TPHA TEST KIT

CATALOGUE NUMBER
TPHA0/010
TPHA0/20
TPHA/0/00

PRODUCT DESCRIPTION
100 Test Kit
200 Test Kit
1000 Test Kit

INTENDED USE
The Plasmatec TPHA test kit is designed for the detection of antibodies to Treponema Pallidum in human serum and plasma.

WARNINGS AND PRECAUTIONS
For in vitro diagnostic use only
For professional use only

Health and Safety warnings:
All patient samples and reagents should be treated as potentially infectious and appropriate precautions should be taken when handling and disposing of these materials. Non-disposable apparatus must be sterilised after use by an appropriate method. Disposable apparatus must be treated as biohazardous waste and autoclaved or incinerated.

COMPOSITION
Do not interchange reagents from different kit batches.

Do not dilute or modify the reagents in any way.

Allow all reagents and samples to reach room temperature (18 - 30°C) before use.

Resuspend test and control cells gently but thoroughly.

Do not modify the test procedure.

Do not dilute or modify the reagents in any way.

Analytical precautions:
Do not modify the test procedure.
Do not dilute or modify the reagents in any way. Allow all reagents and samples to reach room temperature (18 - 30°C) before use. Resuspend test and control cells gently but thoroughly. Do not interchange reagents from different kit batches.

STORAGE AND SHELF LIFE
The kit should be stored at 2-8°C in an upright position at all times. Under these conditions, kit performance characteristics will be maintained for 18 months from the date of manufacture. Store reagents at 2-8°C.
TPHA TEST KIT

Syphilis antibodies detected in the Plasmatec TPHA test persist after successful treatment. Therefore a positive test may indicate past or present infection. In common with other serological tests Plasmatec TPHA cannot distinguish between syphilis and other pathogenic treponemal infections, eg. Yaws. Clinical evidence should always be considered. Although the Plasmatec TPHA test is highly specific, false positive results have been known to occur in patients suffering from leprosy, infectious mononucleosis and connective tissue disorders.

For confirmation the FTA-ABS test should be used, since it allows a differentiation between IgG and the early IgM antibodies. The FTA-ABS test is also very useful in very early syphilis where the haemagglutination test may be negative. For therapeutic control it is advisable to use a quantitative test such as VDRL or RPR test. These reagents are available from Plasmatec.

PERFORMANCE CHARACTERISTICS

Specificity
Two independent studies on 2900 donor sera each showed 100 % consensus with existing test methods. The initial reactive rate was 0.1%, and the repeat reactive rate was 0%
An independent study on 200 antenatal sera showed 100 % specificity. ( 95% confidence 98.04 – 100 % )

Sensitivity
In-house studies on 110 known positive specimens gave 100 % positive results. ( 95% confidence 98.04 – 100 % ) This included 2 specimens negative by other commercially available TPHA tests but positive by FTA and specific IgM EIA tests.

INTERNAL QUALITY CONTROL
Positive and negative controls are provided and should be used to verify the test – See pictorial guide below

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Any specimen giving less agglutination than that shown as “+/-” above is Negative
Any specimen giving greater agglutination than that shown as “+/-” above should be noted as provisionally positive, and the test procedure repeated as above, but in duplicate, adding the Control Cells provided to one set of wells, and Test Cells to the other.
If the agglutination with Test Cells is greater than with Control Cells, the specimen is positive for anti-treponemal antibody, and should be subjected to further tests for confirmation.
If the agglutination with Control Cells is greater or equal to that with Test Cells, the procedure below for absorption of non-specific reactions should be applied.

REFERENCES
1. Rathlev T. - Haemagglutination tests utilizing antigens from pathogenic and apathogenic Treponema pallidum WHO/VDT/RES 1965 ; 77 : 65