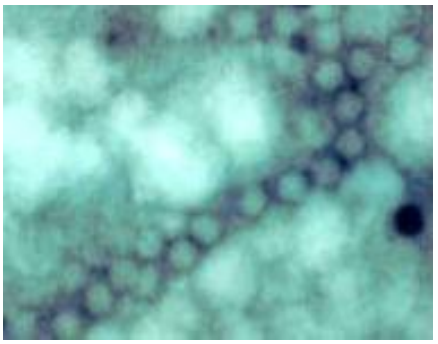
Hepatitis A (HAV)

RAPID TEST



Rapid chromatographic immunoassay for the qualitative detection of ***Hepatitis A antigens*** *in fecal samples*

1. What is HEPATITIS A?

An acute infectious disease of the liver caused by the hepatitis A virus (HAV), which is transmitted person-to-person by ingestion of contaminated food or water or through direct contact with an infectious person. Tens of millions of individuals worldwide are estimated to become infected with HAV each year. The time between infection and the appearance of the symptoms, (the incubation period), is between two and six weeks and the average incubation period is 28 days.

Although HAV is excreted in the feces towards the end of the incubation period the specific diagnosis is made by the detection of HAV-specific IgM antibodies in the blood. IgM antibody **is only present in the blood following an acute hepatitis A infection**. It is detectable from one to two weeks after the initial infection and persists for up to 14 weeks. The presence of IgG antibody in the blood means that the acute stage of the illness is past and the person is immune to further infection, so this diagnosis **doesn't distinguish between the active infection against the previous exposure to the microorganism**. Advantages of the antigen HAV detection: *H&R HAV* antigen test is a noninvasive method which determines the microorganism using the fecal samples, route of excretion of the virus, so it provides a **direct detection.**

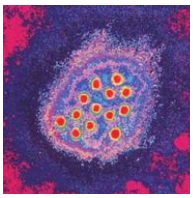
HAV infection produces a self-limited disease that does not result in chronic infection or chronic liver disease. However, 10%–15% of patients might experience a relapse of symptoms during the 6 months after acute illness. These symptoms include: fatigue, fever, abdominal pain, nausea, diarrhea, appetite loss, depression, itching…. Adults have signs and symptoms of illness more often than children and the severity of disease and mortality increases in older age groups. Infected children under six years of age do not usually experience noticeable symptoms, and only 10% develop jaundice. Among older children and adults, infection usually causes more severe symptoms, witºh jaundice occurring in more than 70% of cases. Most people recover in several weeks - or sometimes months - without complications.

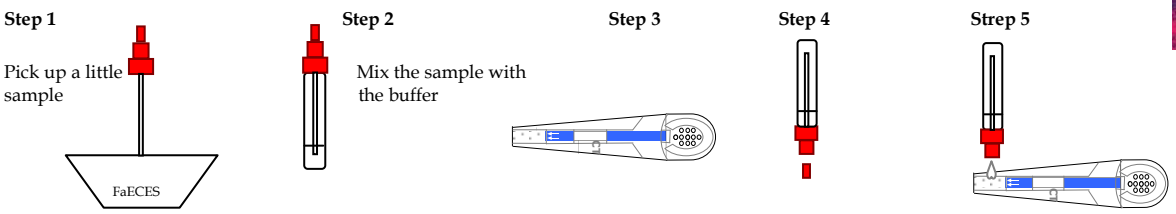
2. What is *H&R HAV* test?

The *H&R HAV* test is a qualitative immunochromatographic assay for the determination of Hepatitis A virus in fecal samples. The membrane is pre-coated with mouse monoclonal antibodies, on the test band region, against viral antigens.

3. How is *H&R HAV* test performed?

1. Unscrew the cap of the vial and introduce the stick in different parts of the faecal specimen to pick up the sample (approx. 150mg). Close the vial with the buffer and stool sample.
2. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the faecal specimen with a dropper and add approx. 150µL into the specimen collection vial with buffer.
3. Remove the *H&R HAV test* from its sealed pouch and use it as soon as possible.
4. Break off the cap of the vial.
5. Dispense exactly 5 drops or 150 µL into the specimen well.





3. Interpretation of results

4. Performance Data

Were analyzed 26 stool samples using *H&R HAV test* and all of them were confirmed by HAV-Antigen EIA assay (Mediagnost®). The results showed >99% sensitivity and >99% specificity.
The antibodies used to elaborate this test recognise HAV epitopes found in stool patients.

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