

INTENDED USE

The Proflow™ HAV test is a single use rapid membrane immunoassay for the qualitative detection of Hepatitis A antigen in faecal samples to aid in the diagnosis of HAV infection. For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

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 viraemia render parenteral transmission of this virus extremely uncommon. Faeces of infected individuals tends 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.

PRINCIPLE OF THE TEST

The Proflow™ HAV test is a single use rapid membrane immunoassay for the qualitative detection of Hepatitis A antigen in human faecal samples.

Monoclonal antibodies to Hepatitis A antigen are coated onto the test line region of the strip. During testing the sample migrates along the membrane by capillary action and is allowed to react with the conjugate on the test strip.

In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. A green line should always appear in the control line region to show that sufficient volume was added, proper flow was obtained and the reagents functioned correctly. Failure of the control line to appear, whether or not test lines are present, indicates an invalid assay.

The test is interpreted by the presence or absence of visibly detectable coloured lines in the test region at 10 minutes or less depending on the concentration of antigen present. A positive result will show a pink/red test line and a green control line, indicating that Hepatitis A antigen is present in the sample. A negative test result, read at 10 minutes, will show only a green control line, indicating that Hepatitis A antigen was not detectable in the sample.

MATERIALS PROVIDED

- PL.3114 Proflow™ HAV Test Devices: 20 devices
- PL.3214 Proflow™ HAV Sample Preparation Device: 20 devices
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Sample collection container
- Timer or stopwatch
- Biohazard disposal container
- Disposable gloves

STABILITY AND STORAGE

- Store all components at 2-30°C.
- Do not freeze or overheat.
- Do not use beyond the expiration date printed on the outer package label.
- The test kits should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For *In Vitro* Diagnostic Use only.
- For professional use only.
- Directions should be read and followed carefully.
- Tests are for single use only. Do not reuse.
- Reagents are provided at the necessary working strength. Do not dilute reagents.
- Do not interchange reagents between kits with different lot numbers.
- Do not use kits or reagents beyond the stated expiration dates.
- Microbial contamination of reagents may decrease the accuracy of the assay.
- Treat all materials as if they were infectious and dispose of all material in accordance with local regulation.

SAMPLE STORAGE AND COLLECTION

- Collect sufficient quantity of faeces (1-2g or mL for liquid samples)
- Faecal samples should be collected in clean and dry containers (no preservatives or transport media).
- Samples may be stored at 2-8°C for 1-2 days or at -20°C for longer periods before testing.
- Allow all samples to equilibrate to room temperature before testing.
- Freezing and thawing cycles are not recommended.

TEST PROCEDURE

Use a separate sample collection vial and test for each sample or control. Allow the tests, faecal samples and buffer to reach room temperature prior to testing.

1. Introduce the swab or stick four times into the faeces up to the thread of the stick to pick up approx. 50 mg and put back into the sample preparation device with buffer. For liquid faecal samples, aspirate with a dropper and add 50 µL into the sample preparation device.
2. Shake the sample preparation device to ensure good sample dispersion.
3. Remove the Proflow™ HAV test from its sealed pouch.
4. Break off the top of the vial on the sample preparation device.
5. Dispense 3 drops (100 µL) into the sample well on the test (S).
6. Read the result at 15 minutes.

QUALITY CONTROL PROCEDURE

It is recommended that a positive and negative control be used to ensure that the test is performing as expected.

The control line (C) is a procedural control and will show that the test has been performed correctly; proper flow occurred and that the test reagents functioned as expected. When a green line appears at the control line position this indicates the test has been performed correctly. The control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the Interpretation of Results section).

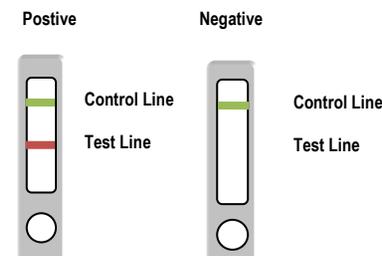
INTERPRETATION OF RESULTS

Positive

A pink/red line of any intensity appears in the test window at the test line position. This indicates a reactive result that is interpreted as positive for Hepatitis A antigen.

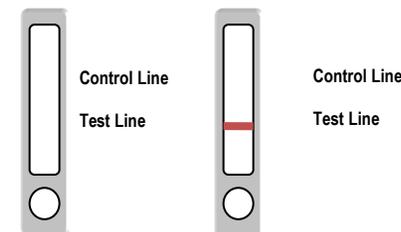
Negative

A single green line of any intensity appears in the test window at the control line position. There is no line at the test line position. This indicates a non-reactive result that is interpreted as negative for Hepatitis A antigen.



Invalid

No line appears in the test window at the control line position. This is an invalid result and cannot be interpreted. This is irrespective of whether or not a pink/red line appears in the test window at the test line position. If either condition below occurs, the test should be repeated with a new test.



Proflow™ Hepatitis A Virus (HAV)

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3014



20 Tests

LIMITATIONS OF THE PROCEDURE

- The test must be carried out within 2 hours of opening the sealed bag.
- An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
- Some faecal samples can decrease the intensity of the control line.
- After one month of infection, the number of viruses in the faeces decreases, making the sample less reactive.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended.
- This test provides a presumptive diagnosis of HAV infection.

PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY

An evaluation was conducted comparing the results obtained using the Proflow™ HAV test with a commercial EIA test.

Proflow™ HAV test showed:

Specificity >99%
Sensitivity >99%

CROSS-REACTIVITY

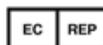
An evaluation was performed to determine the cross-reactivity of the Proflow™ HAV test. There was no cross-reactivity with common intestinal pathogens or other organisms occasionally present in faeces:

- Rotavirus
- Adenovirus
- Astrovirus
- Enterovirus
- Norovirus.

REFERENCES

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

	= Use by
	= Lot number
	= Catalogue number
	= Manufacturer
	= Authorized Representative in the European Community
	= Contains sufficient for <n> tests
	= In vitro diagnostic medical device
	= Temperature limitation
	= Consult instructions for use



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