Syphilis Reactive Results in Pregnancy

1.0 Introduction

This protocol is to standardise the management of pregnant women who have a weakly reactive or equivocal result in the syphilis screening test (ELISA) performed on the initial screening test.

This protocol is intended to be used by midwives, obstetricians and laboratory staff who are involved in the provision of antenatal screening for syphilis 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 syphilis positive results and syphilis negative results see Antenatal Screening Wales Policy, Standards and Protocols to Support the Provision of Antenatal Screening in Wales.

2.0 Background

Currently available syphilis tests are more than 99.9% sensitive and specific for the detection of syphilis antibodies.

The recommended screening test for syphilis (syphilis ELISA) detects syphilis antibodies in the blood test.

- If the syphilis ELISA test is non-reactive then a negative result will be issued.
- A reactive syphilis ELISA should be followed with an assessment of syphilis infectivity on the initial specimen. The confirmatory tests performed indicate both past and acute infection. These tests are:
  - T.pallidum haemagglutination assay (TPHA)/T.pallidum particle agglutination assay (TPPA) - indicates past infection.
  - Venereal Disease Research Laboratory/rapid plasma reagin test (VDRL/RPR) - indicates acute infection.

If one, or both of the confirmatory tests are reactive (or positive), a syphilis 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 primary laboratory test is weakly-reactive, making it difficult to give a definitive syphilis result to the woman. The testing strategy is complicated by the fact that this sort of profile could occur in a recently acquired syphilis infection. In that scenario, syphilis 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.

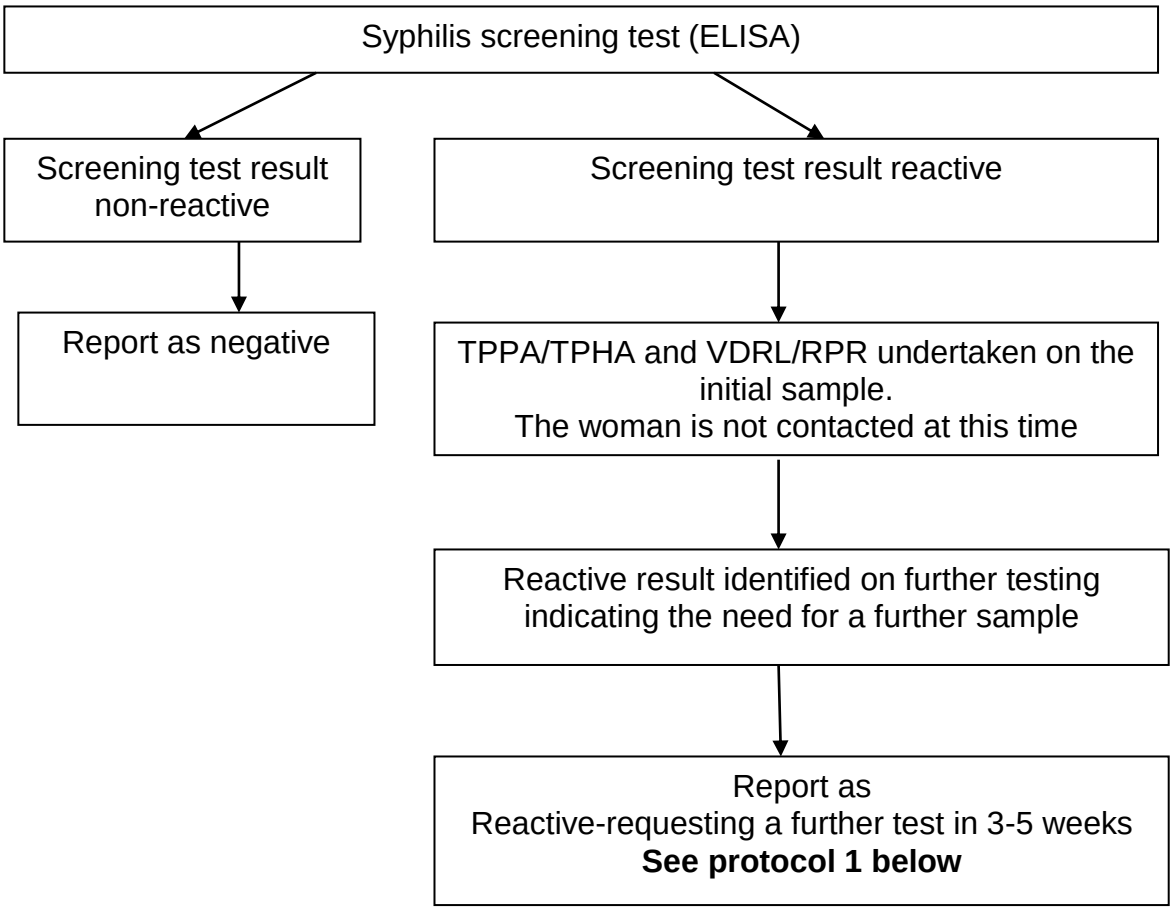
However a recently acquired syphilis infection in pregnancy is an extremely rare event in Wales and the vast majority of these reactive results will be “false positives”. In order to manage women with these results safely, consistently and with minimum uncertainty, consideration needs to be given to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

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 syphilis test in a timely manner.

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

Pathway for syphilis result



Protocol 1

Initial screening test (Elisa) reactive and both TPPA/TPHA plus VDRL/RPR 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 syphilis 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:

- Symptoms of early syphilis- small, painless vulval or anal sore or ulcer called a chancre, sores in the mouth or the lips, tonsils, fingers or buttocks, lymphadenopathy or skin rash (commonly on the palms of the hand, or soles of the feet, small vulval skin growths, flu-like symptoms, swollen lymph glands, weight loss, patchy hair loss.
- A history of other treponemal infections; yaws, pinta
- Obstetric history, potential complications of syphilis eg miscarriage, stillbirth
- Recently returned from a country with high prevalence of syphilis
- Multiple partners (including sex working),
- Have a sex partner who has syphilis
- Co-existing infection eg HIV
- Sexual partner known to have co-existing infection eg HIV

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

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

If the woman had her syphilis 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 results 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.