Disclaimer:

This Testing Policy has been developed as a concise source of standardised, currently available information, to inform government, health professionals and industry about specific matters associated with hepatitis B testing. This Testing Policy is not a set of clinical guidelines or a description of the management of hepatitis B infection. It should not be used as a guide for the clinical management of hepatitis infections. It is designed primarily to inform those involved in ordering and performing hepatitis B tests, and receiving and interpreting results.

This Policy was written by the National Hepatitis B Virus (HBV) Testing Policy Expert Reference Committee, funded by the Australian Government Department of Health. The process was coordinated by the Australasian Society for HIV Medicine, Viral Hepatitis and Sexual Health Medicine (ASHM).

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1.0 INTRODUCTION

1.1 Background and context
Serological testing for hepatitis B has been available in Australia for several decades and in recent years HBV DNA testing has become an integral part of the HBV clinical management pathway. The purpose of this document is to define appropriate diagnostic testing pathways using currently available technologies. It is relevant for all health professionals ordering and interpreting tests for hepatitis B. It is not intended to be a resource for people with or at risk of hepatitis B.

HBV infection is a major public health issue in Australia. It is estimated that there are currently over 213,000 people in Australia with HBV infection with many more having been exposed.\(^1\) The impact of this disease is and will continue to be significant, as the prevalence of HBV-related cirrhosis and incidence of attributable hepatocellular carcinoma (HCC) continue to increase in this country.\(^2\) The majority of newly reported infections in Australia are chronic (having persisted for more than 6 months’ duration), occurring in people from high prevalence countries who were infected at birth or during childhood. The two main priority populations for hepatitis B testing are:
- adults and children from culturally and linguistically diverse (CALD) backgrounds, particularly those born in countries of intermediate and high HBV prevalence (see section 3.1, figure 1)
- Aboriginal and Torres Strait Islander people.

Australia has implemented a universal vaccination program for hepatitis B to reduce the risk of transmission of HBV infection. Universal neonatal vaccination commenced in all States and Territories in May 2000. State and Territory Departments of Health operated catch-up vaccination programs for early adolescents but these programs did not test for current HBV infection before administering vaccine doses and may have led individuals in the targeted age cohort with chronic infection to believe they were immune.

Universal blood donor screening for HBV infection (hepatitis B surface antigen [HBsAg] and in June 2010 HBV DNA) also remains an important strategy for reducing HBV transmission in Australia.

HBV testing and notification policies provide an individual, his or her health professional and the public health services of a State or Territory with information regarding exposure to the virus. Appropriate testing indicates whether exposed individuals have cleared the virus spontaneously or whether they have acute or chronic infection. Testing also allows an assessment of the phase of the chronic HBV infection and this directs decisions on appropriate timing for initiation of antiviral therapy. Chronic hepatitis B infection can lead to cirrhosis and/or HCC in up to 25% of those affected. Ongoing monitoring and timely treatment can help prevent the onset of serious liver disease including HCC. Diagnosis of HBV infection followed by appropriate vaccination and education of at-risk contacts can effectively reduce transmission. Vaccination of at-risk contacts is not only cost effective, it is cost saving. Despite the public health and individual benefits of testing, it is estimated that up to 44% of people with HBV infection in Australia remain undiagnosed.\(^3\) The 2nd National Hepatitis B Strategy 2014-2017\(^4\) sets a target for the proportion diagnosed to increase to 80%.

It is crucial that people responsible for implementing this Policy (particularly those obtaining informed consent (see section 4.0)) and conveying test results (see section 5.0) have the necessary skills and knowledge to fully communicate the significance of each of the available tests to the person being assessed. In 2006, the Australian Bureau of Statistics conducted a health literacy survey\(^5\) that identified that only 43% of Australians had an adequate or better level of health literacy. This proportion drops to approximately one quarter in people whose first language is not English. A lack of health literacy can affect the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.\(^6,7\)

This policy document assumes that all health professionals involved in the testing process are appropriately trained.
1.2 Purpose, scope and objectives

The aim of this Policy is to provide advice on appropriate testing pathways using currently available technologies for all health professionals ordering and interpreting tests for hepatitis B. It does not provide management guidelines. It is not intended to be a resource for people with or at risk of hepatitis B. The Policy is aligned with the 2nd National Hepatitis B Strategy 2014-2017 which identifies the need for a coordinated, accessible and affordable HBV testing system that allows for:

- access to appropriately resourced services for people at risk of acquiring HBV infection and for those diagnosed with HBV infection to optimise monitoring and clinical management, and to ensure timely referral to treatment;
- the reduction of HBV transmission through knowledge of one’s status;
- the reduction of transmission from a mother with HBV infection to her newborn;
- monitoring the response to vaccination against HBV at an individual and community level;
- documenting the epidemic to aid the development of evidence-based public health interventions;
- the improvement of the health of people who have chronic HBV infection.

This Policy sets out the framework for providing relevant and accurate testing and removing actual and perceived barriers to testing. It identifies requirements and provides guidance regarding procedures for the provision of HBV testing.

Changes in the understanding of HBV infection and advances in treatment strategies that are based on test results are occurring rapidly. Accordingly, this HBV testing policy will undergo review by the National Hepatitis B Testing Policy Expert Reference Committee every 12 months to ensure information provided is accurate and current.

1.3 Principles of hepatitis B testing

The basic principles that guide HBV testing in Australia:

- Confidential, voluntary testing with informed consent (see section 4.0) and use of an appropriate process to convey the test result (see section 5.0) are fundamental to Australia’s response to hepatitis B.
- Testing is critical to understanding the epidemiology of HBV infection in the community.
- Testing must be accessible to all those who are or have been at risk of HBV infection.
- Testing will be of the highest possible standard and provided in a timely manner to individuals at every stage of their infection.
- Testing is of benefit to the person being tested (e.g. diagnosis is accompanied by provision of, or referral to, culturally and language-appropriate education, management, treatment (where relevant) and care and support services).
- Anonymous testing should be considered in instances where confidentiality is harder to maintain e.g. in small communities.
- People should have access to culturally appropriate information in their preferred language supported by access to a free professional interpreter when their primary staff contact is not familiar with their language.

1.4 Policy implementation

Testing policies and practices must comply with all relevant Commonwealth, State and Territory anti-discrimination and public health legislation, and other relevant laws and regulations, including those governing Commonwealth funding of pathology tests.

Policies relating to HBV testing, specific to individual States, Territories or institutions, should be consistent with the purpose, objectives and principles of this Policy.

\* The word must has been used when the statement reflects something which is in legislation. The word should has been used to reflect best practice or a higher quality service.
1.4.1 Voluntary confidential testing

Voluntary confidential testing is the standard form of service delivery for HBV testing in Australia. It involves the provision of information on the testing process, the obtaining of informed consent (see section 4.0) for the testing and conveying the test results in an appropriate and meaningful way (see section 5.0).

1.4.2 Mandatory or compulsory testing

Mandatory testing refers to situations where people are prevented from participating in certain activities or from having access to certain services unless they agree to be tested. Circumstances in which mandatory testing is currently required under separate policy or legislation include:

- as a condition of blood, tissue and organ donation;4
- under the migration health requirements applicable to specified visa subclasses;9
- as a condition for entering training or service in the armed forces;
- as a condition for purchasing some types of insurance;
- in the context of a legal instruction, including in forensic or coronial settings;

To all reasonable extents, the processes involved in mandatory testing should be in accordance with the principles in this Policy and basic human rights pertaining to privacy of health information.

1.4.3 Anonymous delinked testing

There may be circumstances where, on public health grounds (e.g. prevalence studies), anonymous delinked testing is legitimately performed in accordance with this Policy. Such testing should occur only where there is compelling scientific justification. This testing for research must be independently judged by a Human Research Ethics Committee constituted in accordance with the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research.10

1.4.4 Introduction of new technologies and strategies

Introduction of new technologies or strategies to target new priority populations must be accompanied by appropriate workforce development to ensure that those providing or offering HBV testing are equipped with:

- up-to-date information about HBV infection, pathophysiology, immunology and epidemiology;
- latest information about hepatitis B monitoring, clinical management and treatment;
- procedures associated with using any new technology;
- information related to referral pathways to culturally and language-appropriate care and support services;
- knowledge of the testing process, of how to obtain informed consent for the testing (see section 4.0) and of conveying the test results in an appropriate and meaningful way (see section 5.0).

Workforce development is particularly relevant in relation to point-of-care testing which is more advanced in relation to human immunodeficiency virus (HIV) than to either HBV or hepatitis C virus (HCV) in Australia (see section 2.1 (C)).
2.0 DIAGNOSTIC STRATEGIES

2.1 Types of hepatitis B diagnostic tests – also called in-vitro diagnostic devices

A range of serological and nucleic acid tests (NATs) are used for donor and diagnostic testing.

Table 1. Technology, purpose and categorisation of assays used for HBV testing.

<table>
<thead>
<tr>
<th>Marker</th>
<th>Abbreviations</th>
<th>Purpose or uses</th>
<th>Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B surface antigen (qualitative)</td>
<td>HBsAg</td>
<td>Donor testing – screening of blood and tissue donations</td>
<td>Immunoassay</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diagnostic testing</td>
<td>Immunoassay</td>
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<tr>
<td></td>
<td></td>
<td>Confirmation of the presence of HBsAg</td>
<td>Immunoassay</td>
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<tr>
<td></td>
<td></td>
<td>Monitoring of therapy</td>
<td>Immunoassay</td>
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<tr>
<td></td>
<td></td>
<td>Determining protective immunity*</td>
<td>Immunoassay</td>
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<tr>
<td></td>
<td></td>
<td>As part of strategy to determine exposure to HBV</td>
<td>Immunoassay</td>
</tr>
<tr>
<td></td>
<td></td>
<td>As part of strategy to diagnose acute hepatitis B infection</td>
<td>Immunoassay</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Determining infectivity of a person with HBV infection and phase of the infection for clinical management</td>
<td>Immunoassay</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Determining seroconversion from hepatitis B e antigen and phase of the infection for clinical management</td>
<td>Immunoassay</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Donor testing – screening of blood and tissue donations</td>
<td>Nucleic acid test (NAT)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Monitoring and management-quantifies virus for clinical management</td>
<td>Quantitative NAT (viral load)</td>
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<td></td>
<td></td>
<td>Confirm the presence of circulating HBV</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Determine the eligibility of a health care worker to perform exposure-prone procedures</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Characterisation of virus for clinical management</td>
<td>Sequencing</td>
</tr>
</tbody>
</table>

*anti-HBs levels fall over time and may become undetectable in people vaccinated years ago or in those who have cleared the virus. In the setting of normal immune function, these individuals are still regarded as having effective immunity. Where relevant, anti-HBc may provide evidence of past exposure when anti-HBs has become undetectable. Refer to the Australian Immunisation Handbook for further advice.\(^1\) HIV infected patients with low CD4 counts and a low anti-HBs despite vaccination are at risk of re-infection\(^1\), as are people with end stage renal failure undergoing haemodialysis.\(^1\) Testing for reinfection would be as for diagnosis of acute HBV infection, although HBV DNA may be the preferred first investigation due to poor antibody responses.

**The above tests are rebatable under the conditions outlined in the Medicare Benefits Schedule, however hepatitis B genotype / mutation conferring resistance is not Medicare rebatable and a fee may be payable.
Tests for hepatitis B virus (HBV) must comply with the regulatory framework for in-vitro diagnostic medical devices (IVDs) under the Therapeutic Goods Act 1989 and subordinate legislation. Testing in laboratories must comply with standards specified by the National Association of Testing Authorities (NATA) and the National Pathology Accreditation Advisory Council (NPAAC).

(A) Donor Screening

Australian laboratories screening blood or tissue prior to transfusion or transplantation must test the donor’s serum or plasma for the presence of HBsAg. Blood donors and donors of most tissues are screened for the presence of HBV DNA using a NAT. IVDs used for donor screening must be intended for that purpose and be included on the Australian Register of Therapeutic Goods (ARTG) as a Class 4 IVD.

(B) Diagnostic Tests

Individuals suspected of exposure to HBV may be tested for a range of diagnostic markers depending on their clinical history, symptoms and previous test results. Examples of the common serological patterns observed in acute and chronic HBV infection are shown (see section 2.2). All assays intended by the manufacturer for the clinical diagnosis of HBV infection are Class 4 IVDs.

Common diagnostic testing strategies encompass:

- diagnosis of acute infection (5% of notifications) – HBsAg, anti-HBc, anti-HBc IgM;
- diagnosis of chronic HBV infection – HBsAg, anti-HBs, anti-HBc;
- determination of protective immunity or its absence in at-risk groups – anti-HBs; (if anti-HBs is negative recommend HBsAg and anti-HBc to exclude undiagnosed infection or distant past infection);
- antenatal – HBsAg; (if possible also perform anti-HBs, to assess the need for vaccination);
- pre-operative/insurance screening – HBsAg;
- investigation of degree of infectivity when HBsAg positive or the assessment of disease phase in a person with chronic hepatitis B – HBV DNA, anti-HBe, HBeAg;
- monitoring of therapy – quantitative HBV DNA, HBsAg, HBeAg, anti-HBs, anti-HBe.

Note that there are three tests for hepatitis antibodies or antigens for the investigation of infectious causes of acute or chronic hepatitis (Medicare Benefit Schedule item 69481). Benefits for these tests are only payable if the request from the ordering practitioner identifies in writing that the patient is suspected of suffering from acute or chronic hepatitis, either by use of the provisional diagnosis or relevant clinical or laboratory information. More detail on HBV testing and the Medicare Benefits Schedule (MBS) are presented in section 12.0 of this Policy or from MBS online – http://www.mbsonline.gov.au/.

(C) Rapid Tests for Use at Point of Care

HBsAg point-of-care (PoC) tests are available in other countries but there are no PoC tests for HBV currently approved by the Therapeutic Goods Administration (TGA) for inclusion on the ARTG. While there are settings where PoC testing would be useful (e.g. testing in remote communities and where there are barriers to accessing traditional health care), HBsAg PoC tests are known to have a lower analytical sensitivity compared to standard laboratory immunoassays and may be unable to detect low levels of HBsAg. Some people in the community may access self-administered PoC test from overseas. Therefore, where a person indicates they have received a positive or negative PoC test the result should be confirmed by standard HBV testing in a NATA certified diagnostic laboratory.
(D) Reference Tests

The presence of HBsAg detected by screening tests must be confirmed by HBV neutralisation testing as recommended by the manufacturer’s instructions and as approved by the TGA. Blood donors in Australia are screened using a multiplex NAT assay that detects HIV-1 RNA, HCV RNA and HBV DNA. Samples reactive on a NAT multiplex assay are further tested by individual discriminatory assays for HIV-1 RNA, HCV RNA and HBV DNA to determine which viral marker(s) are present in the sample.

(E) Hepatitis D Testing

Hepatitis D virus (HDV) is a satellite RNA virus dependent on HBsAg for its viral envelope and thus only infects individuals with active HBV infection. Infection with HDV can occur concurrently with an HBV infection (co-infection) or it may occur in a chronically infected HBV patient (superinfection). It is important to consider testing for HDV in all HBV infected patients as there is evidence this co-infection is substantially under-diagnosed in Australia. Particular situations which should prompt testing for HDV infection include those with a severe presenting illness (suggesting co-infection), a flare of more stable chronic HBV (superinfection) or if they are from a region where HDV infection has a high prevalence. Testing for HDV initially involves anti-HDV serology (both IgM and IgG antibodies can be requested). If the anti-HDV results are positive then HDV RNA should be requested. While HDV RNA assays are not commercially available, laboratories will refer HDV RNA requests to a specialist reference laboratory (note this test is not on the Medicare Benefit Schedule).

2.2 Diagnostic strategies for HBV

Suspected acute HBV

Tests to be ordered

- Hepatitis B surface antigen (HBsAg)
- Hepatitis B core total antibody (anti-Hbc)
- Hepatitis B core IgM antibody (IgM anti-Hbc)

Results

- HBsAg positive
- anti-Hbc positive
- IgM anti-Hbc positive (high titre)*

Serology Interpretation

- Acute infection

Follow up

- Assess disease severity and monitor the clinical status of the patient.
- Follow-up as appropriate to confirm acute or to exclude chronic infection (HBsAg positive > 6 months)

* Note that anti-Hbc IgM can often be detected during an exacerbation of chronic hepatitis B infection. HBV is a notifiable disease and a positive result should be notified to the relevant Public Health Authority.
i. Write in lab request 'testing for possible chronic HBV'

ii. anti-HBs levels fall over time and may become undetectable in people vaccinated years ago or in those who have cleared the virus. These individuals are still regarded as having acquired immunity. Refer to The Australian Immunisation Handbook for further advice.

iii. Further testing is indicated in persons who may be in the window period before the development of any HBV serological markers. HBsAg is usually detected 6-12 weeks after exposure (in high-risk situations, consider post-exposure prophylaxis as appropriate)

iv. Note that there is some risk of HBV reactivation in the setting of intense immunosuppression

v. Consider family screening and contact tracing given possible exposure risks

vi. People at risk of already having advanced liver disease or liver cancer despite resolved HBV infection, which includes people from CALD backgrounds, people who acquired HBV infection perinatally or in early childhood, and people with other risk factors for liver disease, should be referred for assessment of liver fibrosis severity and further specialist management as required

vii. Consider passive transfer in patients who recently received plasma derived products eg. IV Immunoglobulin

viii. Lab report must either say positive or >10 mIU/mL

ix. HBV DNA viral load is NOT rebatable in patients who are HBsAg negative

Please note: A variety of unusual test results may be found in active HBV infection and where these results conflict with standard results, the advice of a specialists should be sought to clarify the interpretation, e.g. in active infection, HBsAg and anti-HBs may co-occur.
3.0 INDICATIONS FOR HBV TESTING

Testing is indicated in all people from the priority populations identified in this section. Most new cases of HBV infection in Australia are identified in people from culturally and linguistically diverse (CALD) backgrounds. Testing people born in countries with intermediate and high prevalence of HBV, including new arrivals to Australia is a crucial part of Australia’s public health response to HBV. Section 3.1 and Figure 1 identify those populations that are at higher risk of infection.

Consideration of an individual’s risk of HBV infection should inform the decision to perform an HBV test. In appropriate clinical circumstances, the absence of a declared risk should not preclude HBV testing. Clinical suspicion of HBV infection may occur in the context of:

- birth in an intermediate or high prevalence country (see Figure 1);
- being an Aboriginal or Torres Strait Islander person;
- children of women who are HBsAg positive;
- unvaccinated adults at higher risk of infection (see section 3.1);
- 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 hepatitis B.

Other situations where HBV testing may be indicated:

- pregnant women or women contemplating pregnancy (see section 8.1);
- health care workers who perform or may be expected to perform exposure prone procedures (EPPs) should be aware of their own hepatitis B (and HIV and hepatitis C) status;
- contact tracing where exposure to blood of a person with the infection is documented;
- diagnosis of another infection with shared mode of acquisition, such as hepatitis C virus (HCV) or HIV;
- a person who reports a reactive result from an HBV test not licensed in Australia;
- 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 may request an HBV test but choose not to disclose risk factors. An individual’s choice not to declare risk factors should be recognised and HBV testing should be offered.
3.1 Priority populations for HBV testing

<table>
<thead>
<tr>
<th>People from priority CALD communities&lt;sup&gt;a,b&lt;/sup&gt;</th>
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<tbody>
<tr>
<td>See Figure 1 below. Please note indigenous populations in these countries often have a higher prevalence.</td>
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</table>

<table>
<thead>
<tr>
<th>Aboriginal and Torres Strait Islander peoples&lt;sup&gt;a,b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients prior to undergoing chemotherapy or immunosuppressive therapy (due to risk of reactivation)</td>
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</table>

<table>
<thead>
<tr>
<th>Unvaccinated adults at higher risk of infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Partner and other household and sexual contacts of people who have acute or chronic hepatitis B infection&lt;sup&gt;ab&lt;/sup&gt;</td>
</tr>
<tr>
<td>• People who have ever injected drugs&lt;sup&gt;ab&lt;/sup&gt;</td>
</tr>
<tr>
<td>• Men who have sex with men&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>• People with multiple sex partners&lt;sup&gt;ab&lt;/sup&gt;</td>
</tr>
<tr>
<td>• People in custodial settings or who have ever been in custodial settings&lt;sup&gt;ab&lt;/sup&gt;</td>
</tr>
<tr>
<td>• People with HIV or hepatitis C, or both&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>• Patients undergoing dialysis&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>• Sex workers&lt;sup&gt;ab&lt;/sup&gt;</td>
</tr>
<tr>
<td>• People from established communities but originate from high prevalence countries</td>
</tr>
<tr>
<td>• Mobile populations, including international students</td>
</tr>
</tbody>
</table>

<sup>a.</sup> If HBsAg-positive persons are found in the first generation, subsequent generations should be tested;

<sup>b.</sup> Those who are seronegative should receive hepatitis B vaccine. Vaccine is not funded for all at-risk groups and cost may be a barrier to vaccine uptake. Some jurisdictions provide vaccine free of charge for certain at-risk groups. Check with the relevant State or Territory health department for details.

Figure 1: Geographic distribution of chronic hepatitis B virus (HBV) infection<sup>23</sup>

For multiple countries, estimates of prevalence of HBsAg, a marker of chronic HBV infection, are based on limited data and might not reflect current prevalence in countries that have implemented childhood hepatitis B vaccination. In addition, HBsAg prevalence might vary within countries by subpopulation and locality. Figure 1 is reprinted from Centres for Disease Control and Prevention (CDC) publication; there is no copyright. China, for example, is now an intermediate prevalence country with the age-adjusted prevalence of hepatitis B dropping from 9.8% in 1992 to 7.2% in 2009. 24
3.1.1 People from priority CALD communities

The term priority CALD communities refers to individuals and their families who were born in or born to parents who came from countries with intermediate (2-7%) to high (≥ 8%) prevalence of HBV infection (see Figure 1). This group includes first and subsequent generations who may have been exposed through ongoing perinatal and horizontal transmission in Australia before the commencement of HBV screening during pregnancy and universal neonatal vaccination.

The majority of people living with chronic hepatitis B in Australia were born overseas, particularly in the Asia Pacific region, Europe and Africa/Middle East. The Victorian Hepatitis B Serosurvey found a strong association between the proportion of residents born overseas in any local government area and HBV prevalence. People from CALD backgrounds from high-prevalence countries now living in Australia have been found to have the same rates of infection as their countries of birth.

All adults from priority CALD communities should be tested once for HBsAg, anti-HBc and anti-HBs to establish whether they have chronic hepatitis B, are immune through past infection or vaccination, or are susceptible to infection. Vaccination should be encouraged for those without immunity who are remaining at risk of infection. The purpose and implications of the test should be clearly explained before testing (see section 4.0), with the assistance of interpreters or multilingual health workers, as needed (see section 9.4). The result should be appropriately conveyed to the patient (see section 5.0) and documented clearly in the patient summary.

See section 8.0 for children born to mothers who are HBV DNA or HBsAg positive.

3.1.2 Aboriginal and Torres Strait Islander peoples

Aboriginal and Torres Strait Islander people are approximately 2.6% of the Australian population, but are estimated to represent 10% of people living with chronic hepatitis B. Estimates of prevalence vary from approximately 2% of urban Aboriginal and Torres Strait Islander populations to 8% for rural Aboriginal and Torres Strait Islander populations, with prevalence likely to be even higher in remote communities. More than a quarter of Aboriginal and Torres Strait Islander people live in remote or very remote areas. There are higher rates of death from liver-related causes in the Indigenous population compared with non-Indigenous Australians, linked to HBV infection. The majority of cases of chronic hepatitis B in the Aboriginal and Torres Strait Islander population are believed to have been acquired by vertical transmission at birth, or infection in early childhood, increasing the likelihood of unknown long-term infection and long term complications. Clinicians should stress that perinatal and early childhood exposures have been the primary routes of exposure for Aboriginal and Torres Strait Islander people.

Hepatitis B vaccine was introduced in many Aboriginal and Torres Strait Islander communities in the mid 1980s to early 1990s, with catch-up hepatitis B vaccination programs for Aboriginal and Torres Strait Islander children and adolescents in the late 1990s, or earlier in some jurisdictions. There is some evidence of early vaccination program failure, thought to be due to limited program roll-out and imperfect adherence to vaccine storage/refrigeration (cold-chain) guidelines. Cold chain guidelines were revised and improved in 2005. All Aboriginal and Torres Strait Islander adults should be tested once in adulthood for HBsAg, anti-HBc and anti-HBs to establish whether they have chronic hepatitis B, are immune through past infection, or are susceptible to infection. Vaccination should be discussed with those without immunity who are remaining at high risk. The purpose and implications of the test should be clearly explained before testing (see section 4.0), with the assistance of Aboriginal health workers, as needed. The result should be appropriately conveyed to the patient (see section 5.0) and documented clearly in the patient summary.

See section 8.0 for children born to mothers who are HBV DNA or HBsAg positive.

a These recommendations should take into account local epidemiology, historical vaccination program uptake and local policy.
3.1.3 All patients undergoing chemotherapy or immunosuppressive therapy

Patients who are undergoing any sort of chemotherapy, prolonged (greater than 4 weeks) steroid therapy or significant immunosuppressive therapy (including biologic modifiers such as anti-TNF agents, or agents for transplantation of immunological diseases) should be tested for HBV.

Patients with chronic hepatitis B (HBsAg positive) are at risk from a serious and sometimes life threatening flare of their disease, often occurring after chemotherapy has finished. All HBsAg positive patients should, therefore receive prophylaxis with anti-viral therapy commencing at the same time or as soon as possible after the commencement of chemotherapy or immunosuppressive therapy.

Patients undergoing rituximab based chemotherapy, or bone marrow transplantation are at particularly high risk of HBV reactivation. If these patients have serology suggestive of prior exposure to HBV (anti-HBc positive) including the high risk subgroup with occult HBV (low level but detectable HBV DNA), they should also be given antiviral prophylaxis for the duration of their treatment and ideally 12 months thereafter.

3.1.4 Partner and other household and intimate contacts of people who have acute or chronic hepatitis B infection

Unvaccinated individuals, who have frequent and prolonged contact with a person with HBV infection, have a higher risk of acquiring hepatitis B. The virus can be transmitted by sharing personal or sharp objects such as razors, toothbrushes, ear-rings and nail clippers; it cannot be transmitted by casual contact through kissing, touching or sharing food utensils. Because HBV has the potential given the right environmental conditions to survive for at least 7 days on surfaces and objects contaminated with traces of blood, these objects remain infectious for a long time after their use by a person with HBV infection. Child-to-child transmission, through everyday occurrences such as cuts, bites, abrasions and scratches, has been documented.

When an individual with HBV infection is identified, close contacts including household, family and intimate contacts, including all children, should be offered testing for HBsAg, anti-HBs and anti-HBc. Those without immunity should be offered vaccination. Post-vaccination serological testing 4 to 8 weeks after completion of the primary course is recommended (anti-HBs). Non-immune household members should have repeat testing for HBsAg after 3 months. For further information please see The Australian Immunisation Handbook.

3.1.5 People with a history of injecting drug use

In 2011, the estimated prevalence of HBV among people who inject drugs (PWID) was 4%.[1] Historically, up to 50% of people who have injected drugs had serological markers of HBV infection, and PWID continue to be a population at high risk of HBV infection. PWID often experience significant barriers to accessing health services including HBV testing, vaccination and treatment. Access to free hepatitis B vaccination is not consistent across States and Territories.[22] In this context, it is critical that testing is conducted in an appropriate and non-judgemental setting to assist people with a history of injecting drug use through the testing and diagnosis process. How testing is carried out will have a profound effect on the person’s understanding of their condition and their likelihood of future engagement with the health system. This includes understanding the current relevance of injecting drug use in the person’s life. Peer education and support may optimise testing uptake and is recommended where these resources are available. Staff in specialist and primary health care services should be cognisant of issues relating to illicit drug use, harm reduction, addressing stigma and discrimination and managing vein care issues. Hepatitis B vaccination should be offered if testing reveals neither immunity nor current infection.[11]

As people with a history of injecting drug use are also at increased likelihood of having acquired HCV or HDV infection, testing for these should be considered (see section 2.1).
3.1.6 Men who have sex with men

Historically, unvaccinated men who have sex with men (MSM) had a prevalence of serological markers of past or current HBV infection of approximately 38%, although more recent estimates are substantially lower. As they are commonly infected in adulthood most MSM will clear acute HBV infection, but a small percentage of MSM remain HBsAg positive. Despite having an increased risk of HBV infection, uptake of vaccination remains suboptimal. MSM should be tested for HBsAg, anti-HBs and anti-HBc (see section 2.2). Hepatitis B vaccination should be offered if testing reveals neither immunity nor current infection.

3.1.7 People in custodial settings or who have ever been in custodial settings

Imprisonment is an independent risk factor for HBV transmission and a history of ever being in custodial settings is an indication to offer testing for HBV with appropriate discussion of risk and benefits (see section 4.0). People entering custodial settings have higher rates of previous HBV infection compared to the general community but only around 50% of people entering custodial settings have immunity to hepatitis B. People should be screened upon entering custodial settings if their hepatitis B status is unknown. Hepatitis B vaccination should be offered if testing reveals neither immunity nor current infection.

An overrepresentation of people from CALD and Aboriginal communities presents an additional burden and risk in custodial settings which requires further consideration in relation to screening, treatment and care delivered in a culturally competent and culturally safe manner.

3.1.8 People living with HIV or hepatitis C, or both

Patients with HIV infection or HCV infection or both are at a greater risk for HBV infection because of shared transmission routes. Routine screening and immunisation are recommended for all people living with HIV or HCV to prevent primary HBV infection. Double dosing of hepatitis B vaccine is recommended for people living with HIV, and booster vaccination every 6-12 months as dictated by anti-HBs titres. For further information please see The Australian Immunisation Handbook.

3.1.9 Patients undergoing dialysis

The frequency of HBV infection is higher in dialysis patients than in the general population because of their potential constant exposure to blood, frequent transfusions and sharing of dialysis equipment, reduced response to vaccination, and reduced durability of vaccine-derived immunity. It is recommended that all people receiving renal dialysis should have hepatitis B vaccination and vaccination is strongly recommended for patients with chronic kidney disease, dialysis-dependent or not, who are candidates for kidney transplantation. Patients should be tested every 6 months for HBsAg/anti-HBs. Double dosing of hepatitis B vaccine is recommended for people receiving dialysis, and booster vaccination every 6-12 months as dictated by anti-HBs titres. For further information please see The Australian Immunisation Handbook.

3.1.10 Children born to mothers who are HBV DNA or HBsAg positive.

See section 8.0.
3.1.11 Transmission and infection control in health care settings

- HBV testing of health care workers and students exposed to clinical settings **should** be conducted in accordance with the general principles set out in this document with regard to privacy, confidentiality and access to appropriate health care and support services.

- Health care workers who test positive for HBV DNA are currently prevented from performing exposure-prone procedures. They should be encouraged and supported to undergo regular testing.

- Testing for all blood borne viruses **should** be undertaken for health care workers following occupational exposure to blood or body substances, for example through needle stick injury.

- Principles of informed consent (**see section 4.0**) and conveying a test result (**see section 5.0**) should be conducted with both the source of the occupational exposure and the recipient. Where patients are involved in occupational exposures, their informed consent to be tested must be sought (**see section 1.4.2** for exceptions).

3.1.12 Sex workers

Sex workers are at an increased risk of HBV infection, particularly if engaging in unprotected sex. Hepatitis B vaccination **should** be offered if testing reveals neither immunity nor current infection.
4.0 INFORMED CONSENT FOR TESTING

Informed consent must be obtained for HBV testing. Exceptions may occur for rare occasions when a legal order is made for compulsory testing or in emergency settings. On these occasions, if informed consent cannot be attained, pre-test provision of all appropriate information to the person should still take place.

Informed consent for testing means that the person being tested agrees to be tested on the basis of understanding the testing procedures, the reasons for testing and is able to assess the personal implications of potential test results. Obtaining informed consent may take more than one consultation.6

The person performing the test should use his or her clinical judgment in securing informed consent. Clinical judgment should be based on his or her understanding of the context in which the test is being performed, taking into account:

• the factors which indicate an urgent need for testing such as clinical presentation, risk exposure, prevalence and individual initiation;

• an assessment that the person being tested understands the testing process, the implications of the possible result, and how to effectively respond to the diagnosis.

General principles of professional conduct and privacy apply in the case of HBV testing and informed consent. Consent to test should not be sought from sexual partners or family members of the person being tested. In the case of testing children or people who are incapable of giving consent (perhaps due to mental illness or cognitive disability) then the responsibility for consent rests with the guardian or other person or agency legally authorised to make such decisions on the person’s behalf.

People involved in HBV testing must use whatever additional support is necessary to assist the person considering testing to become adequately informed in order to minimise the personal impact of a positive diagnosis, change health-related behaviour and reduce anxiety. Additional support can include access to professional on-site and telephone interpreters and referral to multicultural health services. Health promotion information that is culturally sensitive and language-appropriate should be provided when seeking informed consent and providing results.

When offering testing to patients with low English proficiency, clinicians who do not speak the language of the patient should use an accredited interpreter to maintain equality of health outcomes and to obtain informed consent.46 Where available, telephone interpreting has a high degree of acceptability to many people because it allows them to maintain anonymity.

There are also publicly funded health interpreting services available in most states and territories.47 The Translating and Interpreting Service (TIS National) is available to doctors 24 hours a day.47 TEL: 1300 131 450.
5.0 CONVEYING HEPATITIS B TEST RESULTS

The process of conveying a hepatitis B test result to the person being tested (irrespective of the specific result) is affected by:

- the type of test performed and the need for additional testing to determine the individual’s actual hepatitis B status;
- the context in which the test is being performed and the setting of the consultation;
- the attitude and level of health literacy of the patient, and the potential implications of the result in the individual circumstances of each patient.

The health care provider who requests the test is responsible for ensuring that the delivery of the test result is carried out in a setting conducive to discussing the implications of the result and addressing the issues that the result raises. In presenting results to people with low English proficiency, professional interpreter services should be accessed (see section 4.0 for details). The use of family members should not replace the need for an accredited interpreter. In all cases, health care providers should be mindful of health literacy levels and possible misinterpretations of the terms “positive” and “negative” when discussing test results. People being tested may interpret a so-called “positive” result as good and “negative” as bad. One method to help reduce the chance of misunderstanding is the Teach-Back technique.

The decision about how results from a hepatitis B test indicating immunity or otherwise (see section 2.1) is provided (e.g. in person, by phone) should be based on the clinical judgment of the person responsible for conveying the result. This assessment should take into account the psychological capacity of the person being tested to deal with the outcome of testing and his or her understanding of the testing process as evident at the time of the sample collection. A confirmed HBV infection result should always be provided in person by the clinician, except in extenuating circumstances where, for example, it is suspected that the person who has been tested may not return for the result or may engage in risk behaviour(s) based on the wrong assumption that they are HBsAg negative.

5.1 Conveying a hepatitis B test result: susceptible (non-immune)

A susceptible individual is one in whom there is no documented history of completed vaccination, and the anti-HBs, anti-HBc and HBsAg results are all negative. It is imperative that the meaning of a negative (susceptible) result is fully understood and that the person being tested receives appropriate information about and opportunity for hepatitis B vaccination, and is made aware of other harm reduction strategies in relation to the spread of blood borne viruses and sexually transmissible infections. Further testing following a negative result (anti-HBs or HBsAg) is indicated in persons who may:

- be in a window period prior to seroconversion (negative HBsAg, anti-HBc and anti-HBs in a high-risk situation – with consideration of post-exposure prophylaxis as appropriate);
- have been completely vaccinated against hepatitis B without previous confirmation of anti-HBs seroconversion (possible non-response to the vaccine, or a fall in anti-HBs titre over time).

The person should be informed of the reasons why repeat testing after an interval may be necessary. In this situation the clinician should enter the person into a system for automatic recall, rather than relying on the person to follow up on their own initiative.

It is imperative that the clinician make all attempts to ensure that the result is being provided to the person who was tested. This includes:

- confirming the person’s identity by asking for the spelling of all their names;
- making repeated contact to ensure the person is aware of the availability of the result;
- documenting all efforts to contact the person.
5.2 Conveying a hepatitis B test result: immune

When the anti-HBs titre is positive in the setting of previous completed vaccination, or anti-HBc is positive with or without anti-HBs also being positive, a person is regarded as immune. Isolated anti-HBc positive results most commonly indicate distant resolved infection (with the anti-HBs titre having fallen below the threshold of the assay). However, the result is occasionally falsely positive and, rarely, isolated anti-HBc results can indicate a different hepatitis B status (see section 2.0).

When a person is identified as being immune, either through natural infection or vaccination, this should be clearly entered in their medical record and conveyed to the person, to avoid unnecessary repeat serologic testing or vaccination in the future.

Patients immune through natural infection should be advised that they may be at risk in settings of immunosuppression.

5.3 Conveying a hepatitis B test result: confirmed infection

A HBsAg test result that confirms infection (HBsAg positive) can have a significant impact for an individual and his or her significant other(s). This result may indicate either an acute or a chronic HBV infection and the information provided will reflect the clinical situation. Laboratories should provide requesting clinicians with information and the opportunity for consultation and expert advice at the time of diagnosis. In providing results to people with low English proficiency, professional interpreter services should be accessed when health care staff do not speak the person’s preferred language (see section 4.0). The professional interpreter may lack the vocabulary to explain the meaning of “viral hepatitis” and it is important to check understanding and get the person to repeat back what they understand about the information that has been conveyed to them via the interpreter. The use of family members as interpreters is strongly discouraged. Resources for assessing the need for an interpreter can be found on the Centre for Culture, Ethnicity and Health (CEH) website.

The process of conveying a result of confirmed hepatitis B infection should include:

• giving the test result in person and in a confidential manner that is sensitive and appropriate to the gender, culture, behaviour, language and literacy level of the person who has been tested;
• assessing the need for and providing information about the natural history of hepatitis B, and the importance of clinical monitoring to identify resolution of acute infection (95% of adults) or, in the case of chronic hepatitis B, regular, ongoing clinical monitoring to detect progression of liver disease, determine the need for treatment and prevent HCC;
• identifying the importance of lifestyle changes - in particular alcohol consumption, for people with chronic hepatitis B, the availability, efficacy and timing of treatment options;
• assessing use of hepatotoxic medications and over the counter preparations
• advising the patient how hepatitis B is and is not transmitted, and how onward transmission may be prevented, including discussion about hepatitis B vaccination for partners, household contacts and other intimate contacts;
• disclosure strategies to partner and family members, including discussion relevant to whether the person has acute or chronic disease about:
  – the importance of disclosure to children and
  – current and future household and sexual contacts being tested for hepatitis B and subsequently vaccinated if they are susceptible;
• providing information about the legal considerations around disclosure of hepatitis B status;
• the provision of information about (and referral to) available support services.
It is usually necessary to cover these issues over more than one visit, in which case a subsequent consultation should be arranged at the time of diagnosis. It is also important to consider the level of health literacy of the patient, as a positive test result, may be interpreted as a virus free result.

5.4 Contact tracing and family notification
Contact tracing of family members, partner and other household and sexual contacts of people diagnosed with hepatitis B can be complicated by reluctance to disclose their status to significant others, many of whom may be living overseas and may have limited access to health care. Discussion with the patient regarding how to proceed with contact tracing may be appropriate. Bilingual community health workers should be involved if possible. See section 5.6.3 for information on hepatitis B testing for close contacts and family members of the person with hepatitis B.

5.5 Referral for further support
The information and support needs of people who are preparing for diagnostic testing for hepatitis B, or have just received a test result are considerable and diverse. Information provided in a single clinical consultation is often insufficient to meet their needs as understanding develops and different personal factors arise over time. Community-based organisations including hepatitis organisations, multicultural health and support agencies, Indigenous health services and peer-based drug user groups can assist people who are newly diagnosed to better understand the hepatitis B testing and diagnosis process and provide appropriate support through this critical period. Providing referral to relevant community-based organisations is therefore recommended when informed consent for testing is being obtained, at diagnosis and as appropriate at other stages of the hepatitis B diagnosis and management process.

Hepatitis Australia
National Helpline: 1300 437 222 (1300 HEP ABC)
www.hepatitasaustralia.com

Multicultural Health Services in each State and Territory

Cancer Council Helpline
13 11 20
www.cancer.org.au

The National Aboriginal Community Controlled Health Organisation
www.naccho.org.au

The Australian Injecting and Illicit Drug Users’ League (AIVL)
Telephone: 02 6279 1600
www.aivl.org.au

5.6 Special situations
5.6.1 People unconvinced by their test result
Responding to the needs of this group of people can be time consuming and there may be complex psychological and sociological issues that need to be addressed. Assistance in managing these people can be obtained from a range of specialist services that can offer help to refer a person in this predicament to an alternative service for a second opinion.
5.6.2 People who do not return for test results

These people can be unaware of factors that may help them in living with chronic infection and may unknowingly place others at risk. It is important to try and contact these individuals. Taking into account the person’s communication and language needs, it may be more effective to contact these people by phone, through professional interpreters rather than through written correspondence. Bilingual health workers can also be used. The request should be for the person to re-contact the service provider without providing the result per se. Public Health Units of Departments of Health and sexual health clinics can provide advice on individual follow-up.

The decision to stop trying to follow up a person can be a difficult one. Attempts to make contact should be documented in the person’s file. General practitioners (GPs) in particular have limited capacity to perform person follow-up and GPs should pass this responsibility to the local Public Health Unit of their State Department of Health if they have exhausted their resources.

5.6.3 Hepatitis B testing for close contacts and family members of the person with hepatitis B

Hepatitis B occurs most commonly through mother-to-infant transmission during, at or soon after delivery, or between young children early in life. It is possible that siblings in families born in high prevalence countries may all be living with hepatitis B; however, some may be unaware of their hepatitis B status until a family member is diagnosed (see section 5.4 Contact tracing). The diagnosing clinician may not always have a therapeutic relationship with the person’s close contacts and family members. Therefore, adequately preparing the person to inform their close contacts and family members about his or her positive diagnosis and the need for these contacts to be tested is critical. For people with low English proficiency, professional interpreter services should be accessed. Referral to a local hepatitis organisation may be useful. Notification of family members after a positive diagnosis may encourage screening and subsequent diagnosis, which may lead to medical management and a reduced risk of developing serious liver disease and HCC.

5.6.4 People diagnosed with hepatitis B secondary to hepatocellular carcinoma diagnosis

Infection with HBV is the most common cause of HCC worldwide. In Australia, the incidence of HCC has progressively risen over the past 20 years, with the burden of HCC being greatest among populations born in countries with high hepatitis B prevalence. Many patients remain asymptomatic from the underlying hepatitis infection until this complication develops. Although hepatitis B-associated HCC is most common in people living with cirrhosis, a substantial proportion of cases occur in people who do not have hepatic cirrhosis. Once HCC is diagnosed, testing for both HBV and HCV infection is essential to allow appropriate management of patient and family. HCC surveillance recommendations exist to assist clinicians caring for people diagnosed with hepatitis B.
6.0 SURVEILLANCE AND RESEARCH

Laboratories performing HBV testing **must** notify the relevant State and Territory health authorities of any new HBsAg positive laboratory diagnosis in accordance with the relevant legislation/regulations. In some states and territories medical practitioners **must** also notify the relevant State and Territory health authorities.

Where information is available to identify newly acquired HBV infection, such as detection of HBsAg in a patient shown to be negative within the last 24 months; or detection of HBsAg and IgM to hepatitis B core antigen (IgM anti-HBc), in the absence of prior evidence of HBV infection; or detection of HBV by nucleic acid testing, and IgM anti-HBc, in the absence of prior evidence of HBV infection; these cases **should** be reported to the local State or Territory health authorities as a case of newly acquired HBV infection.

6.1 Delinked blood surveys

Delinked anonymous surveys are studies in which specimens taken for other purposes (e.g. residual serum following routine diagnostic testing) are tested for markers of HBV infection and/or immunity without consent after they have been coded so that the results cannot be linked to the individual who originally provided the specimen.

The survey method **should** be considered for Australian surveillance purposes only where there is no other feasible method for reasonably obtaining appropriate data and **should** be subject to scientific justification and be endorsed by an institutional ethics committee in accordance with the requirements prescribed by the NHMRC.

6.2 Use of unregistered in-vitro diagnostic devices

Before the introduction of the new regulatory framework for IVDs in 2010, hepatitis B tests were not required to be registered with the ARTG. For legal supply in Australia under the new regulatory framework, IVDs must be included in the ARTG by 1 July 2014. IVDs not currently supplied in Australia may be required to be used in international collaborative research. Application **must** be made to the TGA under the Clinical Trial or Special Access Scheme to allow for use of these IVDs where they are used for a therapeutic purpose, e.g. to diagnose infection or determine treatment for a patient. IVDs to be used for research only, e.g. where results are de-identified and not used to determine patient treatment, are exempt under Clause 1.3, Schedule 4 of the Therapeutic Goods (Medical Devices) Regulations 2002.
7.0 HEALTH CARE WORKERS

Hepatitis B vaccination is strongly recommended for all health care workers (including ambulance personnel, dentists and all students in these professions who are in clinical settings) and is a requirement in some jurisdictions (see section 3.1.11). The Communicable Diseases Network of Australia, professional societies, colleges and registration boards may from time to time publish guidelines regarding the testing of health professionals. Any testing of health professionals should be done in accordance with this Policy.

As for all tests where testing of a health care worker is undertaken, confidentiality must be maintained.

Health care workers must not perform tests on themselves.
8.0 ANTENATAL AND PERINATAL TESTING

8.1 Routine testing

Women contemplating pregnancy or seeking antenatal care should be made aware of the benefits of diagnosis of hepatitis B infection and management, and prevention strategies available to protect the infant from infection.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) guidelines state that all pregnant women should be screened using the HBsAg test. If a woman is identified as HBsAg positive, further testing (HBeAg and HBV DNA) should be performed to determine the risk of transmission to the infant and the degree of infectivity in general, to inform clinical decision making.

The risk of perinatal HBV transmission is determined by maternal hepatitis B viral factors; highly replicative infection characterised by high HBV DNA viral load and HBeAg positivity is associated with a higher risk of transmission. Timely administration of hepatitis B vaccination and hepatitis B immunoglobulin (HBIG) to the infant within 12 hours of birth will prevent the majority of hepatitis B transmission. Women with a high viral load should receive specialist advice to consider the role of antiviral treatment to further reduce the risk of transmission.

Any woman diagnosed with hepatitis B infection in pregnancy should be assessed by an experienced clinician who will determine the phase and stage of her hepatitis B so that appropriate recommendations about treatment and monitoring can be made.

Jurisdictions should develop operational directives that support the RANZCOG guidelines through education, feedback on compliance and periodic auditing of antenatal medical records to provide evidence of recommended best practice.

8.2 Testing of infants born to HBsAg positive mothers

Infants born to HBsAg positive mothers should be tested for HBsAg and anti-HBs at least 3 months after the final dose of hepatitis B vaccine. Testing for anti-HBc is not useful in the first years of life as maternal antibody is still detectable. A positive anti-HBs indicates a successful response to vaccination. A positive HBsAg test indicates infection and, in this case, the child should be referred to a paediatric gastroenterology or Infectious Diseases Unit for monitoring of liver function.
9.0 PEOPLE FROM CULTURALLY AND LINGUISTICALLY DIVERSE BACKGROUNDS

Over 50% of people living with chronic hepatitis B in Australia are people from priority CALD communities (see section 3.1.1). Clinicians need to be equipped to provide culturally sensitive and competent services, to improve health outcomes for this priority population.02

‘Culturally and linguistically diverse’ is an umbrella term designed to include migrants, temporary residents, international students, refugees, and asylum seekers, as well as their descendants. It draws attention to cultural factors that can influence patterns of health access and outcomes even in people who were born in Australia and speak English proficiently. Understanding a person’s health belief systems and level of health literacy can support the clinician to tailor each episode of care specifically to improve the health outcomes of their patient/s.

9.1 Testing CALD patients at highest risk of HBV

Clinicians should routinely ask patients to identify their country of birth, parents’ countries of birth, and languages spoken at home. This is to establish the relevance of an offer of testing particularly for patients born in countries of high (≥ 8%) and intermediate (2-7%) prevalence rates for HBV (see Figure 1, Section 3.1).23

Clinicians should stress that perinatal and early childhood exposure are the primary routes of transmission for people from priority CALD backgrounds.

9.2 Confidentiality and using interpreters

Clinicians should advise that interpreters are available and are free of charge. Clinicians should reassure the person that all people involved, including interpreters and clinicians, will keep confidentiality.

Clinicians should brief any face-to-face or telephone interpreter, to maintain confidentiality regarding everything they learn from the consultation and ensure the interpreters understand the language and concepts to be conveyed. Professional interpreters are bound by a professional code of conduct to respect confidentiality. Where patients are concerned about confidentiality (e.g. in smaller communities), telephone interpreters may be used, and the clinician may refer to the patient using a pseudonym to disguise his or her identity.

Clinicians should use simple language to explain privacy and when exceptions to privacy may apply.

Clinicians should encourage patients to bring and involve family members in testing, vaccination, monitoring and care as many view health issues as a collective issue. However the use of family members as interpreters is strongly discouraged. Clinicians should also be aware that in certain cultures hepatitis B is highly stigmatized and working with patients in a culturally competent and culturally safe way is crucial for improving the long term health of individual patients, families and communities.
9.3 Screening

9.3.1 Opportunistic testing

Opportunistic testing depends on clinicians proactively offering HBV testing to CALD patients. Patients may see clinicians at multiple practices or different clinicians within the same practice. Clinicians should use patient records to document both the offers and the outcomes of HBV testing in order to avoid repeated offers of testing that may result in unnecessary duplication of testing or vaccination. This should include reasons for any refusal of testing. Information about the need for an interpreter, what language is spoken, and the preferred mode of interpreting (face-to-face or telephone) should also be recorded.

Clinicians should recognise the cultural beliefs when a person refuses a blood test and should offer the option of involving a multicultural health service which are available in most states.

9.3.2 Family testing

Contact tracing, screening and provision of vaccination for household contacts should be guided by reference to cultural understandings of the family in the patient’s own community (such as reconfigured refugee families), as these are what determine the level of risk (for example, frequency of occasions where horizontal transmission may occur).

9.4 Cultural competency in health care

Cultural competence in health care describes the ability of systems to provide care to patients with diverse values, beliefs and behaviours, including tailoring delivery to meet the patient’s social, cultural and linguistic needs.

All cultural and ethnic groups have concepts related to health and illness, whether they are cultural or individual beliefs, that influence their health behaviour. These should be considered when communicating with a patient.

Clinicians and practice staff should be equipped with knowledge, skills and tools to work with people from CALD backgrounds to achieve better health outcomes.
10.0 ABORIGINAL AND TORRES STRAIT ISLANDER PEOPLES

The Fourth National Aboriginal and Torres Strait Islander Blood Borne Virus & Sexually Transmissible Infections Strategy 2014-2017 recommends increasing the assessment of hepatitis B status, immunisation coverage for those at risk, and management of those with chronic hepatitis B. Policies and guidelines should be developed locally, so that health care workers are correctly advised and health services generate culturally appropriate policies and programs (see section 3.1.2).

10.1 Identifying Aboriginal and Torres Strait Islander peoples

Clinical service providers should ask people whether they identify as an Aboriginal or Torres Strait Islander person, and what languages they speak at home.

10.2 Testing in Aboriginal and Torres Strait Islander populations

Testing for HBV infection and offering appropriate management for all those affected by a positive diagnosis is essential for this priority population (see section 3.1.2). Introducing new screening policy in the Indigenous setting requires community consultation. Local health boards or community-controlled health organisations may make decisions about screening the population they serve for HBV infection based on knowledge of local prevalence, health service factors, regional vaccine funding and consultation with the community.
11.0 QUALITY ASSURANCE OF HBV TESTING

11.1 Laboratories
Laboratories that perform HBV testing and claiming Medicare Benefits:

- must be accredited for medical testing in accordance with the National Pathology Accreditation Advisory Council (NPAAC) standards;
- must be enrolled, participate and demonstrate acceptable performance continually in appropriate external quality assurance programs (EQAS);
- should contribute testing statistics to National Serology Reference Laboratory (NRL) to ensure the completeness of test denominator data;
- should report any adverse events to both the IVD sponsor and the TGA.

11.2 Pre-market quality assurance of HBV in-vitro diagnostic devices

11.3 Post-market monitoring and quality assurance of HBV in-vitro diagnostic devices
IVD manufacturers, sponsors and the TGA have the responsibility for post-market monitoring of the IVDs. The manufacturer and sponsor must inform the TGA of all reportable adverse events. Corrective action must be initiated by the manufacturer and sponsor of an IVD in consultation with the TGA. This action must occur as soon as practicable after becoming aware of information relating to any adverse events, malfunction or deterioration in the performance, or inadequacy in the design production and labelling of an IVD. Laboratory users are encouraged to report any adverse event to the TGA through the Medical Device Incident Reporting & Investigation Scheme as well as the sponsor of the IVD.
12.0 FUNDING OF HBV TESTING

Funding for HBV testing is provided directly from the Commonwealth on a fee-for-service basis through the Medicare funding arrangements and also through state and territory funding arrangements.

12.1 Funding arrangements for hepatitis B diagnostic and monitoring tests

More detailed information on Medicare benefits for hepatitis B tests can be found on MBS Online (see the most recent schedule Category 6– Pathology items and descriptions). A Medicare benefit for pathology testing for hepatitis B—and hepatitis D if conducted (see section 2.1)—will be payable where the service was determined to be necessary by the patient’s medical practitioner, was provided by an accredited pathology laboratory, and the patient meets the requirements for the relevant MBS item. Benefits would be payable for the attendance and tests which are considered reasonably necessary according to a patient’s individual circumstances.

12.2 Schedule interpretation

The Australian Government Department of Human Services is responsible for the day-to-day administration and payment of benefits under the Medicare arrangements. Any inquiries concerning matters of interpretation of MBS items, including eligibility, should be directed to the Department of Human Services in the first instance. For enquiries relating exclusively to the MBS, phone 132 150.

Alternatively send an email with your query to: askMBS@humanservices.gov.au
13.0 **GLOSSARY**

### 13.1 Abbreviations and acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AHPPC</td>
<td>Australian Health Protection Principal Committee</td>
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<tr>
<td>ARTG</td>
<td>Australian Register of Therapeutic Goods</td>
</tr>
<tr>
<td>ASHM</td>
<td>Australasian Society for HIV Medicine, Viral Hepatitis and Sexual Health Medicine</td>
</tr>
<tr>
<td>BBVSS</td>
<td>Blood Borne Virus and Sexually Transmissible Infection Subcommittee</td>
</tr>
<tr>
<td>CALD</td>
<td>Culturally and Linguistically Diverse</td>
</tr>
<tr>
<td>DNA</td>
<td>Deoxyribonucleic acid</td>
</tr>
<tr>
<td>EPP</td>
<td>Exposure Prone Procedure</td>
</tr>
<tr>
<td>EQAS</td>
<td>External Quality Assessment Scheme</td>
</tr>
<tr>
<td>GPs</td>
<td>General Practitioners</td>
</tr>
<tr>
<td>HBsAg</td>
<td>Hepatitis B Surface Antigen</td>
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<tr>
<td>HBV</td>
<td>Hepatitis B Virus</td>
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<tr>
<td>HCC</td>
<td>Hepatocellular Carcinoma</td>
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<tr>
<td>HCV</td>
<td>Hepatitis C Virus</td>
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<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<tr>
<td>IVD</td>
<td>In-Vitro Diagnostic Devices</td>
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<tr>
<td>MBS</td>
<td>Medicare Benefits Schedule</td>
</tr>
<tr>
<td>MSM</td>
<td>Men who have sex with men</td>
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<tr>
<td>NAT</td>
<td>Nucleic Acid Test</td>
</tr>
<tr>
<td>NATA</td>
<td>National Association of Testing Authorities</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>NPAAC</td>
<td>National Pathology Accreditation Advisory Council</td>
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<tr>
<td>NRL</td>
<td>National Serology Reference Laboratory, Australia</td>
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<tr>
<td>PoC</td>
<td>Point of Care Testing</td>
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<tr>
<td>PWID</td>
<td>People who inject drugs</td>
</tr>
<tr>
<td>RANZCOG</td>
<td>Royal Australian and New Zealand College of Obstetricians and Gynaecologists</td>
</tr>
<tr>
<td>RNA</td>
<td>Ribonucleic Acid</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
</tr>
</tbody>
</table>
13.2 Glossary

Analytical Sensitivity
The smallest amount of the target marker that can be precisely detected.

Compulsory Testing
Where a person has no choice in being tested, e.g. as directed under a Public Health Order.

Exposure Prone Procedure
Defined by the Infection Control Guidelines as a subset of ‘invasive procedures’ characterised by the potential for direct contact between the skin (usually finger or thumb) of the health care worker and sharp surgical instruments, needles or sharp tissues (spicules of bone or teeth) in body cavities or in poorly visualised or confined body sites (including the mouth). In the broader sense, an exposure-prone procedure is considered to be any situation where there is a potentially high risk of transmission of blood borne disease from health care worker to patient during medical or dental procedures.

Mandatory testing
Refers to situations where people may neither participate in certain activities nor access certain services unless they agree to be tested. Examples of circumstances in which mandatory testing is appropriate include before blood, tissue and organ donation, and for immigration purposes.

Occupational exposure
An exposure that may place an employee at risk of HIV or HCV infection through percutaneous injury (e.g. a needlestick or cut with a sharp object, contact of mucous membranes, or contact of skin with blood, tissues or other potentially infectious body fluids to which Universal Precautions apply).

Serology
Refers to testing for the presence, evidence of, or quantity of antibodies or antigens specific for infectious or other agents, biochemistry, or substances in blood (serum or plasma or whole blood).
14.0 REFERENCES

1.0 Introduction


2.0 Diagnostic strategies


3. Indications for HBV testing


4. Informed consent for testing

5. Conveying hepatitis B test results

6. Surveillance and research

7. Health care workers

8. Antenatal and perinatal testing

9. People from culturally and linguistically diverse backgrounds

10. Aboriginal and Torres Strait Islander Peoples

11. Quality assurance of HBV testing

12. Funding of HBV testing