

Hepatitis B Testing Guide

Background

Hepatitis B virus (HBV) infection is a major global public health threat. Early diagnosis and treatment, as well as vaccination of susceptible persons, can reduce the population incidence of liver cirrhosis, liver cancer and death from liver failure.

The majority of hepatitis B infections in Australia are chronic (having persisted for more than 6 months duration) and occur in people born in countries or communities of intermediate and high prevalence who contracted the infection at birth or during early childhood.

Appropriate testing indicates whether an individual has:

- current hepatitis B infection (acute or chronic)
- cleared the virus spontaneously (natural immunity)
- immunity through previous hepatitis B vaccination.

Testing can also help determine the severity and stage of infection, and these results direct decisions about whether antiviral therapy is indicated.

Testing for HBV includes serology and, sometimes, nucleic acid testing – usually HBV DNA.

Indications for testing

An individual's risk of HBV infection should inform the decision to perform HBV testing. It is recommended that informed consent be obtained for HBV testing.

Clinical suspicion of HBV infection may occur in the context of:

- birth in an intermediate or high prevalence country
- being an Aboriginal or Torres Strait Islander person
- children of women who are HBsAg positive
- unvaccinated adults at higher risk of infection
- individual or family history of chronic liver disease or liver cirrhosis
- individual or family history of hepatocellular carcinoma (HCC)
- evaluation of abnormal liver function tests
- acute hepatitis
- family, sexual or household contact with a person known or suspected to have HBV infection

Other situations where HBV testing may be indicated:

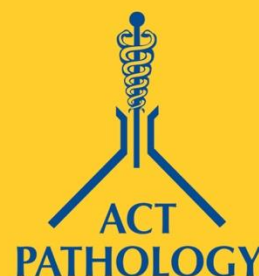
- pregnant women or women contemplating pregnancy
- healthcare workers
- contact tracing (where exposure to blood or body fluids of a person with the infection is documented)
- following occupational or non-occupational exposure to blood or body fluids of another person
- diagnosis of another infection with shared mode of acquisition, such as hepatitis C virus (HCV) or HIV
- a person who reports a reactive HBV result from a test not licensed in Australia;

Phone 02 5124 2932 Fax 02 5124 2815

actpathology@act.gov.au

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Gilmore Crescent Garran ACT 2605 PO Box 11 Woden ACT 2606



- on the diagnosis of other conditions that may be caused by HBV infection e.g. glomerulonephritis, vasculitis
- a person who requests an HBV test in the absence of declared risk factors – a small number of individuals request an HBV test but choose not to disclose their risk factors. An individual's choice not to declare risk factors **should** be recognised and it is **recommended** that HBV testing be offered.
- an assessment of immunity to HBV infection

Sample type and laboratory frequency of testing

Test	Preferred sample	Alternative sample	Lab testing frequency
Hepatitis B serology	Serum	Lithium heparin plasma (but not for HepBeAg or HepBeAb testing) EDTA plasma	Daily on Mon to Fri
HBV DNA	EDTA plasma	Serum	Weekly

Hepatitis B serology

Serology testing is used to diagnose current HBV infection or detect immunity. Please indicate in the 'clinical notes' section on the request from which of these is the reason for testing, as this may influence the testing workflow.

When investigating for current HBV infection, request HBsAg and anti-HBc.

When investigating for immunity following vaccination, request anti-HBs.

Hepatitis B surface antigen (HBsAg)

This test is used for detecting current HBV infection. If initially reactive on testing, the presence of this in a patient's blood sample will be confirmed with a secondary test. If confirmed, and if anti-HBc is also present, it generally implies current HBV infection - but does not distinguish between acute or chronic infection. If HBsAg has been present for more than 6 months, then the patient has chronic HBV infection. In rare circumstances, HBV infection with mutant strains may not produce detectable HBsAg.

Hepatitis B core antibody (anti-HBc or HBcAb)

The presence of this in a patient's blood sample means that the patient has had natural HBV infection at some point in time. In itself, this does not indicate whether the person is currently infected or has a past infection. Patients with current infection will have HBsAg detected in most cases [see above]. In circumstances where it is necessary to distinguish acute/recent HBV infection from chronic HBV infection, anti-HBc IgM may be requested. False positive anti-HBc results can rarely occur.

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Hepatitis B surface antibody (anti-HBs or HBsAb)

This is a marker of immunity to HBV. Following a full vaccination course, a protective response is considered to be an anti-HBs level of ≥ 10 mIU per mL. Provided the person had a full-course of vaccination and is not immunocompromised or having chronic kidney disease, they can be considered protected from HBV infection even if subsequent anti-HBs tests show declining levels. Patients who have detectable anti-HBs in the presence of anti-HBc and absence of HBsAg are considered to be immune on the basis of past resolved HBV infection.

Hepatitis B e antigen (HBeAg) and Hepatitis B e antibody (anti-HBe or HBeAb)

These tests are not requested as first-line for HBV infection diagnosis, but are useful in monitoring chronic HBV infection, especially during antiviral therapy. The presence of HBeAg relates to viral replication. Patients with HBeAg are generally considered to be more infectious than those with anti-HBe and without HBeAg. However, some mutants can cause liver damage despite producing no detectable HBeAg. Therefore, HBV DNA testing is better in such circumstances.

Summary of HBV serology interpretation (from the Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine, ASHM)

HBsAg	positive	Chronic HBV infection ⁺
anti-HBc	positive	
anti-HBs	negative	
HBsAg	positive	Acute HBV infection * (high titre)
anti-HBc	positive	
IgM anti-HBc*	positive	
anti-HBs	negative	
HBsAg	negative	Susceptible to infection (vaccination should be recommended)
anti-HBc	negative	
anti-HBs	negative	
HBsAg	negative	Immune due to resolved infection
anti-HBc	positive	
anti-HBs	positive	
HBsAg	negative	Immune due to hepatitis B vaccination
anti-HBc	negative	
anti-HBs	positive	
HBsAg	negative	Various possibilities including: distant resolved infection, recovering from acute HBV, false positive, 'occult' HBV
anti-HBc	positive	
anti-HBs	negative	

+ note that acute HBV infection also has a similar pattern of results, so testing other markers is required

Hepatitis B DNA (also known as HBV Viral Load)

HBV DNA testing is a nucleic acid amplification test used to detect viral replication and aid clinical assessments of need for therapy.

HBV DNA is not the usual first-line test to diagnose HBV infection. It is sometimes used to aid in diagnosing current HBV infection if the serological results are uncertain. Patients who have detectable HBV DNA in the absence of HBsAg are considered to have 'occult' HBV infection.

HBV DNA testing is recommended for everyone living with chronic hepatitis B (HBsAg positive). HBV DNA levels, along with liver function test results and an assessment of liver fibrosis, help determine eligibility for antiviral therapy.

For further information please contact one of our Clinical Microbiologists or Registrars on 02 5124 0000.

Hepatitis D testing Guide

Hepatitis D virus (HDV), also known as hepatitis delta virus, is a defective RNA virus dependent on HBsAg for its viral envelope and thus requires the presence of HBV.

HDV can occur concurrently with HBV infection (co-infection) or it may occur as a superinfection in a person with chronic HBV.

Particular situations which should prompt testing for HDV infection include:

- persons presenting with a severe acute HBV illness (co-infection)
- persons with a flare of more stable chronic HBV (superinfection)
- persons with chronic HBV who are from a region where HDV infection has a high prevalence

Testing for HDV initially involves requesting anti-HDV serology (both IgM and IgG). If the anti-HDV results are positive then HDV RNA should be requested.

References

Australasian Society for HIV Medicine, Viral Hepatitis and Sexual Health Medicine (ASHM). 2020. National Hepatitis B Testing Policy 2020. Commonwealth of Australia: Canberra.

Available at:

http://testingportal.ashm.org.au/files/HBV_testing_policy_15_October_2020.pdf

Australasian Society for HIV Medicine, Viral Hepatitis and Sexual Health Medicine (ASHM). 2015. Decision-making in HBV.

Available at:

<https://ashm.org.au/resources/HBV-Resources-list/decision-making-in-hbv/>

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