HIV Reactive Results In Pregnancy

1.0 Introduction

This protocol is to standardise the management of pregnant women who have a reactive or equivocal result in one or two of the three different assays 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 HIV in Wales.

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

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

2.0 Background

Currently available HIV tests are more than 99% sensitive and specific for the detection of HIV antibodies.

The recommended first-line assay is one which tests for HIV-1 antibody, HIV-2 antibody and HIV p24 antigen simultaneously. These are termed fourth generation assays and have the advantage of reducing the time between infection and testing HIV positive to one month. This is at least one week earlier than tests used previously (third generation assays), which detected HIV 1 and HIV 2 antibodies only

The large-scale use of these fourth generation assays in low risk populations (such as most of those receiving antenatal screening) has resulted in an increase in the number of reactive results in the primary laboratory test and in one of the additional 2 tests carried out on the initial sample. It is these results this protocol will address.

If the primary laboratory test is non-reactive then a negative result will be issued. However, if the primary laboratory test is reactive, additional tests with 2 different assays are required. These tests may be provided within the primary testing laboratory, or by a referral laboratory.

If all of the confirmatory tests are reactive (or positive), a new HIV 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, one or both of the additional tests are negative, making it difficult to give a definitive HIV result to the woman. The testing strategy is complicated by the fact that this sort of profile could occur in a recently acquired HIV infection. In that scenario, HIV antibodies 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.

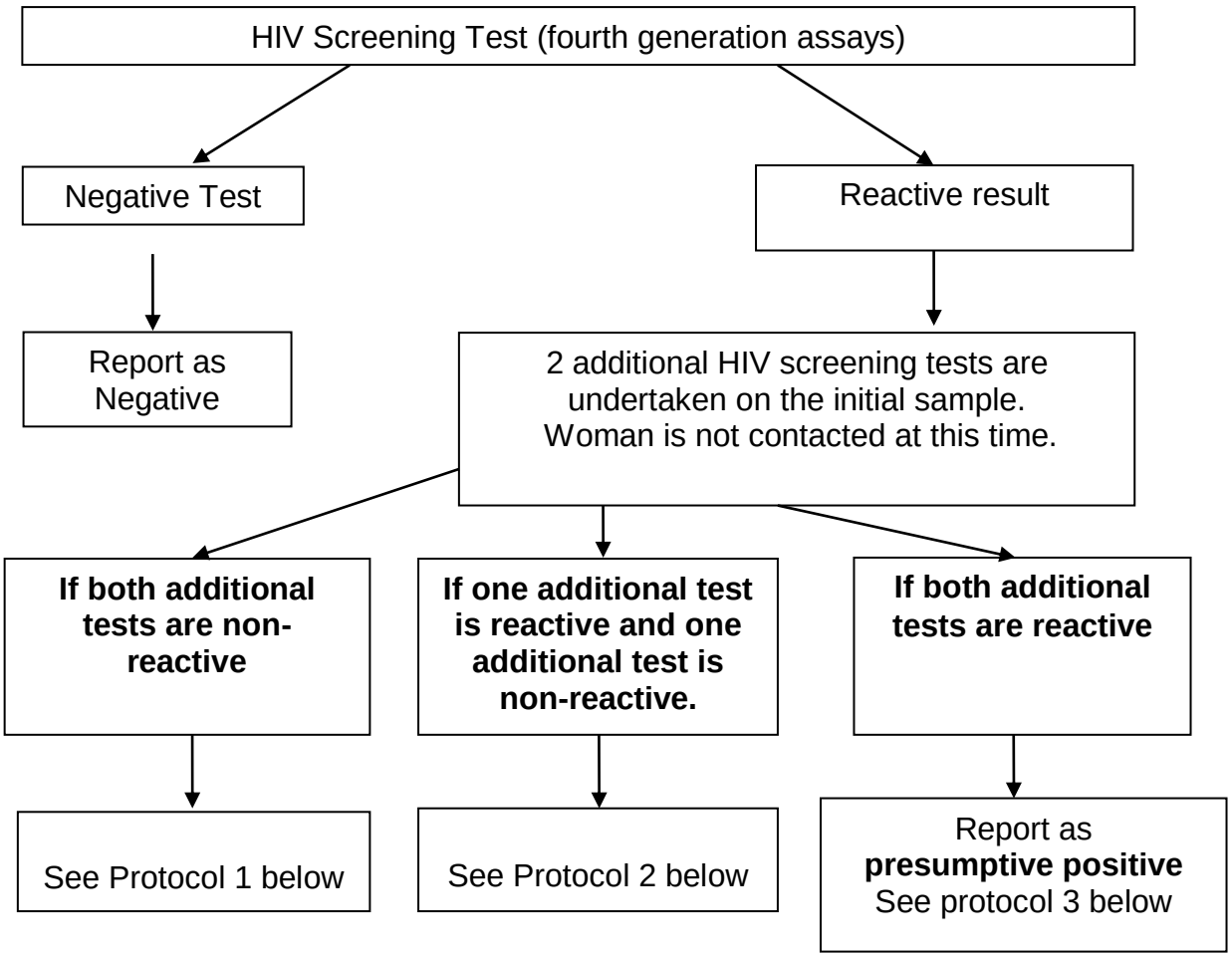
However a recently acquired HIV infection in pregnancy will be an extremely rare event in Wales and the vast majority of these reactive results will be “false positives”. In order to manage women with these results safely, consistently and with minimum uncertainty, consideration needs to be given to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

3.0 Aim of the Protocol

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

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

Pathway for HIV result



Protocol 1

Initial Screening test Reactive and 2 additional 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. The expectation is that these women do not have HIV 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 either the laboratory clinicians or the Sexual Health physician.

Table 1: Risk History:
Resident or recent resident of Sub-Saharan Africa
Sexual partner of resident or recent resident of Sub Saharan Africa
Asylum Seeker or victim of trafficking?
Multiple partners (including sex working)
Rape victim
Sexual partner known to have HIV
Born in a country with high prevalence of HIV

In the absence of any identified risk factors the woman should be regarded as HIV 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 HIV infection, 3-5 weeks after the first sample was taken. If the woman had her HIV screening test before 12 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 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.

Protocol 2

Initial Screening test Reactive, 1 additional test Reactive and 1 additional test Non-reactive.

This result is less commonly encountered than that above but is also more difficult to interpret. The most likely scenario is usually that of non-specific reactivity but it is harder to distinguish from a possible recent HIV infection. In these cases the result will be telephoned/ e-mailed to the antenatal screening co-ordinator /deputy. The laboratory representative and the antenatal screening co-ordinator should discuss any relevant risk factors for the women (table 1) and what additional test(s) or action is required. Consideration should also be given as to whether the Consultant Obstetrician, Antenatal Screening Coordinator/deputy and Sexual Health Doctor should be included in a dialogue to discuss the significance of the result and to identify the next steps for the management of the woman.

The woman should be informed of the difficulty in interpreting the results of the test and informed that she may need a series of blood tests that would need to be sent to a reference laboratory, to confirm or refute infection.

Protocol 3

Initial Screening test Reactive/ and 2 additional tests also Reactive

Where there are 3 reactive results reported, the report will be issued as "**Presumptive Positive**" and the result telephoned /e-mailed to the Antenatal Screening Co-ordinator/deputy to initiate the management in a timely manner as per Antenatal Screening Wales Standards.

Continue with **ASW Standards and Protocols for Antenatal HIV Screening** and confirm the diagnosis with a repeat sample from the woman to ensure that there has been no issues with patient identity.