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, a joint working party of the Blood Borne Virus and Sexually Transmissible Infections Standing committee (BBVSS) and the Ministerial Advisory Committee on Blood Borne Viruses and Sexually Transmissible Infections (MACBBVS). The process was coordinated by the Australasian Society for HIV Medicine (ASHM).

The views expressed in this Testing Policy are not necessarily those of the Commonwealth. The Commonwealth, the Ministerial Advisory Committee on Blood Borne Viruses and Sexually Transmissible Infections and the Blood Borne Virus and Sexually Transmissible Infections Standing Committee of the Australian Health Protection Committee do not accept any liability for any injury, illness, damage or loss incurred by any person arising from the use of or reliance on the information or advice that is provided in this Testing Policy.

The web-based provision of the 2012 National HBV Testing Policy allows for regular revision, and access to related resources (e.g. related policies, operational guidelines, evidence of best practice) with a download and print function. It can be found at: http://testingportal.ashm.org.au. Any references or web links to products, services or information contained in this publication do not constitute an endorsement of those references or web links.

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1.0 INTRODUCTION

1.1 Background and context

This is the first national testing policy for hepatitis B virus (HBV) infection. Serological testing for hepatitis B has been available in Australia for several decades and now 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 220,000 people in Australia with HBV infection with many more having been exposed. The impact of this disease is and will continue to be significant, as HBV-related cirrhosis and hepatocellular carcinoma (HCC) continue to increase in prevalence. The majority of newly reported infections in Australia are chronic (lasting 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 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 HBV DNA) is also 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 contact with 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. HBV infection can lead to cirrhosis and HCC (in up to 25% of people with chronic hepatitis B). Ongoing monitoring and timely treatment can help manage and prevent the onset of serious liver disease or 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.

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 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.

This policy document assumes that all health professionals involved in the testing process are appropriately trained in both the management of HBV and the management of chronic illness.
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 first National Hepatitis B Strategy 2010 – 2013 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. ASHM will coordinate the annual reviews.

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.
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;
- under the migration health requirements applicable to specified visa subclasses;
- 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;
- as a condition for performing exposure-prone procedures in health care settings in some jurisdictions.

To all extents reasonable, 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.

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 HBV than to either human immunodeficiency virus (HIV) 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 hepatitis B virus 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>
</tr>
<tr>
<td></td>
<td></td>
<td>Particle agglutination</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rapid, short incubation assay</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>including PoC</td>
<td></td>
</tr>
<tr>
<td>Hepatitis B surface antigen neutralisation</td>
<td>HBsAg</td>
<td>Confirmation of the presence of HBsAg</td>
<td>Immunoassay</td>
</tr>
<tr>
<td>Hepatitis B surface antigen (quantitative)</td>
<td>HBsAg</td>
<td>Monitoring of therapy</td>
<td>Immunoassay</td>
</tr>
<tr>
<td>Hepatitis B surface antibody</td>
<td>anti-HBs or HbsAb</td>
<td>Determining protective immunity*</td>
<td>Immunoassay</td>
</tr>
<tr>
<td>Hepatitis B core total antibody</td>
<td>anti-HBc or HbcT or HbcAb</td>
<td>As part of strategy to determine exposure to hepatitis B virus</td>
<td>Immunoassay</td>
</tr>
<tr>
<td>IgM to hepatitis B core antigen</td>
<td>IgM anti-HBc or HbcIgM</td>
<td>As part of strategy to diagnose acute hepatitis B infection</td>
<td>Immunoassay</td>
</tr>
<tr>
<td>Hepatitis B e antigen</td>
<td>HBeAg</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>Hepatitis B e antibody</td>
<td>Anti-HBe or HBeAb</td>
<td>Determining seroconversion from hepatitis B e antigen and phase of the infection for clinical management</td>
<td>Immunoassay</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. These individuals are still regarded as having acquired 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. HIV infected patients with low CD4 counts and a low anti-HBs despite vaccination are at risk of re-infection. Testing for this would be as for diagnosis of a new infection and HBV DNA may be the relevant first investigation.
Tests for hepatitis B virus (HBV) must comply with the regulatory framework for in-vitro diagnostic medical devices 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. In-vitro diagnostic devices (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 infection by HBV are Class 4 IVDs.

Common diagnostic strategies include testing for:
- diagnosis of acute infection (5% of notifications) – HBsAg, anti-HBs, 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;
- antenatal/pre-operative/insurance screening – HBsAg;
- investigation of degree of infectivity when HBsAg positive – HBV DNA;
- monitoring of therapy – quantitative HBV DNA, HBsAg, HBeAg, anti-HBs, anti-HBe;
- assessment of disease phase in a person with chronic hepatitis B – HBeAg, anti-HBe, HBV DNA.

Note that there are three tests for hepatitis antibodies or antigens for the investigation of infectious causes of acute or chronic hepatitis (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 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 and may be useful in some settings (e.g., testing in remote communities and where there are barriers to accessing traditional health care). However, 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. PoC tests must comply with the regulatory framework for IVDs and be included in the Australian Register of Therapeutic Goods. A positive or negative PoC test should be confirmed by standard HBV testing in a NATA certified diagnostic laboratory.

(D) Reference Tests

The presence of HBsAg is confirmed by HBV neutralisation testing as recommended by the manufacturer’s instructions and as approved by the Therapeutic Goods Administration (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 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 HDV in all HBV infected patients but particularly in those with a severe presenting illness (likely a 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 is initially with 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.

2.2 Diagnostic strategies for HBV

Suspected acute HBV

* Note that IgM anti-HBc 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.
Suspected chronic HBV

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

vii. 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 hepatitis B virus (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 which 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;
- 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:

- attending an antenatal clinic (see section 8.1);
- health care workers who perform or may be expected to perform exposure prone procedures (EPPs) must 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 human immunodeficiency virus (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 reports prior vaccination – clinicians should ask patients who report prior vaccination, if they were tested for HBV infection before vaccination. Those unaware of their status should be tested to clarify their situation;
- 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(^ab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>See Figure 1 below. Please note indigenous populations in these countries often have a higher prevalence.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Aboriginal and Torres Strait Islander peoples(^ab)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients undergoing chemotherapy or immunosuppressive therapy (due to risk of reactivation)</td>
</tr>
</tbody>
</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(^ab)</td>
</tr>
<tr>
<td>• People who have ever injected drugs(^ab)</td>
</tr>
<tr>
<td>• Men who have sex with men(^b)</td>
</tr>
<tr>
<td>• People with multiple sex partners(^ab)</td>
</tr>
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<td>• People in custodial settings or who have ever been in custodial settings(^ab)</td>
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<td>• People with HIV or hepatitis C, or both(^b)</td>
</tr>
<tr>
<td>• Patients undergoing dialysis(^b)</td>
</tr>
<tr>
<td>• Sex workers(^ab)</td>
</tr>
</tbody>
</table>

a. If HBsAg-positive persons are found in the first generation, subsequent generations should be tested;
b. 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\(^20\)

For multiple countries, estimates of prevalence of hepatitis B surface antigen (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 a Centres for Disease Control and prevention (CDC) publication; there is no copyright.\(^22\) HBsAg prevalence is shifting in many endemic countries which have adopted universal infant vaccination. China, for example, is now an intermediate prevalence country with the the age-adjusted prevalence of hepatitis B dropping from 9.8% in 1992 to 7.2% in 2009.\(^21\)
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 are born overseas, particularly in the Asia Pacific region, Europe, Africa and the 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 in adulthood 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 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 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 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 vaccination, 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.
3.1.3 All patients undergoing chemotherapy or immunosuppressive therapy

Chemotherapy and its related immunosuppression can cause reactivation of HBV with associated morbidity, interruption of chemotherapy or other treatments, and mortality. All patients undergoing chemotherapy or immunosuppressive therapy (e.g. monoclonal antibody therapy; high dose steroids) should be tested (see section 2.2) to allow patients with HBV infection to be monitored, and treated as appropriate with prophylactic antiviral therapy to prevent reactivation.11

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 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, partners and other household and intimate contacts, including children, should be tested for HBsAg, anti-HBs and anti-HBc. Those without immunity should be vaccinated.11 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.11

3.1.5 People with a history of injecting drug use

Up to 50% of people who inject drugs have serological markers of HBV infection. The majority of newly acquired hepatitis B cases notified to Australian health departments are in people who inject drugs. The prevalence of HBsAg is considerably lower than that of anti-HBc (3-5% versus 20–50%) due to high rates of spontaneous HBsAg clearance among adolescents and young adults. People who inject drugs often experience significant barriers to accessing health services including HBV testing, vaccination and treatment. 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 for people who inject drugs will have a profound effect on their understanding of their condition and their likelihood of future engagement with the health system. Peer education and support will 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

People with a history of injecting drug use are also at increased risk of having acquired HDV infection and testing for this should be considered (see section 2.1).

3.1.6 Men who have sex with men

Unvaccinated men who have sex with men have a prevalence of serological markers of past or current HBV infection of approximately 38%.12 A small percentage of this group remains HBsAg positive. Coverage rates of the HBV vaccine in men who have sex with men are low. Hepatitis B vaccination should be offered if testing reveals neither immunity nor current infection.11
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.¹¹

3.1.8 People 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.¹² For further information please see The Australian Immunisation Handbook.¹³

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.¹⁴ 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.¹¹ For further information please see The Australian Immunisation Handbook.¹¹

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.¹⁵ 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.¹¹
4.0 INFORMED CONSENT FOR TESTING

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 testing. Obtaining informed consent may take more than one consultation.3

When offering testing to patients with low English proficiency,25 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.36

The Translating and Interpreting Service is available 24 hours/7 days per week.37 Contact the Doctors’ Priority Line 1300 131 450. There are also publicly funded health interpreting services available in most states and territories.38 Where available, telephone interpreting has a high degree of acceptability to many people because it allows them to maintain anonymity.

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

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 a 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 apply in the case of HBV testing and informed consent; consent 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 their 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.
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 understanding 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 as interpreters is strongly discouraged. 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.

The decision about how a result 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 hepatitis B virus (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 language (see section 4.0). The use of family members as interpreters is strongly discouraged.

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 hepatocellular carcinoma (HCC);
- identifying the importance of lifestyle changes - in particular alcohol consumption and, for people with chronic hepatitis B, the availability, efficacy and timing of treatment options;
- 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 may be necessary to cover these issues over a period of time, in which case a subsequent consultation should be arranged at the time of diagnosis.
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.hepatitisaustralia.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 which 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). 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 hepatocellular carcinoma (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 hepatitis C virus (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.

5.6.5 Post-mortem testing

Hepatitis B tests are not standardised in the post-mortem setting. A pathologist ordering hepatitis B testing as part of the process of a coronial examination or other post-mortem examination is responsible for ensuring that the other provisions in this policy are adhered to.
6.0 SURVEILLANCE AND RESEARCH

Laboratories performing hepatitis B virus (HBV) testing must notify the relevant State and Territory health authorities of any new hepatitis B surface antigen (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.\(^6\)

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 National Health and Medical Research Council (NHMRC).

6.2 Use of unregistered in-vitro diagnostic devices

Before the introduction of the new regulatory framework for in-vitro diagnostic devices (IVDs) in 2010, hepatitis B tests were not required to be registered with the Australian Register of Therapeutic Goods (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 Therapeutic Goods Administration 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).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.¹² 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. Women with a high viral load should receive specialist advice including the role of antiviral treatment to reduce the risk of transmission. Timely administration of hepatitis B vaccination and hepatitis B immunoglobulin (HBIG) to the infant within 12 hours of birth will reduce the risk of hepatitis B transmission by approximately 90%.

Women identified as HBsAg positive should be referred to a gastroenterologist, hepatologist or Infectious Diseases Unit for monitoring, management and possible treatment.

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, after the final dose of hepatitis B vaccine (most practically at 12 months of age). Testing for anti-HBc is not useful at this age, because 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 culturally and linguistically diverse (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.45

The term ‘culturally and linguistically diverse’ was adopted by the Commonwealth Government Ministerial Council of Immigration and Multicultural Affairs in 1996 to replace descriptors like ‘ethnic’ or ‘non-English-speaking background’.46

‘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.

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).20

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. 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. However the use of family members as interpreters is strongly discouraged. Clinicians should be aware that in certain cultures health issues are faced collectively rather than as an individual.
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 Third National Aboriginal and Torres Strait Islander Blood Borne Virus & Sexually Transmissible Infections Strategy 2010-2013 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 hepatitis B virus (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 hepatitis B virus (HBV) testing:

- **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 sponsor and the Therapeutic Goods Administration (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 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.

- There is a Medicare Benefits Schedule (MBS) rebate for hepatitis B virus (HBV) serological testing.
- There is a MBS rebate for quantitative nucleic acid testing for HBV DNA.

12.1 Funding arrangements for hepatitis B diagnostic and monitoring tests

More detailed information on funding of 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 and was provided by an accredited pathology laboratory. 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: medicare.prov@medicareaustralia.gov.au.
13.0 GLOSSARY

13.1 Abbreviations and acronyms

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<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tr>
<td>ARTG</td>
<td>Australian Register of Therapeutic Goods</td>
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<td>ASHM</td>
<td>Australasian Society for HIV Medicine</td>
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<tr>
<td>BBVSS</td>
<td>Blood Borne Virus and Sexually Transmissible Infection Subcommittee</td>
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<tr>
<td>CALD</td>
<td>Culturally and Linguistically Diverse</td>
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<tr>
<td>EPP</td>
<td>Exposure Prone Procedure</td>
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<tr>
<td>EQAS</td>
<td>External Quality Assessment Scheme</td>
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<td>HBsAg</td>
<td>Hepatitis B Surface Antigen</td>
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<td>HBV</td>
<td>Hepatitis B Virus</td>
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<td>HCC</td>
<td>Hepatocellular Carcinoma</td>
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<td>HCV</td>
<td>Hepatitis C Virus</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>IVD</td>
<td>In-Vitro Diagnostic Devices</td>
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<td>MBS</td>
<td>Medicare Benefits Schedule</td>
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<td>MACBBVS</td>
<td>Ministerial Advisory Committee on Blood Borne Viruses and Sexually Transmissible Infections</td>
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<td>NAT</td>
<td>Nucleic Acid Test</td>
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<td>NATA</td>
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<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<td>NPAAC</td>
<td>National Pathology Accreditation Advisory Council</td>
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<td>NRL</td>
<td>National Serology Reference Laboratory, Australia</td>
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<td>PoC</td>
<td>Point of Care Testing</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).

**Seroology**
Is testing for the presence, evidence of, or quantity of antibodies 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


8. Antenatal and perinatal testing


9. People from culturally and linguistically diverse backgrounds


11. Quality assurance of HBV testing


12. Funding of HBV testing
