HAV MonlabTest®

MO-804027 20 TESTS

One step test to detect Hepatitis A

A rapid, one step test for the qualitative detection of Hepatitis A virus in human feces.
For professional in vitro diagnostic use only.

INTENDED USE

HAV MonlabTest® is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis A virus in fecal samples in order to aid in the diagnosis of HAV infection.

SYNTHESIS

The Hepatitis A virus is a single-stranded RNA virus that belongs to the *Picornaviridae* family of viruses. The majority of acute HAV infections are subclinical. When symptoms do appear, they tend to be mild and non-specific in nature. Most commonly they include fever, general malaise, fatigue, abdominal discomfort and change in bowel habits. When severe, dark urine, pale stool and jaundice may appear. The severity of acute HAV infections is proportional to the age of the patient, with younger patients tending to have milder disease than the elderly.
HAV is spread through faecal contamination of food or drinking water. Although the virus is present in blood, the limited amount of circulating virus and short duration of viremia render parenteral transmission of this virus extremely uncommon. Faeces of infected individuals tend to contain the virus for a 2-week period prior to the onset of illness and for at least 2 weeks and perhaps as long as 3 months thereafter.
Acute hepatitis A is one of the well known vaccine preventable diseases and active Hepatitis A virus (HAV) vaccination is recommended in high risk populations.
HAV MonlabTest® provides a rapid detection of Hepatitis A directly from the faecal samples.

PRINCIPLE

The HAV MonlabTest® is a qualitative lateral flow immunoassay for the detection of Hepatitis A virus in human feces samples. The membrane is pre-coated with antibodies against HAV antigens on the test line region. During testing, the sample reacts with the particle coated with anti-HAV antibodies which was 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 coloured lines. A green coloured band always appears in the control 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 pack until use.
- Do not use the test if pack 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 pack either at refrigerated or room temperature (2-30ºC/36-86ºF). The test is stable through the expiration date printed on the sealed pack. The test must remain in the sealed pack until use. Do not freeze.

MATERIALS PROVIDED	MATERIALS REQUIRED BUT NO PROVIDED
- 20 Tests - Instruction for use - 20 Specimen collection vial with buffer	- 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 (2º-8ºC/36º-46.4ºF) for 1-2 days prior to testing. For longer storage (maximum 1 year) 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.

PROCEDIMIENTO

To process the collected stool samples (see illustration 1):
Use a separate specimen collection vial for each sample (with 1mL of the buffer). Introduce the swab or stick two or three times into the fecal specimen to pick up the sample (approx. 125 mg) and put into the testing tube or vial with buffer. Shake the testing tube or vial in order to assure good sample dispersion. For liquid stool samples, aspirate the fecal specimen with a dropper and add 125µL into the testing tube or 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 HAV 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 top of the vial.
3. Use a separate device for each sample. Dispense 4 drops into the specimen well (S). Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.

Illustration 1

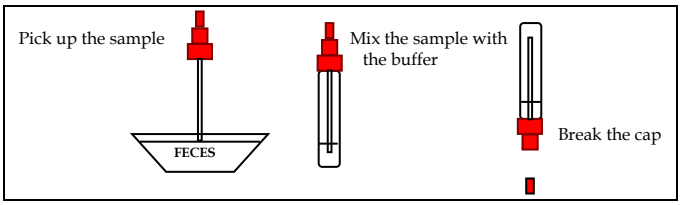
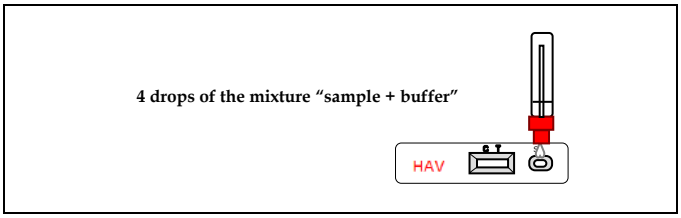


Illustration 2

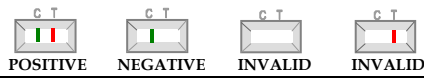


Ref: MO-804027
Revision: October 2015

Manufacturer: Monlab SL Selva de Mar 48 08019 Barcelona Spain +34 93 433 58 60 Fax +34 93 436 38 94 pedidos@monlab.com www.monlab.com

INTERPRETATION OF RESULTS

Illustration 3



POSITIVE**:** Two lines appear 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 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.

LIMITATIONS

1. HAV MonlabTest® will only indicate the presence of HAV in the specimen (qualitative detection) and should be used for the detection of HAV antigens in feces specimens only. Neither the quantitative value nor the rate of increase in HAV antigens concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown lines appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control line.
4. After one month of infection, the number of viruses in faeces is decreasing, making the sample less reactive. Faecal samples should be collected previously to the onset of symptoms to stop the spread of viruses.
5. Si If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of HAV infection.
6. This test provides a presumptive diagnosis of infection caused by HAV. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

EXPECTED VALUES

The severity of acute HAV infections is proportional to the age of the patient, with younger patients tending to have milder disease than the elderly. Indeed, overall mortality rates are only 0.1% in the general population as opposed to 1–2% in the elderly.

PERFORMANCE CHARACTERISTICS

Sensitivity and specificity

It was performed an evaluation using HAV MonlabTest® and compared with other immunochromatographic test. The result was confirmed by HAV-Antigen EIA (Mediagnost®). The results were >99% of sensitivity and >99% of specificity.

Cross-Reactivity

It was performed an evaluation to determine the cross reactivity of HAV MonlabTest®. There is not cross reactivity with common gastrointestinal pathogens, other organisms and substances occasionally present in feces.

- Adenovirus
- Astrovirus
- Enterovirus
- Norovirus
- Rotavirus

REFERENCES

- MINUK, G.Y. et al. "Viral hepatitis and surgeon". *HPB*, 2005; 7: 56-64.
- BRUGUERA, M. et al. "Prevención de las hepatitis virales". *Enferm Infecc Microbiol Clin. 2006;24:649-56.*

SYMBOLS FOR IVD COMPONENTS AND REAGENTS

	Manufacturer	IVD	For i*n 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

Manufacturer: Monlab SL Selva de Mar 48 08019 Barcelona Spain +34 93 433 58 60 Fax +34 93 436 38 94 pedidos@monlab.com www.monlab.com