SYPHILIS RPR-TEST

For *in vitro* diagnostic use only

Quick test for the qualitative and semi-quantitative determination of reagins antibodies in serum or plasma

TEST SUMMARY
A suspension of cardiolipidic antigen gives a flocculation reaction with reagin in serum. The antigen used in the kit is a modification of V.D.R.L. antigen which contains microparticulate charcoal to enhance the visual difference between a positive and negative result.

SPECIMEN
Plasma or fresh serum. Stability 5 days at +4°C or 4 weeks at -20°C.

REAGENTS COMPOSITION
Antigen suspension: cardiolipin suspension, containing microparticulate charcoal.
Positive control: stabilized liquid control, reactive with RPR antigen.
Negative control: stabilized liquid control, non-reactive with RPR antigen.
Store the reagents at +4°C. Do not freeze.

TEST PROCEDURE
Bring all reagents and serum samples to room temperature. Mix the RPR antigen. The antigen suspension must be totally homogeneous before use.

QUALITATIVE DETERMINATION
1. Place 50 µl of the sample, or 1 drop of positive control or 1 drop of negative control into separate circles on the slide test.
2. Place 20 µl of the antigen suspension next to the sample or to the control to be tested using disposable tips.
3. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
4. Place the slide on a mechanical rotator at 100 r.p.m. for 8 minutes. False positive results could appear if the test is read later than 8 minutes. Read the results macroscopically in direct light.

INTERPRETATION OF RESULTS
A positive result is indicated by large aggregates in the centre or the periphery of the test circle. Very weak positivity is indicated by the presence of small aggregates around the edge of the test circle. A negative result has an homogeneous appearance with no visible aggregates. Samples with positive results should be retested with the semiquantitative test.

SEMIQUANTITATIVE TEST
Prepare dilutions of the sample with physiological saline (1:2, 1:4, 1:8, 1:16, 1:32). Proceed as in qualitative test.

INTERPRETATION OF RESULTS
The last dilution step that contains macroscopic aggregates indicates the titer of the sample. If the last dilution gives a positive result, the dilution series should be extended.

NOTES
The test may gives false positive results. These results can be caused by diseases such as leprosy, lupus erythematosus, infectious mononucleosis, malaria and viral pneumonia.
Contaminated sera and a longer reaction time may cause false positive results.
All reactive test samples should undergo a further serological test (TPHA Cod. UC80500).
All reagents of human source have been tested for HBsAg and HIV antibody and found to be negative. However, the material should still be regarded as potentially hazardous.
If the test area of the slide is hydrorepellent, clean it with alcohol.
As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
The components of this I.v.D. are tested always each other without verify the compatibility with components produced by other manufacturers. Is not excluded that these components can be used with components of same chemical composition but produced by other manufacturers, but there is not an experimental evidence of this compatibility.
The kit must be used by clinical test trained personnel only.

PRECAUTIONS
Slides are made by plastic, so that they can be wash with normal water.

REFERENCES
1. Stout G. W. e coll. - J. Conf. Pub. Health Lab. Directors - 7, 26; (1968)
2. Mc Grew B. E. e coll. - Amer. J. Clin. Path. - 52, 50; (1968)
3. Mc Grew B. E. e coll. - Amer. J. Med. Tech. - 634, 34; (1968)
4. Schroeter A. L. e coll. - Adv. in Automated Analysis - M. Y. Medical - Pag. 256 (1970)
5. Stevens R. W., Stroebel E. - Amer. J. Clin. Path. - 32, 53; (1970)

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT KIT	**Code UC80600 (100 tests)**	**Code UC80610 (300 tests)**	**Code UC80610A (300 tests)**	***Code* UC80620 (300 tests)**	***Code* UD80602**
Antigen suspension (white cap)	1 x 2.2 mL	3 x 2.2 mL	3 x 2.2 mL	3 x 2.2 mL	
Positive control (red cap)	1 x 0.5 mL	1 x 0.5 mL	1 x 0.5 mL		1 x 0.5 mL
Negative control (green cap)	1 x 0.5 mL	1 x 0.5 mL	1 x 0.5 mL		1 x 0.5 mL
Slides (1x 6wells)	3 items	3 items	50items(300 wells)		
Stirrers (1x25)	1 item	1 item	12 items		
EDMA Code	15 01 03 90 00	15 01 03 90 00	15 01 03 90 00	15 01 03 90 00	15 50 01 01 00

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