Hepatitis B Reactive Results in Pregnancy

1.0 Introduction

This protocol is to standardise the management of pregnant women who have a reactive or equivocal result on the initial antenatal screening blood sample that is sent to the laboratory.

This protocol is intended to be used by midwives, obstetricians and laboratory staff who are involved in the provision of antenatal screening for hepatitis B in Wales.

There is an accompanying factsheet for health professionals and an information leaflet to aid the discussion with women.

For the management of confirmed hepatitis B positive results and hepatitis B negative results see Antenatal Screening Wales Policy, Standards, and Protocols to Support the Provision of Antenatal Screening Wales.

2.0 Background

Currently available hepatitis B tests are more than 99.9% sensitive and specific for the detection of hepatitis B surface antigen.

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 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. The further tests used to assess infectivity will identify such cases.

- A non-reactive result confirms a negative result.
- A reactive HBsAG screening test should be confirmed using an alternative HBsAG test of equivalent sensitivity on the initial sample. If the alternative HBsAG is also reactive a number of other serological tests will been performed on the initial sample. These tests will be performed at a referral laboratory.

A new hepatitis B diagnosis should ONLY be made after taking a second sample from the woman to ensure that there have been no errors with sample identity, as detailed in ASW standards.

In a small number of cases, the initial hepatitis B surface antigen test is reactive and the alternative surface antigen test and the serum markers are inconclusive making it difficult to give a definitive hepatitis B result to the woman. The testing strategy is complicated by the fact that this sort of profile could occur in a recently acquired hepatitis B infection. In that scenario, hepatitis B surface antigen can take up to a further 3 weeks to become fully detectable in laboratory systems, leading to a long potential period of confusion and anxiety for both staff and pregnant women when such results occur.

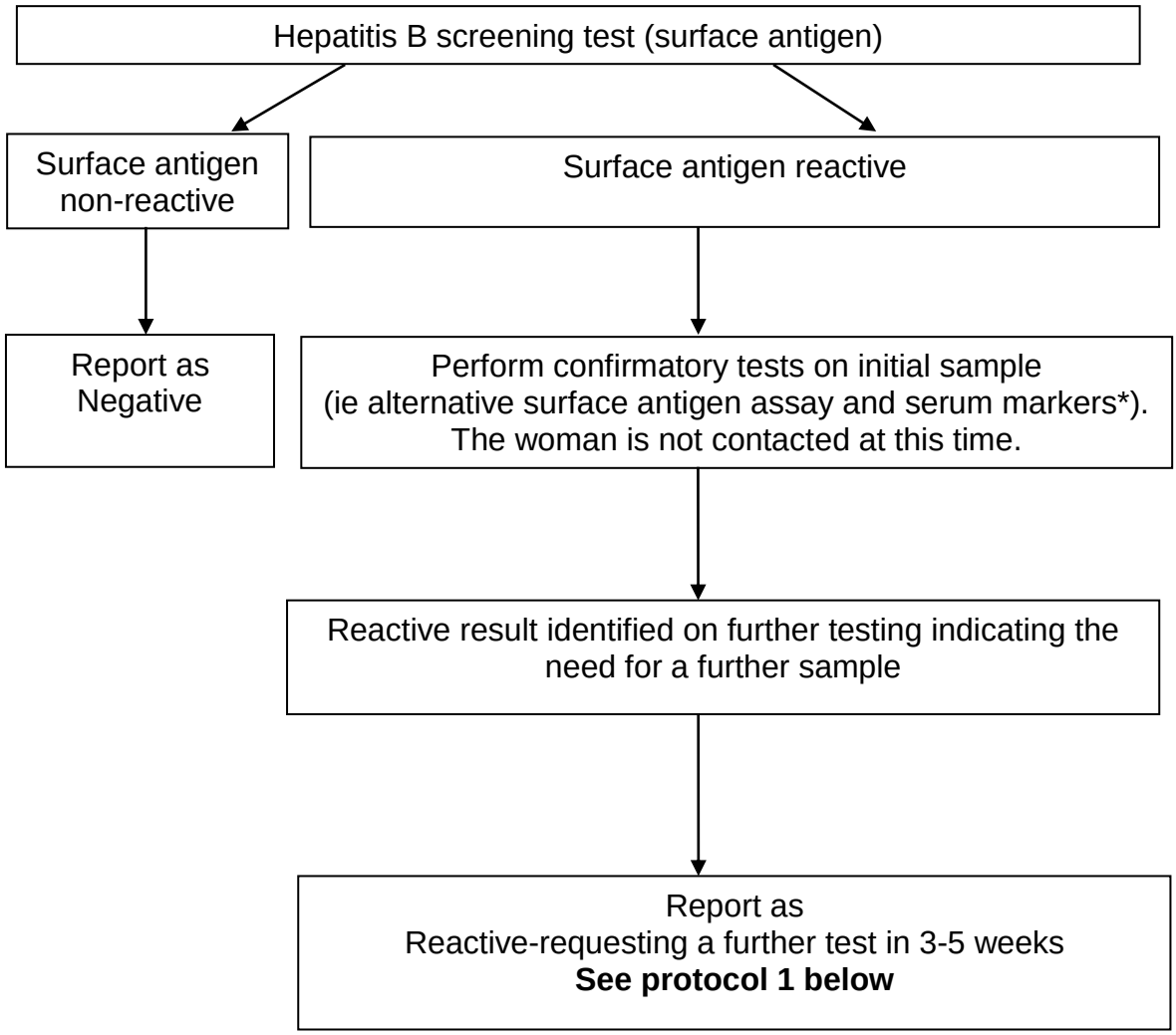
However a recently acquired hepatitis B infection in pregnancy will be an extremely rare event in Wales and the vast majority of these reactive results will be “false positives”. In order to manage women with these results safely, consistently and with minimum uncertainty, consideration needs to be given to individual women’s risk factors for acquiring hepatitis B.

3.0 Aim of the Protocol

This protocol has been devised to standardise the process of managing these reactive results throughout Wales, to minimise any unnecessary anxiety for women and staff and to ensure woman are given the correct result of their hepatitis B test in a timely manner.

The pathway below identifies the range of results that may occur from a hepatitis B test:

Pathway for Hepatitis B result



***Serum markers performed if surface antigen reactive:**

- Hepatitis B core antibody
- AntiHBc IgM
- Hepatitis B e antigen HBeAg)
- Hepatitis B e-antibody (AntiHBe)

Protocol 1

Initial Surface antigen test reactive and confirmatory tests non-reactive.

This test result is most likely to be due to non-specific reactivity within the screening assay (false positive) and as such should be managed as a normal result and in a non-urgent manner.

It will be reported as **"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 result will be reported from the laboratory to the antenatal screening co-ordinator, as per the local protocol. The expectation is that these women do not have a hepatitis B infection, however the antenatal screening co-ordinator should identify whether the woman has any identified risk factors (see table 1 below) and, if so, discuss the case with the laboratory clinicians.

Table 1: Risk History:

- Symptoms of acute hepatitis B -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

In the absence of any identified risk factors the woman should be regarded as hepatitis B negative, until her status is confirmed by a repeat (see below).

The antenatal screening co-ordinator/ deputy should arrange for a repeat sample to be taken, to confirm absence of hepatitis B infection, 3-5 weeks after the first sample was taken.

If the woman had her hepatitis B screening test before 13 weeks it would be appropriate to repeat this test at the routine 16 week antenatal clinic visit when the community midwife discusses and documents the screening test results with the woman. The Community midwife should discuss non-specific reactivity with the woman (an ASW factsheet for health professionals is available) and provide the woman with the ASW leaflet – **communicable disease reactive result in pregnancy.**

This result should be conveyed to the woman in a way that ensures that she is not alarmed, and the emphasis should be that this is most probably a non-specific reactivity of doubtful clinical significance.