

# Place of Point-of-Care Tests (POCTs) in hepatitis B screening strategy

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**HAS recommends the combined use of hepatitis B virus (HBV), human immunodeficiency virus (HIV) and hepatitis C virus (HCV) POCTs as complementary screening tools to conventional laboratory screening specially in high risk populations located far away from common access structures, frequenting medico-social and community structures. HAS reiterates that these point-of-care tests do not replace serological screening, which remains the standard.**

## WHAT IS THE PLACE OF POCT IN THE HEPATITIS B SCREENING STRATEGY?

### Hepatitis B in France

Despite the availability of an HBV vaccine, hepatitis B remains to date a major public health challenge. In France it affects about 280,000 people who are chronic carriers of the hepatitis B virus surface antigen (HBsAg), more than half (55%) of which are unaware of their status, and it is responsible for around 1,300 deaths per year.

While hepatitis B screening activity in France is substantial and constantly expanding (3.8 million HBsAg serologies in 2013), screening is still insufficiently targeted and there is still a delay in diagnosis in about 11% of people who have a severe form of liver disease at diagnosis.

### A screening strategy based on detection of the three hepatitis B virus infection markers

The hepatitis B screening strategy is currently based on detection of the three HBV infection markers (HBsAg, anti-HBs Ab, anti-HBc Ab) by an Elisa test performed using a venous sample.

Testing for the three markers at the outset offers the benefit of allowing the exact immune status of the person screened to be determined, and thus to achieve the dual objective of the screening, which aims to identify:

- persons with chronic hepatitis to allow early treatment;
- high risk persons who have never had contact with hepatitis B to offer them vaccination.

**HAS recommends harmonising the National Health Insurance coverage rate for serological screening for HBV infection with that for serological screening for HIV or HCV infection for which no contribution by the insured is expected.**

## A small HBV POCTs market

The majority of existing HBV POCTs detects HBsAg, satisfying only one of the hepatitis B screening objectives (i.e. Identification of individuals who are chronic carriers).

In France, the market of HBV POCTs available is currently limited. A single test detecting HBsAg on whole blood having obtained CE marking is marketed in France. This is the Vikia® HBsAg test from Biomérieux, France. This test is properly evaluated by independent manufacturer studies, and has performances deemed satisfactory in whole blood (sensitivity ranging from 59.5% to 96.5% based on sampling conditions and specificity above 99.8%).

However, market developments are expected in the short term in France.

A test detecting anti-HBs Ab (Toyo anti-HBs Ab® from Turklab, Turkey) has obtained CE marking but is not currently marketed in France.

### HBV POCT: a detection limited to the HBsAg

- Today, **screening by HBV POCTs (HBsAg) can in no way replace laboratory screening** due to the unavailability of rapid tests that detect all three markers of viral hepatitis B infection.
- Laboratory (serological) screening remains the standard.

## Confirmed benefits of POCT

Although their performances are lower, the feedback on the use of HIV POCTs in France and experiments conducted with HBV POCTs (+/- in combination with others HIV and HCV POCTs) confirm the benefits of POC testing in terms of acceptability and ease of access to screening in a medicalised and non-medicalised framework, especially in populations not sufficiently reached by the conventional laboratory screening. The cost per positive screening by POCT appears lower in community associations than the laboratory screening, due to the higher rates of positivity observed and despite a higher unit cost.

Moreover, the results of studies on the impact of POC testing on the link to care are encouraging, since the persons screened by POCT are oriented toward medical care at a level equivalent to that observed in case of laboratory screening, provided that coordination or links are planned between the actors and the structures involved in screening, care, and social medicine.

### POCT : a complementary screening tool to hepatitis B laboratory screening

#### In support of a use of HBV POCTs

- The use of HBV POCTs is recommended as a **complementary screening tool to conventional laboratory screening** since it may be more appropriate for high risk populations not or insufficiently screened and distant from common access structures.

#### For the following populations

- Persons from high and medium endemic areas, drug users, persons already infected by HIV or HCV and who are not under medical monitoring, detainees, sex workers, the most isolated and vulnerable persons who are in a precarious situation, and who frequent centres such as Continuous Access to Health Care (PASS) centres, Care and Support Centres for Reduction of Risks for Drug Users (CAARUD), Centres for Care, Support and Prevention in Addition (CSAPA), community associations, places for medico-social assistance, resocialisation, or marginalised populations hard-to-reach outside of specific “extramural<sup>1</sup>” actions.

1. “Extramural” actions are implemented outside of association premises, in mobile structures (bus, tent, mobile stands, etc.) or in places where the target populations live and during the day or at night.

## Interpretation of the results of a rapid test and advice to give during the HBV POC screening

The screening must be an opportunity for counselling about the methods of contamination and means of prevention of the HBV infection, both for tested people and for their family. In particular **reminder of the benefit of the HBV vaccination must be given systematically**.

### HBV POCTs in practice

#### If positive

- A positive HBsAg POCT (direct infection marker) indicates the likely active nature of the viral infection.
- The person who screened positive should be guided toward specialised care, allowing for a full diagnostic serological assessment to be done (with confirmation of the positivity of HBsAg by Elisa immunoenzymatic assay), as well as an assessment of liver damage before deciding on treatment needs.

#### If negative

- A negative HBsAg POCT, at least 3 months after the presumed date of infection, suggests lack of infection; however, only laboratory screening can confirm the result.
- The screened person must be encouraged to undergo a laboratory screening in a biomedical testing laboratory or a free information, screening and diagnostic centre (CeGIDD) allowing testing of the three infection markers and check vaccination needs.

## TOWARD A COMBINED SCREENING APPROACH FOR CHRONIC VIRAL DISEASES

Considering:

- the epidemiological similarities in terms of contamination risk factors, frequency of co-infections;
- the possibility of performing tests in combination with other HIV and HCV POCTs, including combining actors and resources;

every screening opportunity in these high risk populations who do not frequent the usual screening structures must be considered, and this justifies the proposal of a combined screening by HIV/HCV/HBV POCT.

### In support of a combined use of HIV/HCV/HBV POCTs

- Within these high risk populations, HAS recommends the development of a combined screening offer for sexually transmitted infections, including by HIV, HCV and HBV POCTs.

Screening by POCTs must also be part of a **more global objective of health education and reduction of risks and harm** and constitutes, for the populations distant from care, a contact opportunity with the health system, allowing dissemination of general prevention messages related to these infections and a reminder about the opportunity for screened people or their friends and family members to receive a hepatitis B vaccination.

## OPTIMISATION OF THE COMBINED SCREENING

To optimise the implementation of combined screening actions by HIV/HCV/HBV POCTs, and considering the accumulated experience in France in studies conducted with the HBV POCTs and experiments on the use of HIV POCTs in medico-social and community structures, HAS recommends:

- applying the **same regulatory and quality requirements as those in place for HIV** for actors in the medico-social or community field;
- a **coupling of training (extended to STIs and vaccination) and authorisations** for community structures;
- a **spread of the device to a larger number of volunteer associations**;
- an **expansion to other actors** such as general practitioners or pharmacists when they are volunteers or involved in the healthcare networks.

### Improved efficiency of the POC testing

#### By better targeting of actions

- To screen people in populations where the prevalence of infections is likely to be higher.

#### By a link upstream of the screening structures, healthcare networks and medico-psycho-social structures

- To promote the relationship toward care and keeping screened persons in the healthcare system.

#### By a sustainable and equitable funding system regardless of the actors

- To ensure access to POCTs throughout the country.

#### By national tenders for POCTs orders

- To reduce the costs for the actors involved.

Finally, HAS recommends **continuing monitoring** the implementation of the offer of combined screening by HIV/HCV/HBV POCTs **and assessment of its impact on access to care and to the medico-social system. HAS also deems it necessary to implement studies to document the impact of POC screening on the prognosis of infections and the efficiency of the POC testing.**



This document presents the key points from the public health recommendation:  
“Place of rapid diagnostic tests in the hepatitis B screening strategy” – June 2016  
These recommendations and the scientific justification are available in their entirety  
on [www.has-sante.fr](http://www.has-sante.fr)