*This fact sheet is intended to provide a guide for health professionals who are involved in providing information to women on receiving a **reactive hepatitis B result in pregnancy**. This information is to be used alongside the All Wales Protocol for the Management of hepatitis B reactive results in pregnancy and as an aid in the discussion with women on their "reactive" hepatitis B results. The information for women leaflet 'reactive results in pregnancy' should be provided to the woman at the same time as she is informed of her result.*

The term "reactive" is used throughout this factsheet and indicates there is a reaction to the screening test. An initial reactive test result will need confirmatory tests to diagnose or refute a positive test result.

What is hepatitis B?

Hepatitis B is an infectious disease of the liver caused by the hepatitis B virus (HBV). It is transmitted through infected blood and other body fluids. Transmission can occur, for example, through sexual contact, needle sharing or antenatal transmission from mother to baby.

Infection can result in an acute or chronic infection. A chronic infection with HBV may result in cirrhosis of the liver and liver cancer. It is recognised that, without intervention, the earlier in life the infection occurs the greater the risk that it will lead to chronic infection, liver disease and early death.

What does the hepatitis B test identify?

- The recommended screening test for hepatitis B is an immunoassay to detect hepatitis B surface antigen (HBsAg).
- The screening test is designed to detect women who have an acute or chronic infection with hepatitis B virus.
- Tests for HBsAg are very sensitive and may detect women who are in the early incubation phase of an infection. If the screening test is positive further tests are used to confirm the result and assess infectivity.

Confirmed positive screening tests should be followed with an assessment of hepatitis B infectivity on the initial specimen. This is the first step in a more comprehensive clinical evaluation of the pregnant woman which also determines whether the baby requires postnatal HBIG (Hepatitis B immunoglobulin) as well as receiving 4 hepatitis B vaccinations within the first year of life to decrease the chances of mother to baby transmission of the virus.

How accurate is the hepatitis B test?

This test is more than 99% sensitive and specific for the detection of hepatitis B surface antigen

- More than 99.9% of the results will be positive when Hepatitis B is present (sensitivity)
- More than 99.9% of the results will be negative when Hepatitis B is not present (specificity).

In approximately 1:1000 samples the test causes a reaction within the screening test that is unlikely to be due to the hepatitis B virus. This is what is termed as 'non-specific' reactivity and is known as having a false positive result. Therefore a reactive result in the initial screening test only is very likely to be due to non-specific reactivity and give a 'false positive result'.

A 'false positive result' means that the test incorrectly indicates that hepatitis B surface antigen is present in a non-infected person.

What causes non-specific reactivity?

This is a relatively uncommon problem, but can result from:

- new antibodies detected due to a recent mild illness such as a cold
- the blood sample was not transported to the laboratory at the correct temperature, this can cause the blood cells to break down
- other unknown causes.

What is a negative result?

A negative result is issued if the initial laboratory test (screening test) is non-reactive. This will be the definitive result for this test.

What is a positive result?

A positive result is when:-

- hepatitis B surface antigen is reactive and,
- a second test on the initial sample is also reactive

The following markers will also be tested on the initial screening sample to assess infectivity:

- Hepatitis B core antibody (AntiHBc – total antibody)
- AntiHBc IgM
- Hepatitis B e antigen (HBeAg)
- Hepatitis B e-Antibody (AntiHBe).

However, this would be a presumptive positive test result as a new hepatitis B diagnosis should ONLY be made after a second sample is taken from the woman to ensure that there have been no errors with sample identity.

What is a reactive test result?

A reactive result is when:

- initial laboratory test (hepatitis surface antigen) is **reactive** and,
- confirmatory tests (as below) performed on the initial sample are **non-reactive-**
  - hepatitis B core antibody (AntiHBc – total antibody)
  - antiHBc IgM
  - hepatitis B e antigen (HBeAg).
  - hepatitis B e-Antibody (AntiHBe)

The most likely scenario is that of non-specific reactivity, however the possibility that this is a very recently acquired infection needs to be given consideration and a detailed review of any of the risk factors should be made.

A reactive result will only be issued if the laboratories, after completion of confirmatory tests, are unable to issue a negative result.

Result reporting

"*Initial screen result reactive, most probably due to non-specific reactivity. Please send a further sample in 3-5 weeks to confirm the absence of infection".*

The virologist/microbiologist will inform the antenatal screening co-ordinator directly of the result.

Care following a reactive result

The antenatal screening co-ordinator will assess if the woman has any of the following risks and inform the laboratory accordingly to enable the woman to receive re-testing in the most appropriate timeframe.

- Symptoms of acute hepatitis- fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, clay-coloured bowel movements.
- Born in, or has been resident, in an area of high prevalence for hepatitis B eg Middle East/ South East Asia/ Africa.
- Has had unprotected sex with a known carrier of hepatitis B or an individual from a high prevalence country
- Close/household/ contact of a hepatitis B carrier

If any of the above risk factors are identified the antenatal screening co-ordinator will need to discuss this with the virologist/microbiologist.

Taking the repeat sample

A repeat sample will be requested from the woman to be able to provide her with a definitive test result. The re-test will be performed (alongside verbally checking their risk history) during their next routine antenatal appointment.

- Screening before 13 weeks of pregnancy- retest at the routine 16 week appointment by the community midwife ie approximately 3-5 weeks after the initial screening test.
- Screening after 15 weeks of pregnancy- retest would be performed at the next routine antenatal appointment.

If any risk factors identified this should be discussed with a virologist / microbiologist.

If the woman has recently become infected, then testing too early means that the body has not yet had time to produce the antibodies, which will mean that a definitive result cannot be issued.

Could this be a newly acquired hepatitis B infection?

A recently acquired hepatitis B infection in pregnancy will be an extremely rare event in Wales and the vast majority of reactive results, will, on further testing with a second sample, be confirmed as negative for hepatitis B.

Suggested wording on how to discuss hepatitis B reactive results

- The woman should be informed that receiving a reactive result does not mean that she is infected with hepatitis B virus.
- A reactive test result on the initial screening test only is most probably due to a reaction caused within the screening test that is unlikely to be from the hepatitis B virus.
- In the absence of risk factors, she should be informed that the assumption is that she will receive a negative result on re-testing.
- She should be regarded as hepatitis B negative until her status is confirmed by a repeat.
- Use the word reactive, not equivocal or false positive.
- Sometimes a woman will need to have more than one repeat sample to be able to provide her with a definite result and she should be informed of this at the time of her re-test.
- Ensure that a local pathway is in place to ensure that there is a process for results handling and giving of the results within a timely manner.
- Provide the woman with the ASW Information for women leaflet at the same time as giving the verbal information.

Further information is available from

- Consultant virologist/consultant microbiologist in the Health Board.