Introduction

Syphilis is a highly infectious sexually transmitted disease caused by the spirochaete, *Treponema pallidum*. After infection a primary lesion or chancre appears on the genitalia at the site of entry of the infecting organism. The disease is systemic from the onset and the course of an untreated case of syphilis can span decades.

Pathogenic treponemes include *T. pallidum*, the causative agent of syphilis, *T. pertenue*, the causative agent of yaws and *T. carateum*, the causative agent of pinta. In addition many commensal species of treponemes exist and it is important to differentiate these from *T. pallidum* before a diagnosis of primary syphilis is given. Commensal treponemes can be cultured in artificial media whereas attempts to culture pathogenic treponemes in vitro have been unsuccessful.

The clinical diagnosis of syphilis is confirmed in the laboratory by either demonstrating the presence of *T. pallidum* in the exudates from lesions or by demonstrating the presence of serum or CSF antibodies against the organism. Antibodies become detectable at about 3-4 weeks after exposure, and may remain at detectable levels for long periods after treatment. Methods used to measure antibody responses to treponemal infection can be divided into two major categories:

1. Tests to measure antibodies against non-specific treponemal antigens i.e. cardiolipin or lipoidal antigens. These include the Rapid Plasma Reagin (RPR) test, Venereal Disease Reference Laboratory (VDRL) test and modified Wasserman test.

2. Tests to measure antibodies against antigens specific for pathogenic treponemes i.e. *T. pallidum* Immobilisation Assay (TPI), *T. pallidum* Haemagglutination Assay (TPHA), the Fluorescent Treponemal Antibody Absorbance Test (FTA-ABS) and Enzyme Linked Immunosorbent assays (EIA) which may be specific for IgG antibodies, IgM antibodies or both.

In practice, for rapid screening purposes, a combination of lipoidal and TPHA tests are performed, and if necessary confirmed by the FTA-ABS test. TPHA and FTA-ABS tests are especially recommended as diagnostic aids for patients with reactive RPR who have atypical signs of primary or secondary syphilis or who have no signs of syphilis. To diagnose syphilis and monitor its treatment, quantitative assays such as antibody titre measurements have become widely used.

Description

MAST-TPHA is a highly specific and sensitive passive haemagglutination test for the detection of antibodies to *Treponema pallidum*. The test is easy to perform and provides an economic system for screening purposes.

Principle of the test

Patients serum samples are diluted and mixed with tanned fowl erythrocytes, coated with inactivated antigen from *T. pallidum* (Nicholl's strain), in microtitre wells. Interaction of antibody from the patients sample with the antigen sensitised cells results in agglutination and a characteristic pattern in the wells as the cells settle to the bottom. The Cell Suspensions contain an extract of the non-pathogenic Reiter's treponeme, which removes any cross-reactive non-pathogenic treponemal antibodies. In the presence of specific antibody, cells settle as a 'mat' in the well and in the absence of specific antibody, cells form a compact button.

Any non-specific reactions that occur are detected using Control Cells which are tanned fowl erythrocytes not coated with *T. pallidum* antigen. Should any non-specific reactions occur they may be absorbed out using Control Cells.

Packaging and Ordering Details

MAST-TPHA is presented as kits for the performance of 200 qualitative tests. Order code: HA101.
Stability and Storage

MAST-TPHA should be stored at 2-8°C and may be used until the expiry date given on the label. **Do not freeze reagents.**

Shelf life - 18 months from date of manufacture. Store all serum specimens at -20°C until required up to a maximum of 4-6 weeks.

Limitations of the Test

1. The test has only been validated for use with serum or CSF samples.
2. No serological agglutination test can discriminate between antibody due to infection with *Treponema pallidum* and antibody due to infection with other pathogenic treponemes i.e. *T.pertenue* and *T.carateum*.
3. It is recommended that all positive samples should be confirmed by testing with the FTA-ABS procedure, which can allow for differentiation between IgG and IgM antibodies.
4. The test may give a negative result in cases of early active Syphilis or in late latent Syphilis. To complete the profile of results, it is recommended that a VDRL/carbon antigen or RPR test is performed on the patient's sample, since these tests will detect active Syphilis.
5. Although the MAST-TPHA test is highly specific, false positives have been known to occur in patients suffering from leprosy, infectious mononucleosis and connective tissue disorders.

6. Syphilis antibodies detected in the MAST-TPHA test persist after successful treatment, hence a positive test may indicate past or present infection.

References