V.D.R.L. test

Stabilized antigenic suspension to perform VDRL modified test (USR) for syphilis' detection

SUMMARY

Syphilis is a venereal disease caused by *Treponema pallidum*, which invades intact mucous membranes or damaged skin areas. Sexual contact is the most common way of transmitting this disease.
Microorganisms multiply and spread quickly after invasion. Illness' detection and treatment in early stages, are essential to avoid severe complications as neurosyphilis, cardiovascular syphilis and congenital syphilis. Disease's diagnosis has always been confronted with the difficulty to detect the etiological agent when skin lesions are not yet observed, as well as with the lack of culture methods for microorganisms' isolation.
However, certain substances called “reagins” appear in the serum of an infected individual from the disease's onset and they react with cardiolipin/lecithin/cholesterol antigen. These reactions, together with clinical signs, are thus the quickest and more useful procedure available for syphilis diagnosis.

PRINCIPLE

Reagins present in individuals infected with *T. pallidum* are detected in serum by their reaction with a purified and stabilized cardiolipin antigen. If the sample contains reagins, they will bind to the antigen yielding a flocculation visible by microscope. Non-specific reactions are avoided using a highly purified antigen and adding choline chloride, which is distinctive of the USR (Unheated Serum Reagin) technique where inactivation of the sample is not necessary.

PROVIDED REAGENTS

A. Reagent A: aqueous suspension of purified cardiolipin and lecithin antigen, in phosphate buffer with choline chloride and EDTA, according to WHO's recommendations.

NON-PROVIDED REAGENTS

- Saline solution (required for semi-quantitative test).
- 10 g/dl sodium chloride (required for cerebrospinal fluid technique).

STABILITY AND STORAGE INSTRUCTIONS

Reagent A: is stable at 2-10ºC until the expiration date stated on the box. Do not freeze.

INSTRUCTIONS FOR USE

Reagent A: ready to use. Mix well before use.

WARNINGS

Reagent A is for “in vitro” diagnostic use.
All samples from patients should be handled as capable of transmitting infection.
Use the reagents according to the working procedures for clinical laboratories.
The reagents and samples should be discarded according to the local regulations in force.

REQUIRED MATERIAL

1- Provided

-1 dropper

2- Non-Provided

- Rotating shaker adjustable at 180 rpm.
- Transparent glass slide with sections of approximately 14 mm each.
- Micropipettes for measuring the stated volumes.
- Microscope.

SAMPLE

Serum or cerebrospinal fluid
a) Collection: obtain in the usual way. Do not inactivate.
b) Additives: not required.
c) Known interfering substances: hemolysis or hyperlipemia may cause erroneous results.
d) Stability and storage instructions: in case they are not processed immediately, samples can be store for up to one week at 2-10ºC.

PROCEDURE

Bring reagents and sample at room temperature before testing.

I- QUALITATIVE SLIDE TEST IN SERUM

In each section of a slide, place:

Sample	50 ul
With the provided dropper, add:	
Reagent A	1 drop

Rotate slide horizontally at 180 rpm during 4 minutes. Observe tests immediately after rotation, with a microscope (60 to 100 x).

II- SEMI-QUANTITATIVE SLIDE TEST IN SERUM

Prepare sample dilutions of 1:2; 1:4; 1:8; 1:16 and 1:32 with saline solution and complete test for each dilution as described in I).

III- QUALITATIVE TEST FOR CEREBROSPINAL FLUID

Dilute the Reagent A 1:2 with 10 g/dl sodium chloride solution. Use within the 2 hours of preparation.
In each section of a slide, place:

Sample	50 ul
With needle, caliber 6, add:	
Diluted Reagent A	1 drop (10 ul)

Mix thoroughly and rotate slide horizontally at 180 rpm during 8 minutes. Read tests immediately after rotation in a microscope (60 to 100 x).

INTERPRETATION OF RESULTS

Reactive: flocculation presence.
Non-reactive: complete absence of flocculation.
Semi-quantitative test: titer will be given as the inverse of the last dilution producing Reactive result. Read PROCEDURE LIMITATIONS carefully.

QUALITY CONTROL METHOD

In order to control system quality, process, as if it were samples, a Positive Control (serum known to be reactive) and a Negative Control (serum known to be non-reactive).

PROCEDURE LIMITATIONS

See Known Interfering Substances under SAMPLE.
Falsely positive results can be observed in individuals suffering from hepatitis, influenza, brucellosis, leprosy, malaria, asthma, tuberculosis, cancer, diabetes and autoimmune diseases.
These are not common cases and they generally show reactions with low titer and a medical record not coincident with syphilis symptoms.
For these reasons, it is absolutely necessary to perform a semi-quantitative test when a reactive qualitative test appears. Falsely negative results can be observed when a prozone phenomenon appears. For this reason, it is recommended to repeat test on serum diluted 1:5 with saline to verify results. If flocculation is observed under these conditions, sample is reactive.
In spite of the advantages of this method, the results obtained as well as those from any other serological methods must be considered only as a diagnostic aid, which must be checked against patient's medical record.

PERFORMANCE

On 2,140 samples from a local hospital were assayed using **V.D.R.L. test** and immunofluorescence as a reference method. The concordance observed was higher than 96%.

WIENER LAB. PROVIDES

Kit for 250 tests (Cat. 1853151).

REFERENCES

- Zinsser Microbiología, Joklik, W., Willett, H., and Amos, D.; 17º edition, Editorial Médica Panamericana, 1983.
- Manual of Tests for Syphilis, Ch. 8, 1990. American Public Health Association, Washington, D.C. 20005.
- Podestá, D.;Svetaz, M.J.; Ricomi, R.; Capriotti, G.; Rojkín, L.; Lorenzo, L. - "Evaluación de tres reactivos para detección de sífilis" - VIII Congreso Argentino de Bioquímica, 54º Triduo Bioquímico Científico Anual 1990 - Revista ABA - Vol. 54, Nº3, 1990.

Symbols

The following symbols are used in the packaging for Wiener lab. diagnostic reagent kits.

This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices

Authorized representative in the European Community

"In vitro" diagnostic medical device

Contains sufficient for <n> tests

Use by

Temperature limitation (store at)

Do not freeze

Biological risks

Volume after reconstitution

Contents

Batch code

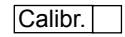
Manufactured by:

Harmful

Corrosive / Caustic

Irritant

Consult instructions for use



Calibrator

Control

Positive Control

Negative Control

Catalog number

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