INTERPRETING HEPATITIS B SEROLOGY

RECOMMENDED WORDING FOR NATIONAL LABORATORIES TO REPORT HEPATITIS B DIAGNOSTIC TEST RESULTS

THIS DOCUMENT HAS BEEN ENDORSED BY: Australasian Society for HIV Medicine, Austin Pathology, Australasian Society for Infectious Diseases, Australasian Hepatology Association, Australian Institute of Medical Scientists, Australian Liver Association, Communicable Diseases Network Australia, National Research Laboratory, National Coalition of Public Pathology, RCPA Quality Assurance Programs Pty Limited, Royal College of Pathologists of Australasia.

ashm | ASID | Australasian Hepatology Association | Australian Institute of Medical Scientists | GESA Gastroenterological Society of Australia | ala Australian Liver Association | Communicable Diseases network AUSTRALIA | NRL Science of Quality | NCOPP National Coalition of Public Pathology | RCPA The Royal College of Pathologists of Australasia | RCPAQAP

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This document has been developed as a concise source of standardised, currently available information to inform those performing hepatitis B diagnostic testing within a laboratory setting about the recommended wording to use when reporting results to health professionals. The advice in this document is a guide only and is considered correct as of October 2013.

CONTENTS

KEY

- All writing in black is instructional for the laboratories performing hepatitis B testing
- All writing in grey is the recommended wording to use on the pathology reports

GLOSSARY OF TERMS

hepatitis B surface antigen (HBsAg)	hepatitis B e antibody (anti-HBe)
hepatitis B surface antibody (anti-HBs)	hepatitis B virus (HBV)
hepatitis B core antibody (anti-HBc)	hepatitis C virus (HCV)
hepatitis B core IgM antibody (anti-HBc IgM)	hepatitis D virus (HDV)
hepatitis B e antigen (HBeAg)	human immunodeficiency virus (HIV)

1.0 THE AIM OF THIS DOCUMENT

The aim of this document is to be a guideline and resource for laboratories performing hepatitis B testing. The actual testing and reporting strategies used in each laboratory remain under the direction of the pathologists.

It is understood that not all of the recommended testing strategies will be adequately funded by the current Medicare rebate scheme. However like the National Hepatitis B Testing Policy 2012 (http://testingportal.ashm.org.au/hbv), this document aims to promote best practice hepatitis B testing and reporting to improve diagnosis and management of hepatitis B infection and improve the understanding and interpretation of hepatitis B serology by requesting doctors. Not all laboratories are dictated to by Medicare and with ongoing rationalisation of pathology services, best practice guidelines can facilitate the maintenance of standards.

It is recommended that all three hepatitis B markers (HBsAg, anti-HBc and anti-HBs) be tested for, in patients with unknown serology status who may be at risk of hepatitis B virus (HBV). Testing for all three hepatitis B markers identifies if the patient has been exposed and/or has immunity, and follows the recommendations of the National Hepatitis B Testing Policy 2012.

It is also recommended that all HBsAg reactive samples are confirmed by neutralisation testing or in accordance with the manufacturer's instructions, at least the first time the patient presents.

2.0 HEPATITIS B SURFACE ANTIGEN (HBsAg) POSITIVE RESULTS

2.0	HBsAg POSITIVE	Anti-HBc	Anti-HBc IgM	Anti-HBs	Interpretation (Lab use only)	Suggested wording for pathology form
2.1	**+**	If the **HBsAg** marker is POSITIVE and has been requested on its own, it is **not** advised that this marker be reported on its own, *unless* it is a *known* hepatitis B case. In the case where the patient is not known to be hepatitis B positive, it is advised: the lab adds anti-HBc and IgM or other markers that prove hepatitis B infection. OR requests further testing by the doctor.			**Possible current infection.** Be aware that HBsAg can be ***transiently*** positive following ***very recent*** vaccination or a laboratory contamination or splash ***of the tested sample***. In these cases, anti-HBc will be negative.	**If known CHRONIC hepatitis B infection, use following comment:** Evidence of current (chronic) hepatitis B infection. Recommend serology testing (HBsAg, anti-HBc, anti-HBs) of household, close and intimate contacts and vaccination of non-immune individuals. Recommend testing for HBeAg and anti-HBe, HBV viral load, HCV, HDV, HIV and assessment of liver function including liver ultrasound and specialist referral. For further information see **www.hepbhelp.org.au**. *If preferred, lab may use similar hepatitis B management website in their jurisdiction.* Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.* **If NOT known to have hepatitis B infection and lab does NOT add other markers, use following comment:** Suggestive of CURRENT hepatitis B infection. Recommend repeat HBsAg, together with anti-HBc and Anti-HBc IgM. HBsAg positive result should NOT be acted upon in the absence of results for repeat HBsAg and testing for anti-HBc and anti-HBc IgM. HBsAg positivity for 6 months or more is consistent with CHRONIC hepatitis B infection. Recommend serology testing (HBsAg, anti- HBc, anti-HBs) of household, close and intimate contacts and vaccination of non-immune individuals. If CHRONIC hepatitis B infection: recommend testing for HBeAg, anti-HBe, HBV viral load, HCV, HDV, HIV, assessment of liver function including ultrasound and specialist referral. For further information see **www.hepbhelp.org.au**. *If preferred, lab may use similar hepatitis B management website in their jurisdiction.* Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.* **If anti-HBc positive and anti-HBc IgM is added and is positive - See 2.6** **If anti-HBc positive and anti-HBc IgM is negative - See 2.9** **If anti-HBc is negative See 2.3**
2.2	**+**			**–**	**Current Infection** (SEE ABOVE: **2.1**)	**Use comment AS ABOVE in 2.1**
2.3	**+**	**–**		**–**	Be aware that HBsAg can be ***transiently*** positive following ***very recent*** vaccination or a laboratory contamination or splash ***of the tested sample.*** *Very rarely a patient may be HBsAg positive but does not develop anti-HBc.*	Atypical serology. May represent very early hepatitis B infection, recent vaccination or (rarely) chronic hepatitis B without development of anti-HBc. Recommend repeat testing of HBsAg, anti-HBs and anti-HBc in 1-2 weeks. If result remains unchanged recommend HBV viral load.

2.0	HBsAg POSITIVE	Anti-HBc	Anti-HBc IgM	Anti-HBs	Interpretation (Lab use only)	Suggested wording for pathology form
2.4	+	+			**Current infection.** Lab should consider initiating **anti-HBc IgM** test, *unless* known chronic hepatitis B infection or there is a cumulative history over 6 months which allows diagnosis of chronic disease.	**If known CHRONIC hepatitis B infection, use following comment** Consistent with CHRONIC hepatitis B infection. Recommend serology testing (HBsAg, anti- HBc, anti-HBs) of household, close and intimate contacts and vaccination of non-immune individuals. Recommend testing for HBeAg, anti-HBe, HBV viral load, HCV, HDV, HIV and assessment of liver function including liver ultrasound and specialist referral. For further information see **www.hepbhelp.org.au**. *If preferred, lab may use similar hepatitis B management website in their jurisdiction.* Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.*
	+	+		–		**If NOT known chronic hepatitis B infection and anti-HBc IgM not added, use following comment** Evidence of CURRENT hepatitis B infection. Recommend serology testing (HBsAg, anti- HBc, anti-HBs) of household, close and intimate contacts and vaccination of non-immune individuals. HBsAg positivity for 6 months or more is consistent with CHRONIC hepatitis B infection. If CHRONIC hepatitis B infection: recommend testing for HBeAg, anti-HBe, HBV viral load, HCV, HDV, HIV, assessment of liver function including ultrasound and specialist referral. For further information see **www.hepbhelp.org.au**. *If preferred, lab may use similar hepatitis B management website in their jurisdiction.* Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.* **If NOT known chronic hepatitis B infection and anti-HBc IgM is added and is NEGATIVE, use following comment:** Most likely CHRONIC hepatitis B infection. HBsAg positivity for 6 months or more is consistent with CHRONIC hepatitis B infection. Occasionally represents resolving acute hepatitis B infection with early loss of the anti-HBc IgM so repeat testing may be indicated. Recommend serology testing (HBsAg, anti- HBc, anti-HBs) of household, close and intimate contacts and vaccination of non-immune individuals. If CHRONIC infection: recommend testing for HBeAg, anti-HBe, HBV viral load, HCV, HDV, HIV, and assessment of liver function including ultrasound and specialist referral. For further information see **www.hepbhelp.org.au**. *If preferred, lab may use similar hepatitis B management website in their jurisdiction.* Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.*

2.0	HBsAg POSITIVE	Anti-HBc	Anti-HBc IgM	Anti-HBs	Interpretation (Lab use only)	Suggested wording for pathology form
2.5	+	+		+	**Current infection.** *(*Lab should consider initiating **anti-HBc IgM** test, *unless* known chronic hepatitis B infection*)*	**Use comment AS ABOVE in 2.4 plus add to each:** Co-existence of HBsAg and anti-HBs may occur in chronic hepatitis B infection. The clinical significance of this is not yet known.
2.6	+	+	+		**Acute infection or chronic hepatitis B flare.**	**If known to be HBsAg negative in the recent past, use following comment:** Consistent with ACUTE hepatitis B infection. Recommend repeat testing as HBsAg positivity for 6 months or more is consistent with chronic hepatitis B infection. Recommend serology testing (HBsAg, anti-HBc, anti-HBs) of household, close and intimate contacts and vaccination of non-immune individuals. Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.* **If NOT known to be HBsAg negative in the recent past or to have chronic infection, use following comment:** Evidence of **ACUTE** hepatitis B infection **OR CHRONIC** hepatitis B infection with a flare of the disease as HBc IgM is positive. Repeat testing in 2-3 months. Clinical correlation and past hepatitis B serology are required to distinguish between acute or chronic. Recommend serology testing (HBsAg, anti- HBc, anti-HBs) of household, close and intimate contacts and vaccination of non-immune individuals. If CHRONIC hepatitis B infection: recommend testing for HBeAg, anti-HBe, HBV viral load, HCV, HDV, HIV, assessment of liver function including ultrasound and specialist referral. For further information see **www.hepbhelp.org.au.** *If preferred, lab may use similar hepatitis B management website in their jurisdiction.* Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.* **If known chronic hepatitis B, use following comment** Consistent with CHRONIC hepatitis B infection with probable flare of hepatitis. Recommend serology testing (HBsAg, anti- HBc, anti-HBs) of household, close and intimate contacts and vaccinate non-immune individuals. Recommend testing for HBeAg, anti-HBe, HBV viral load, HCV, HDV, HIV and assessment of liver function including ultrasound and specialist referral. For further information see **www.hepbhelp.org.au.** *If preferred, lab may use similar hepatitis B management website in their jurisdiction.* Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.*
	+	+	+	–		
	+	+	+	+		

2.0	HBsAg POSITIVE	Anti-HBc	Anti-HBc IgM	Anti-HBs	Interpretation (Lab use only)	Suggested wording for pathology form
2.7	+	+	+	+	**Acute infection or chronic hepatitis B flare**	Use comments AS ABOVE IN **2.6** **Plus if known CHRONIC hepatitis B infection add following comment:** Co-existence of HBsAg and anti-HBs may occur in chronic hepatitis B infection. The clinical significance is not yet known.
2.8	+	Should be added	–		**Possible chronic hepatitis B infection.** However, this *may* indicate recent vaccination or a laboratory contamination or splash unless confirmation of HBV infection by positive anti-HBc or other markers.	**If known CHRONIC hepatitis B infection – See 2.1** **If NOT known to have hepatitis B infection and lab does NOT add other markers – See 2.1** **If anti-HBc is added and is positive – See 2.9 for comment** **If anti-HBc is added and is negative –See 2.3 for comment**
	+	Should be added	–	–		
2.9	+	+	–		**Probable chronic hepatitis B infection.**	**If known CHRONIC hepatitis B infection, use following comment:** Consistent with CHRONIC hepatitis B infection. Recommend serology testing (HBsAg, anti-HBc, anti-HBs) of household, close and intimate contacts and vaccination of non-immune individuals. Recommend testing for HBeAg, anti-HBe, HBV viral load, HCV, HDV, HIV and assessment of liver function including ultrasound and specialist referral. For further information see **www.hepbhelp.org.au**. *If preferred, lab may use similar hepatitis B management website in their jurisdiction.* Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.* **If NOT known chronic hepatitis B infection, use following comment:** Most likely CHRONIC hepatitis B infection. HBsAg positivity for 6 months or more is consistent with CHRONIC hepatitis B infection. Occasionally represents resolving acute hepatitis B infection with early loss of the anti-HBc IgM so repeat testing may be indicated. Recommend serology testing (HBsAg, anti- HBc, anti-HBs) of household, close and intimate contacts and vaccination of non-immune individuals. If CHRONIC infection: recommend testing for HBeAg, anti-HBe, HBV viral load, HCV, HDV, HIV and assessment of liver function including ultrasound and specialist referral. For further information see **www.hepbhelp.org.au**. *If preferred, lab may use similar hepatitis B management website in their jurisdiction.* Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.*
	+	+	–	–		

3.0 HEPATITIS B SURFACE ANTIGEN (HBsAg) NEGATIVE RESULTS

3.0	HBsAg NEGATIVE	Anti-HBc	Anti-HBc IgM	Anti-HBs	Interpretation (Lab use only)	Suggested wording for pathology form
3.1	–				**Current infection unlikely.**	**Pre-operative patients or antenatal screening, use following comment:** No evidence of acute or chronic infection with hepatitis B **All other cases, use following comment:** No evidence of acute or chronic hepatitis B. However HBsAg may not be present in the rare case of occult hepatitis B, or very early in acute infection. Consider further testing in high-risk individuals. Recommend testing for anti-HBc and anti-HBs in accordance with the National Hepatitis B Testing Policy. See Diagnostic Strategies: **www.testingportal.ashm.org.au/hbv/diagnostic-strategies** Discuss patient's suitability for vaccination if susceptible to hepatitis B infection.
3.2	–	–		Lab should consider initiating anti-HBs	**Current infection unlikely.**	Acute or chronic infection with hepatitis B is highly unlikely. **If anti-HBs is NOT added, use following comment:** No evidence of past or current hepatitis B infection. Recommend testing of anti-HBs to identify immune status. See **www.testingportal.ashm.org.au/hbv/diagnostic-strategies** for information on further investigation and management. **If anti-HBs is added – see 3.12 and 3.13 for comments**
3.3	–	+	–	Lab should consider initiating anti-HBs	**Resolved infection (anti-HBs positive) or isolated core antibody (anti-HBs negative)**	Test for anti-HBs to identify immune status. See **www.testingportal.ashm.org.au/hbv/diagnostic-strategies** for information on further investigation and management. **If anti-HBs is NOT added, use following comment:** Most likely past infection with hepatitis B. Uncommonly may be an occult hepatitis B. Test for anti-HBs to identify full hepatitis B status. See **www.testingportal.ashm.org.au/hbv/diagnostic- strategies** for information on further investigation and management. **If anti-HBs is added – see 3.12 and 3.13 for comments**

3.0	HBsAg NEGATIVE	Anti-HBc	Anti-HBc IgM	Anti-HBs	Interpretation (Lab use only)	Suggested wording for pathology form
3.4	–	+	It is strongly recommended lab initiates HBc IgM	–	**Isolated core antibody.**	**If HBc IgM NOT done, use following comments:** Possible explanations for isolated hepatitis B core antibodies (anti-HBc) are: 1. Resolving acute infection in the window period before anti-HBs response; suggest test hepatitis B core IgM (anti-HBc IgM) and repeat test in 6 weeks 2. Recovery from past HBV infection with persistence of hepatitis B core antibodies (anti-HBc) and loss of detectable hepatitis B surface antibodies (anti-HBs). a) Consider single dose vaccination and retest anti-HBs in 1 month 3. Low level (undetectable) hepatitis B surface antigen (occult hepatitis B infection). If there is evidence of liver disease, or immunosuppression, concurrent hepatitis C or D infection, recommend measuring HBV viral load. 4. False positive anti-HBc. See **www.testingportal.ashm.org.au/hbv/diagnostic-strategies** for information on further investigation and management.
3.5	–	+	–	–	**Isolated core antibody.**	No evidence of recent hepatitis B infection. Probable hepatitis B core window period. Suggest repeat test in 6 weeks. Possible explanations for isolated hepatitis B core antibodies are: 1. Recovery from past HBV infection with persistence of hepatitis B core antibodies and loss of detectable hepatitis B surface antibodies. a) Consider single dose vaccination and retest anti-HBs in 1 month 2. Low level (undetectable) hepatitis B surface antigen (occult hepatitis B infection). If there is evidence of liver disease, or immunosuppression, concurrent hepatitis C or D infection, recommend measuring HBV viral load. 3. False positive anti-HBc. 4. Less likely resolving acute infection in the window period before anti-HBs response, suggest repeat test in 6 weeks. See **www.testingportal.ashm.org.au/hbv/diagnostic-strategies** for information on further investigation and management.
3.6	-	+	+	- Or not done	**Probable resolving ACUTE hepatitis B infection.**	Probable resolving ACUTE hepatitis B infection. Recommend repeat hepatitis B serology and liver function tests. Recommend serology testing (HBsAg, anti- HBc, anti-HBs) of household, close and intimate contacts and vaccination of non-immune individuals. Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.*

3.0	HBsAg NEGATIVE	Anti-HBc	Anti-HBc IgM	Anti-HBs	Interpretation (Lab use only)	Suggested wording for pathology form
3.7	–	If not a request for post vac immunity, anti-HBs is required. Lab should automatically add it.		**> 10 mIU/mL**	**Immune either through past infection or vaccination.**	Evidence of immunity to hepatitis B due to past infection or vaccination. If post vaccination, an anti-HBs titre of 10 mIU/mL or greater is considered protective. • In immunocompetent people, protection is considered lifelong, provided a full vaccination course has been received. In this case further testing and booster vaccines are not indicated. • In immunocompromised people, especially dialysis and HIV patients, it is recommended to check anti-HBs levels regularly. Booster doses of vaccine should be offered to maintain anti-HBs >10 mIU/mL. Recommend testing for anti-HBc to look for past infection in accordance with the National Hepatitis B Testing Policy. See **www.testingportal.ashm.org.au/hbv/diagnostic-strategies** **If anti-HBc performed – See 3.8, 3.9 and 3.12**
	–		–	**> 10 mIU/mL**		
3.8	–	+		**> 10 mIU/mL**	**Immune through past infection.**	Evidence of past, resolved hepatitis B infection indicating immunity to hepatitis B. No evidence of current acute or chronic hepatitis B infection.
	–	+	–	**> 10 mIU/mL**	**Immune through past infection.**	
3.9	–	–		**> 10 mIU/mL**	**Immune through vaccination.**	Evidence of immunity due to vaccination. If post vaccination, an anti-HBs titre of 10 mIU/mL or greater is considered protective. • In immunocompetent people, protection is considered lifelong, provided a full vaccination course has been received. In this case further testing and booster vaccines are not indicated. • In immunocompromised people, especially dialysis and HIV patients, it is recommended to check anti-HBs levels regularly. Booster doses of vaccine should be offered to maintain anti-HBs >10 mIU/mL. No evidence of current or past hepatitis B infection.

3.0	HBsAg NEGATIVE	Anti-HBc	Anti-HBc IgM	Anti-HBs	Interpretation (Lab use only)	Suggested wording for pathology form
3.10	–			**> 10 mIU/mL**	**Immune through past infection or vaccination.**	Evidence of immunity due to past resolved infection or immunisation. If post vaccination, an anti-HBs titre of 10 mIU/mL or greater is protective. • In immunocompetent people, protection is considered lifelong, provided a full vaccination course has been received. In this case further testing and booster vaccines are not indicated. • In immunocompromised people, especially dialysis and HIV patients, it is recommended to check anti-HBs levels regularly. Booster doses of vaccine should be offered to maintain anti-HBs >10 mIU/mL. Recommend testing for anti-HBc in accordance with the National Hepatitis B Testing Policy. See **www.testingportal.ashm.org.au/hbv/diagnostic-strategies**
3.11	–			**< 10 mIU/mL**	**Waning or no immunity** **OR past infection** **OR chronic infection.**	No *serological* evidence of immunity to hepatitis B. Post vaccination, an anti-HBs titre of less than 10 mIU/mL is considered NOT IMMUNE. • Except where there has been documentation of seroconversion after a full vaccination course. – In vaccinated people, antibody levels may decline with time and may become undetectable without loss of immunity. Repeat testing and vaccination are not required. • In immunocompromised people, especially dialysis and HIV patients, it is recommended to check anti-HBs levels regularly. Booster doses of vaccine should be offered to maintain anti-HBs > 10 mIU/mL. If patient has not been previously vaccinated consider vaccination according to The Australian Immunisation Handbook. **If anti-HBc performed – See 3.4, 3.5, 3.13**
3.12	–	–	–	+	**Immune through vaccination.**	Evidence of immunity due to vaccination. For post vaccination, an anti-HBs titre of 10 mIU/mL or greater is considered protective. • In immunocompetent people, protection is considered lifelong, provided a full vaccination course has been received. In this case further testing and booster vaccines are not indicated. • In immunocompromised people, especially dialysis and HIV patients, it is recommended to check anti-HBs levels regularly. Booster doses of vaccine should be offered to maintain anti-HBs > 10 mIU/mL. No evidence of acute or chronic infection with hepatitis B.
3.13	–	–		–	**Susceptible.**	No evidence of current hepatitis B infection and no evidence of immunity to hepatitis B. Post vaccination, an anti-HBs titre of less than 10 mIU/mL is considered NOT IMMUNE. • Except where there has been documentation of seroconversion after a full vaccination course. – In these vaccinated people, antibody levels may decline with time and may become undetectable without loss of immunity. Repeat testing and vaccination are not required. • In immunocompromised people, especially dialysis and HIV patients, it is recommended to check anti-HBs levels regularly. Booster doses of vaccine should be offered to maintain anti-HBs > 10 mIU/mL. If patient has not been previously vaccinated consider vaccination according to The Australian Immunisation Handbook.
	–	–	–	–	**Susceptible.**	

4.0 ANTENATAL SCREENING: HEPATITIS B SURFACE ANTIGEN (HBsAg) POSITIVE RESULTS

Strongly recommend adding anti-HBc and HBc IgM and HBeAg. It makes no difference to the result if the anti-HBs result is positive or negative.

4.0	HBsAg POSITIVE	Anti-HBc	Anti-HBc IgM	Anti-HBs	HBeAg	Interpretation (Lab use only)	Suggested wording for pathology form
4.1	+	+	–		+	**Current hepatitis B infection.**	Evidence of CHRONIC hepatitis B infection. In chronic hepatitis B infection in a pregnant woman: measurement of hepatitis B viral load and referral to an antenatal infectious diseases clinic or hepatologist for assessment and management are strongly recommended. A positive HBeAg usually indicates high infectivity and increased risk of transmission to baby. **Hepatitis B hyperimmune immunoglobulin and vaccination should be administered to the neonate within 12 hours of birth.** Recommend serology testing (HBsAg, anti- HBc, anti-HBs) of household, close and intimate contacts and vaccination of non-immune individuals. Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.*
4.2	+	+	–		–	**Current hepatitis B infection.**	Evidence of CHRONIC hepatitis B infection. In chronic hepatitis B infection in a pregnant woman: measurement of hepatitis B viral load and referral to an antenatal infectious diseases clinic or hepatologist for assessment and management are strongly recommended. **Hepatitis B hyperimmune immunoglobulin and vaccination should be administered to the neonate within 12 hours of birth.** Recommend serology testing (HBsAg, anti- HBc, anti-HBs) of household, close and intimate contacts and vaccinate non-immune individuals. Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.*

4.0	HBsAg POSITIVE	Anti-HBc	Anti-HBc IgM	Anti-HBs	HBeAg	Interpretation (Lab use only)	Suggested wording for pathology form
4.3	**+**	**+**	**+**		**-/+**	**Current hepatitis B infection.**	The presence of hepatitis B core IgM may indicate **ACUTE** hepatitis B infection or **CHRONIC** hepatitis B infection with a flare of the disease. **IF ACUTE** infection, **urgent referral** to an antenatal infectious diseases clinic or hepatologist for assessment and management is recommended. **IF CHRONIC** infection: • In chronic hepatitis B infection in a pregnant woman: measurement of hepatitis B viral load and referral to an antenatal infectious diseases clinic or hepatologist for assessment and management are recommended. • A positive HBeAg usually indicates high infectivity and increased risk of transmission to baby. • **Hepatitis B hyperimmune immunoglobulin and vaccination should be administered to the neonate within 12 hours of birth.** • Recommend serology testing (HBsAg, anti- HBc, anti-HBs) of household, close and intimate contacts and vaccination of non-immune individuals. • Hepatitis B is a notifiable disease. Notification to the state or territory health department is required. *Use notification wording appropriate to jurisdiction.*
4.4	**–**	In antenatal screening: If HBsAg is negative and patient is low risk there is no need to perform other markers. However if high risk consider recommending performing other markers.					No evidence of acute or chronic infection with hepatitis B.

5.0 HEPATITIS B SURFACE ANTIGEN (HBsAg) UNCONFIRMED

This result cannot be interpreted without results of the other markers. Discussion with the managing Medical Officer is recommended before taking the investigation further.

5.0	HBsAg UNCONFIRMED	Anti-HBc	Anti-HBc IgM	Anti-HBs	Interpretation (Lab use only)	Suggested wording for pathology form
5.1	Unconfirmed	**+**	**–**	**-/+**	The HBsAg did not confirm by supplementary testing and may be a false positive. Would also suggest repeat testing on any doubtful or probable false positive results. **BUT** as the anti-HBc is positive it can be a true positive IF: Low level HBsAg with confirmatory test less sensitive than HBsAg test. OR Surface antigen mutant not detected by confirmatory test (may occur if the two tests are done on different platforms)	The hepatitis B serology is likely to indicate resolved hepatitis B infection. However, it may represent a low level of HBsAg or a surface antigen mutant. Consider measuring hepatitis B viral load if liver function tests are abnormal or patient is immunosuppressed.
5.2	Unconfirmed	**–**	**–** (or not done)	**–**	As anti-HBc is negative this HBsAg result did NOT confirm therefore the HBsAg is negative.	The HBsAg result did NOT confirm therefore the HBsAg is negative. There is no evidence of past or current infection with hepatitis B. No serological evidence of immunity to hepatitis B. Post vaccination, an anti-HBs titre < 10 mIU/mL is considered NOT IMMUNE. • Except where there has been documentation of seroconversion after a full vaccination course. – In these vaccinated people, antibody levels may decline with time and may become undetectable without loss of immunity. Repeat testing and vaccination are not required. • In immunocompromised people, especially dialysis and HIV patients, levels should be regularly checked and booster vaccines given to keep anti-HBsAg > 10 mIU/mL. If patient has not been previously vaccinated consider vaccination according to The Australian Immunisation Handbook.

5.0	HBsAg UNCONFIRMED	Anti-HBc	Anti-HBc IgM	Anti-HBs	Interpretation (Lab use only)	Suggested wording for pathology form
5.3	Unconfirmed	–	– (or not done)	+	As anti-HBc is negative this means no evidence of exposure to HBV. So the unconfirmed HBsAg is a false positive result.	The HBsAg result did NOT confirm, therefore the HBsAg is negative. There is no evidence of past or current infection with hepatitis B. Evidence of immunity due to vaccination. Post vaccination, an anti-HBs titre of 10 mIU/mL or greater is protective. • In immunocompetent people, protection is considered lifelong, provided a full vaccination course has been received. In this case further testing and booster vaccines are not indicated. • In immunocompromised people, especially dialysis and HIV patients, levels should be regularly checked and booster vaccines given to keep anti-HBsAg > 10 mIU/mL.