Please use the reagent after reading this package insert

RPR

Quantitative turbidimetric latex assay for the measurement of RPR

【General attention】

1. This reagent is for in vitro diagnostic use, and do not use for other purpose.
2. The doctor in charge along with clinical conditions and other laboratory results, etc. must judge the clinical diagnosis based on the result of a measurement overall.
3. Please use it according to use and the dosage regimen described in the package insert. The reliability of the result of a measurement cannot be guaranteed when use excluding described use and dosage regimen.

【Reagent Composition】

1. Buffer (R1) …… Liquid
2. Latex reagent (R2) …… Liquid

(Cardiolipin-Lecithin-Cholesterol-sensitized latex)

【Intended use】

Measurement of Anti-phospholipid antibodies of syphilis in serum or plasma.

【Principle】

1. Principle of measurement

Anti-phospholipid antibodies of syphilis in the sample and Cardiolipin-Lecithin-Cholesterol adsorbed on latex particles react immunologically, and causing the latex particles to agglutinate. This agglutination results in a change of turbidity, and the change in absorbance is a measure of the amount of Non-treponema Lipid Antibody in the sample.

2. Feature

1. Measurement principle is latex immuno turbidimetric assay.
2. It is possible to adjust to various general-purpose automatic analyzers.
3. unnecessary for preparation of reagent
4. The preprocessing of the sample (dilution of the sample) is unnecessary.

【Handling Precautions】

1. Measurement sample

Please use fresh serum or plasma samples.

Please save the sample at 2-8℃ after drawing blood, freeze thawing the sample rarely causes the false-positive.

2. Interfering substance etc.

a. The following components did not interfere with the test result: bilirubin F ≤20 mg/dL, bilirubin C ≤20 mg/dL, and RF ≤500 IU/mL. In the case of hemolyzed samples, it may affect the determination results of negative samples in particular, so please be careful when handling hemolyzed samples. About chyle, please collect blood in fasting because there might be the false reaction.

b. The following anticoagulant did not interfere with the test result: heparin 150units/mL, EDTA·2Na 150mg/dL, sodium citrate 1500mg/dL.

3. Others

a. Storage reagents at (2-10℃), and the freezing preservation must be avoid

b. Please request material separately about the adaptation example to various automated analyzers.

【Procedure】

1. Preparation of the reagents

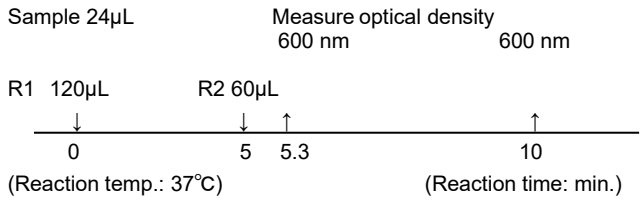
Buffer solution (R1) and Latex reagent (R2) are used as it is.

2. Stability

The reagents will remain stable until the expiration date printed on the label, when stored tightly closed at 2-10℃ and contaminations are prevented during their use.

3. Procedure

[Standard procedure]



4. Calibration

Using optional RPR calibrator and measure them as sample based on the above-mentioned procedure, and made the calibration line.

【Judgment method of result】

(1) Normal reference values [3]

Negative ＜1.0 R.U.

Positive ≧1.0 R.U.

The value used in this product is given in [R.U.] being determined in-house and is based on diluting the highest positive RPR control.

(2) The nonspecific reaction can happen in various infectious diseases and autoimmune disease patients' serums. Please judge the diagnosis based on the result of a measurement overall in consideration of other inspections and clinical conditions.

(3) This reagent measures Non- Treponema Lipid Antibody. And it does not measure syphilitic infection directly. In this case a biological false-positive except the syphilis may happen, and it is therefore recommended to include other test (for example, TPHA methods, FTA-ABS method) results and clinical symptoms to determine test results.

【CLINICAL SIGNIFICANCE】

Immunological syphilis detection can be divided into a cardiolipin antigen method (STS method) and pathogenic Treponema Pallidum (TP) antigen method. The STS methods are recognized as superior methods regarding specificity and sensitivity. However, STS methods are rather complicated, and some kind of subjectivity is involved. This product consists of Cardiolipin-Lecithin-Cholesterol-coated latex, being used in a turbidimetric immunoassay. Non-Treponema Lipid Antibodies in sample are quantitatively determined by optical means (turbidity); specificity and sensitivity of the reagents is high with objective tests results. In addition, reagents can be adapted to various automatic analyzers.

【PERFORMANCE】

1. ANALYTICAL PERFORMANCE

1. Sensitivity

(a) When measured saline liquid as the sample, absorbance

change (⊿OD) is below 0.003/min.

(b) When measure known concentration sample, absorbance change of RPR concentration 5.0R.U. /mL is between 0.006 to 0.060/min.

2. Accuracy

When measured the control serum of known concentration is measured, measurement value is within ±20% of the known value.

3. Reproducibility

When measure the same sample five times at the same time, the C.V of the absorbance value is 10% or less.

4. Measurement range

Measurement range of the RPR in the sample is 20R.U./mL.

5. Standard material

Measurement results of the WHO standard of (1st IS for human syphilitic plasma IgG and IgM: NIBSC code 05/132) with this kit was 1 R.U. = 0.44 IU.

Measurement results of the WHO standard of (1st IS for human syphilitic plasma IgG: NIBSC code 05/122) with this kit was 1 R.U. = 0.16 IU.

2. Correlation

Comparing this kit (y) with a commercially available LIA method (x), resulted in a good correlation: n=200, y=0.916x + 0.586, and r=0.9740.

【Attention in handling for use】

1. Attention in handling (dangerous prevention)

(1) An infectious microorganism such as hepatitis B viruses might exist in the sample, please handle it assuming that there is a risk for infection.

(2) Sodium azide of 0.09w/v% is contained in the reagents as preservative. When entering eyes and mouths or adhering to the skin by mistake, flushing enough them with water as a stop-gap measure. If there is a necessity receive the doctor's treatment.

2. Directions

(1) Do not use the reagents after the expiration date.

(2) After open the reagents, use them as early as possible. When preserve them, please close the lid and preserve on a specified condition.

(3) Please do not use the bottle and the accessory in this kit for other purposes.

(4) Please set the buffer and the latex reagent at the position correctly after gently mixing by invert the bottle before measure. Please remove the bubble when bubbling.

(5) When the measurement value exceeds the measure range, please dilute with saline liquid, and measure the specimen material. Those obtained by multiplying the dilution factor in value is the measured value.

(6) Please do not use the reagent with different lot.

(7) Please make the working curve at each measurement. Moreover, please measure the calibration sample for two times or more respectively.

(8) Please use the calibrator sold separately, and refers to the manual of the goods before use.

(9) Preserve the reagent at refrigerated condition (2-10℃)and avoid the freezing.

3. Attention for Disposal

(1) Sodium azide of 0.09w/v% is contained in the reagents as preservative. The sodium azide might generate the metallic azide that it reacts with the lead pipe and the copper pipe and explosiveness is strong, and flush it in volumes of water, please when you abandon it.

(2) An infectious microorganism such as hepatitis B viruses might exist in the sample, and process a used sample, the reagent container, and apparatus, etc. by sterilization, disinfection (0.5% solution of sodium hypochlorite), and incineration, etc.

(3) Please process it according to regulations of Wastes Disposal and Public Cleaning Law and Water Pollution Control Law, etc. when you abandon and apparatus, etc.

【Storage and validity period】

1. Storage : 2-10℃

2. Validity period : 1 year after production

Expiration date is displayed on the outer box and bottle labels.

【Package】

Product Name	Contents
RPR reagent	
Buffer (R1)	40mL ×1
Latex reagent (R2)	20mL ×1

〔Optional goods〕

(Product Name)	(Contents)
RPR Calibrator	5 conc. x 1mL each
RPR Control	Positive and Negative ×2mL each

The indicated value is displayed on the label

【References】

1) Hart G. : Ann Intern Med. 104, 368-376, 1986.

2) Kazuhisa Osato : HifuRinshou 41, 999-1007, 1999.

3) Internal documents by manufacturer and distributor.

【Inquiries】

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【Manufacturing and distribution】

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