RPR

IVD CE

Non-treponemic flocculation test for luetic reagin in human serum

Instructions for Use (IFU)

ORDERING INFORMATION

Format	Code	Composition
Kit 250 test	**REF. CSI087243**	**n° 1 vl. x 5 ml** (RPR Reagent) **n° 1 vl. x 1 ml** (Positive Control) **n° 1 vl. x 1 ml** (Negative Control)

INTENDED USE

In vitro diagnostic medical device for the execution of non-treponemic flocculation test for qualitative research, and / or semi-quantitative dosage, of luetic reagins in human serum. Test results should always be interpreted in relation to the clinical context. For professional use only.

CLINICAL SIGNIFICANCE

Syphilis is a chronic venereal disease, contagious and often congenital caused by Treponema pallidum. Reagins are antibodies against some components of the damaged tissues from patients infected by T. pallidum. This microorganism produces some damages to liver and heart, releasing some tissue fragments. The patient's immune system reacts producing regains. The test is useful for following the response to treatment with antibiotics.

PRINCIPLE OF THE METHOD

The R.P.R. reagent is a non-treponemal slide agglutination test for the qualitative and semi-quantitative detection of plasma reagins in serum of syphilis infected patients. The test is composed from charcoal particles coated with a lipidic complex. When the luetic reagins are significantly present in the specimen, R.P.R. test gives a positive result with an evident flocculant reaction; when regains are absent the RPR test results negative and no flocculation is visible.

Storage and Stability

= Storage temperature 2-8 °C

Store reagent and control at 2-8° C avoiding direct light. Do not freeze. If stored as described, reactives are stable until the expiry date printed on the label.

KIT CONTENTS AND COMPOSITION

Reagent 1 Ready to use. Carbon particles coated with a lipid complex (cardiolipin, lecithin, cholesterol) in phosphate buffer.
Reagent 2 Positive Control (artificial serum) Titolo > 1:4 **red cap** *
Reagent 3 Negative Control (animal serum) **blue cap**
32 X 8 Disposable slides (white screen)
Dispensing vial **green cap**
n. 5 x 25 disposable sticks (to mix the reaction)

**GHS07* – Warning – Contains Citric Acid CAS 5949-29-1
H319 - Causes severe eye irritation.
P280 - Wear protective gloves/clothing/eye protection/face protection/hearing protection/. P501 - Dispose of the product in a suitable container according to current regulations

OTHER REQUIRED MATERIALS, BUT NOT SUPPLIED

Micropipettes 50 µl; PBS; Mechanical Rotator with adjustable speed to 80 -100 rpm

PRECAUTIONS AND WARNINGS

1. Reagents and waste materials shall be disposed of in accordance with Community waste provisions or national or regional provisions.
2. In addition to any risk claims relating to active components, reagents may contain non-active components such as preservatives and detergents. The total concentration of these components is below the limits set out in Directive 1272/2008 EC and subsequent amendments and additions.
3. It is recommended that the reagent be handled in accordance with the rules of good laboratory practice and that appropriate personal protective equipment be used.
4. All human samples must be handled and disposed as potentially infectious materials.
5. The kit should only be used by qualified and properly trained technical personnel.
6. Diagnoses shall only be carried out by authorised and qualified personnel.
7. It is recommended to handle the reagent according to the rules of good laboratory practice and to use appropriate personal protective equipment.
8. Comply with national directives on occupational safety and quality assurance.
9. Use equipment that comply with current standards.

Reporting of serious incidents

Please inform the manufacturer (through your distributor) and the competent authority of the member state of the European Union in which the user and/or patient is established, of cases of serious incident that has occurred in relation to the device. For other jurisdictions, reports of serious incidents must be made in accordance with the regulatory requirements of the home Member State. By reporting serious incidents, you help provide more information about the safety of your in vitro medical diagnostic device.

PROCEDURE

QUALITY CONTROL

It is recommended to use positive and negative controls in each session to monitor the performances of the procedure and for having a comparative pattern for a better result interpretation.

CALIBRATION

The sensitivity of the test is calibrated against the WHO International Standard (1st Standard Human Syphilitic Serum, ref. 05/132).

REAGENT PREPARATION

Reagents are liquid and ready to use. Bring reactive and samples to room temperature before use (the sensitivity of the test maybe reduced at low temperatures) and mix gently Reagent 1 (RPR) to have a homogeneous suspension without visible clumps; use the dispensing vial (present in the kit), and fill it with the Reagent 1. Once the test is completed, return the reagent to the original vial and rinse the micropipette and vial with distilled water. Sensitivity of the test is strictly connected with the volume of the drop of reagent dispensed. All the variations can affect the result of test.

PREPARATION AND STORAGE OF THE SAMPLE

Fresh serum obtained by centrifugation. Do not use highly hemolized or lipemic samples. Samples with presence of fibrin should be centrifuged before testing. The sample can be stored for 7 days at 2-8°C or three months at -20°C.

PROCEDURE

Qualitative method

1. Mix gently the Reagent 1 (RPR) to obtain a homogeneous suspension
2. Place a drop (50 µL) of each sample (UNDILUTED), Reagent 2 Positive Control (red cap) and Reagent 3 negative control (blue cap) into separate circle of the slide.
3. Place in each circle one drop (20 µL) of Reagent 1 placing the micropipette in a vertical position and perpendicular to the slide.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle.
5. Rotate the slide manually or place it in a mechanical rotator at 80-100 r.p.m. for 8 minutes. Observe for the presence of visible agglutination.
6. The timing of reading is critical. Later agglutinations are to be considered aspecific.

Semiquantitative technique

Make serial two-fold dilutions of the sample in PBS (es. 1:2; 1:4; 1:8; 1:16). Proceed for each dilution as in the qualitative method. Titer is calculated as the higher dilution giving visible agglutination.

Reading and interpretation

Positive Result: Visible agglutination (evident black clumps).
Weakly Positive Result: Less evident ring-shaped agglutination in the middle of the circle.
Negative Result: Absence of agglutination (uniform grey suspension).

REFERENCE INTERVAL

Positive results from the R.P.R. test indicate the presence of "luetic reagins" determined with a serological not-treponemic method.

PERFORMANCE CHARACTERISTICS

1. Analytical sensitivity: Accurate titer determination of the reference material ("Human Reactive Serum" coming from Centre for Disease Control C.D.C.) under the described assay conditions;
2. Prozone effect: No prozone effect was detected up to titer > 1:128;
3. Diagnostic sensitivity: 85% (primary syphilis) and 100% (secondary syphilis);
4. Diagnostic specificity: 98%.

INTERFERENCES

Rheumatoid Factor interfere over 300 IU/L. Bilirubin (≤20 mg/dL), haemoglobin (< 10 g/L) and lipemia (< 10 g/L) do not interfere; other substances may interfere.
Note: High temperature may cause the drying of test components on the slide giving false agglutinations; execute the test in a moist environment.

PROCEDURE LIMITATIONS

RPR carbon test is a screening test non-specific for syphilis. All reactive samples should be retested with treponemic methods (TPHA, FTA - ABS). False positive results may be obtained (as antigen is not specific for Treponema) in case of specimen from patients affected from lupus erythematosus, infectious mononucleosis, leprosy, toxoplasmosis and sometimes drug addiction. Low reaction temperature may cause false negative results. Avoid touching reaction circles with fingers, as this can result in leaving grease stain which might alter the result. Negative results by itself does not exclude a diagnosis of syphilis; clinical diagnosis shouldn't be made on findings of a single test result, but should integrate both clinical and laboratory data.

Bibliography

1) George P. Schimid Current opinion in Infectious Diseases 1994; 7, 34-40.
2) Sandra A. Larsen et al. Clinical Microbiology Reviews 1995; 8 (1), 1-21.
3) Sandra A. Larsen et al. A manual of Test for Syphilis American Public Health Ass. 1990; 1-192.
4) Joseph Earle Moore et al. Gastrointestinal Haemorrhage 1952; 150(5), 467-473.
5) Young DS. Effects of drugs on clinical laboratory test. 4th ed. AACC Press, 1995

Symbols used for IFU and Packaging	
IVD In vitro diagnostics medical device	Manufacturer
REF Catalog number	Instruction for Use
LOT Lot Number	Storage Temperature
Expiration Date	Biological Risk

REVISION	DATE	CHANGES
D	12-2022	Change of title from technical File to Instructions for Use

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