Sgrinio Cyn Geni Cymru Antenatal Screening Wales http://www.antenatalscreening.wales.nhs.uk



This fact sheet is intended to provide a guide for health professionals who are involved in providing information to women on receiving a reactive syphilis result in pregnancy. This information is to be used alongside the All Wales Protocol for the Management of syphilis reactive results in pregnancy and as an aid in the discussion with women on their "reactive" syphilis 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 when 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 syphilis?

Syphilis is an infectious disease caused by the *Treponema pallidum* bacterium. It is transmitted primarily through sexual contact but can be transmitted from mother to baby during pregnancy (congenital) and via infected blood products.

Acquired and congenital syphilis infection is staged according to the time from the primary infection. The risk of transmission from mother to baby ranges from:

- 70% –100% in primary syphilis
- 40% in early latent syphilis
- ➤ 10% in late latent syphilis

Maternal syphilis infection can result in a range of adverse pregnancy and neonatal outcomes. These include late miscarriage, stillbirth, hydrops fetalis and low birth weight. If left untreated, congenital syphilis can result in both neurological impairment and physical impairment affecting the child's bones, teeth, vision and hearing.

What does the syphilis test identify?

The recommended screening test for syphilis is the syphilis ELISA and detects syphilis antibodies in the blood. If the initial screening test is reactive confirmatory tests will be performed on the initial sample.

These confirmatory tests performed indicate both past and acute infection:

- T.pallidum haemagglutination assay (TPHA)/T.pallidum particle agglutination assay (TPPA) – used to assess past infection.
- Venereal Disease Research Laboratory/rapid plasma reagin test (VDRL/RPR) – used to assess acute infection.

Public Health Wales NHS Trust

How accurate is the syphilis test?

This test is more than 99.9% sensitive and specific for the detection of syphilis antibody.

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

In approximately 1:1000 samples there is a reactive result that is unlikely to be due to the syphilis antibody. 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 non-specific reactivity and give a 'false positive result'.

A false positive result means that the test identifies syphilis antibody as being 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 nonreactive. This will be the definitive result for this test.

What is a positive result?

A positive result is when:-

- > the initial laboratory test is reactive and,
- either of the confirmatory tests are reactive.

The confirmatory tests undertaken on the initial sample are:

- T.pallidum haemagglutination assay (TPHA)/T.pallidum particle agglutination assay (TPPA) – used to assess past infection.
- Venereal Disease Research Laboratory/rapid plasma reagin test (VDRL/RPR) – used to assess acute infection.

However, this would be a presumptive positive test result as a new Syphilis 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 test result is when the:

- initial laboratory test (syphilis ELISA) is reactive.
- two confirmatory tests (TPPA/TPHA) and (VDRL/RPR) undertaken on the initial blood sample are both negative.

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.

Result reporting

Syphilis ELISA **reactive** and TPPA/TPHA and VDRL/RPR **negative**: "Initial screen result weakly 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 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)
- · Has had unprotected sex with a person who has syphilis
- Co-existing infection eg HIV
- Has had unprotected sex with a person known to have co-existing infection e.g. HIV.

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

Public Health Wales NHS Trust

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 i.e. 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 syphilis infection?

A recently acquired syphilis infection in pregnancy will be an extremely rare event in Wales and the vast majority of these reactive results detected on the initial screening test will, on further testing with a second sample, be confirmed as a negative syphilis result.

Suggested wording on how to discuss syphilis weakly reactive results

- The woman should be informed that receiving a reactive result does not mean that she has syphilis.
- 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 syphilis antibody.
- She should be informed that it is the assumption that she will receive a negative result on re-testing.
- She should be regarded as syphilis 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<u>leaflet</u> at the same time as giving the verbal information.

Further information is available from

• Consultant virologist/consultant microbiologist in the Health Board.