SYPHILIS TPHA

Qualitative and semiquantitative determination, by passive hemagglutination, of anti-Treponema pallidum antibodies

**TEST SUMMARY**

Anti-Treponema Pallidum antibodies, contained in the serum or plasma, produce agglutination of erythrocytes coated with antigens of Treponema Pallidum.

**SAMPLES**

Serum or plasma citrate specimens should be free of blood cells. Stability 7 day at 2-8°C. Specimens needing longer storage should be frozen at -20°C. Frozen specimens should be thawed and well mixed before testing.

**REAGENTS**

**Test cells**
Chicken’s tannate erythrocytes and coated with total extractive antigen of Treponema Pallidum cultivated in rabbit’s testicles; conservative and stabilizer.

**Control cells**
Preserved chicken erythrocytes; conservative and stabilizer.

**Diluent**
Saline solution; conservative and stabilizer.

**Positive control**
Human base stabilized solution of anti-Treponema Pallidum antibodies with a titre that gives a clear agglutination.

**Negative control**
Protect solution not reactive with suspension.

**RESSOURCES PREPARATION AND STORAGE**

Reagents are ready to use. Erythrocytes suspension must be resuspended with much care. Make the suspension homogeneous by slow inversion.

Stability: The reagents are stable until expiration date on the label at 4°C. Do not freeze.

**MATERIAL REQUIRED BUT NOT SUPPLIED**

Normal equipment of laboratory.

Microplate with U bottom, micropipette, centrifuge, test-tube for centrifuge.

**PRECAUTION**

All reagents contain 0.095% of sodium azide. Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Perform the test according to the general “Good Laboratory Practice” (GLP) guidelines.

**QUALITATIVE PROCEDURE**

Predispose dilutions of serum, into a microplate with “U” bottom, following scheme below, pipetting diluent and serum.

Using the same pipette (inspiring and discharging many times) mix with care contents of well before to transfer into the following well. Discharge 25 µl from last well of every series. Execute test using positive and negative control instead of sample.

The TPHA kit is intended for screening large numbers of specimens and contains only a small volume of Control Cells. It is intended that specimens are screened using only Test Cells in the first instance, and the Control Cells be used when repeating tests on specimens giving a positive result when first tested.

The TPHA kit is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

**RESULTS INTERPRETATION**

Positive (strong): Full cell pattern covering the bottom of the well.

Positive (weak): Cell pattern covers approx. 1/3 of the well bottom.

Negative: Cells settle to a compact button, typically with a small clear centre.

Indeterminate: Cells pattern shows a distinctly open centre.

Non specific: Positive reaction.

Intermediate results, for ex. a ring of hemagglutination with bottom in centre, indicate uncertain results. The well 2 (control well) has to give negative result to indicate sample fitness to be tested, in fact eventual agglutinates depend on a specific agglutinates that invalidate the test, therefore they must be removed by incubation of 25 µl of sample with 500 µl of erythrocytes control for 30 minutes and following centrifugation. Use the supernatant during the test.

**SEMIQUANTITATIVE PROCEDURE**

Follow the scheme of qualitative procedure continuing dilutions until 10° well.

**CODE AK00601** (200 TESTS)

Test cells 1 x 8 ml

Control cells 1 x 5 ml

Diluent 1 x 25 ml

Positive control 1 x 0.5 ml

Negative control 1 x 0.5 ml

**CODE AK00600** (100 TESTS)

Test cells 1 x 16 ml

Control cells 1 x 10 ml

Diluent 1 x 25 ml

Positive control 1 x 0.5 ml

Negative control 1 x 0.5 ml

**REFERENCES**


**MANUFACTURER**

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**SYMBOLS**

IVD Only for IVD use

LOT Lot of manufacturing

REF Code number

Storage temperature interval

Expiration date

Warning, read enclosed documents

Read the directions

Biological risk

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