



Terms of Reference/ Technical Specification Clauses

Code: FOR/043

Edition: 01

Implementation date: 24/04/2018

Item Name: TPHA Treponema pallidum haemagglutination test for the Serodiagnosis of Syphilis.

I- Specifications:

Passive haemagglutination test for the detection of antibodies to Treponema pallidum in serum or CSF.

The test kit should contain:

T. pallidum sensitized erythrocytes; unsensitized erythrocytes, diluent and control sera.

PRINCIPLE OF THE TEST:

When diluted positive samples are mixed with sensitized erythrocytes, antibody to the sensitizing antigen causes agglutination of the cells.

The cells form a characteristic pattern of cells in the bottom of a micro titration plate well.

In the absence of antibody, they form a compact button in the well.

The test should be FDA approved.

II- Training:

- To be done upon delivery.

III- Documents to be delivered:

- Compliance Certificate
- User Manual.
- Test Validation (if available).

IV- Accessories required:

Any additional material should be mentioned and provided by the company.

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