Norovirus because of the presence of specific monoclonal antibodies against enterovirus.

X. LIMITS OF THE KIT

1. Enterovirus Mascia Brunelli will only indicate the presence of Enterovirus in the specimen (qualitative detection). Neither the quantitative value nor the rate of increase in enterovirus antigens concentration can be determined by this test.
2. The test must be carried out within 2 hours of opening the sealed bag.
3. A positive result does not preclude the possibility of infections by other pathogens
4. An excess of stool sample could result in wrong results (brown bands appear or absence of the control coloured band).
5. After one month of infection, the number of viruses in faeces is decreasing, making the sample less reactive. Stool samples should be collected as soon as possible after to the onset of symptoms and also at 24-48 hours.
6. This test provides a presumptive diagnosis for Enterovirus group infection. A confirmed infection diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated and the serotype of Enterovirus should be determined to establish the type of disease.
7. If the patient has been recently vaccinated (for example against Poliovirus), a positive result could appear.

XII. REFERENCES

- 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.
- AFFI, 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: p. 3230-3238.

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT (25 tests)	**COD. VC1026**
ENTEROVIRUS card	25 Devices (Card)
Extraction Buffer-Diluent	25 x 1,0 mL
Plastic dropper	6 items
Instruction for use	1item

EDMA (EDMS) CODE 1504800200 CE IVD