This package insert follows the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

In Vitro Diagnostics
Marketing Approval No. 21200AMZ00424000

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This package insert must be read carefully prior to use.

Non-treponemal lipid antibody assay kit

MEDIACE RPR

General Precautions

1. This product is for in vitro diagnostic use only, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on consideration of the assay results together with the patient's symptoms and the results of other examinations.
3. The reliability of results cannot be guaranteed if this product is used for purposes or testing is done by methods other than those stated in this package insert.
4. Before use, be sure to read the package insert and the user's manual for the automated analyzer. Contact the manufacturer for further details. Analyzers should be cleaned before use to ensure accurate calibration.
5. RPR Standard Serum contains human-derived components. The reagent should be considered potentially infectious and handled with great care in the same manner as the samples.

Description (Kit Components)

1. Buffer Solution
   Phosphate buffer solution containing bovine serum albumin

*2. Latex Suspension
   Lipid antigens (cardiolipin and lecithin) coated latex

3. RPR Standard Serum (5 concentrations) (sold separately) [Note1]
   RPR-positive human serum

[Note 1]: Contains human-derived serum. Refer to "1. Precautions for Handling (to Ensure Safety)" in the "Precautions for Use or Handling" section for further details.

Intended Use

Measurement of syphilis anti-lipid antibody in serum or plasma
(Aid in diagnosis of treponema pallidum infection)

Assay Principle

A sample is reacted under certain conditions with polystyrene latex coated by lipid antigens (cardiolipin and lecithin), consequently syphilis anti-lipid antibody in the sample causes agglutination of the latex. The syphilis anti-lipid antibody titer in the sample is determined from the increase of turbidity due to formation of aggregates, which is calculated as the difference between the turbidity of the sample before and after reaction (change of turbidity).

Procedural Precautions

1. Properties of Samples and Sampling Methods

**1) Use serum or plasma (heparin plasma) as the sample.
2) Samples should be tested while fresh.
3) Handle the samples carefully to prevent infection.

2. Interfering Substances or Drugs

1) Assay results are not affected by free bilirubin (up to 19.7 mg/dL), conjugated bilirubin (up to 21.0 mg/dL), hemoglobin (up to 488 mg/dL), rheumatoid factors (up to 450 IU/mL), or heparin (up to 30 IU/mL).

*2) Assay results may be affected by chyle. If chylemia is seen in the sample, centrifuge the sample at 2000*g* or more for 10 minutes before use.

Dosage/Administration (Assay Procedure)

1. Preparation of reagents

1) Buffer Solution
   Gently invert the Buffer Solution bottle to mix it thoroughly and then use the solution as it is.
2) Latex Suspension
   Gently invert the Latex Suspension bottle to mix it thoroughly and then use the solution as it is.
3) RPR Standard Serum
   Gently invert the RPR Standard Serum bottle to mix it thoroughly and then use the solution as it is.

2. Assay Procedure

Perform the assay according to the instructions for operating the automated analyzer. Refer to the Method Sheet for the details of the assay method. Contact SEKISUI MEDICAL CO., LTD. for information about the parameters for other automated analyzers.

1) Preparation of the calibration curve
   Mix the RPR Standard Serum, Buffer Solution, and Latex Suspension to start the reaction. Prepare a calibration curve by measuring the difference of turbidity (change of turbidity) at predetermined times.
2) Sample measurement
   Measure the change of turbidity by following the procedure described in "Preparation of the calibration curve", and determine the anti-lipid antibody titer in the sample from the calibration curve.
3) Parameters (on Hitachi 7170 automated analyzer)
   (1) Mix 180 µL of Buffer Solution and 20 µL of the sample, and warm for approximately 5 minutes at 37 °C.
   (2) Add 60 µL of the Latex Suspension to the mixture and warm the mixture at 37 °C.
   (3) Then measure the change of turbidity at a wavelength of 700 nm from approximately 50 seconds to 4 minutes.
   (4) Prepare a calibration curve by measuring the change of turbidity in each standard solution by the same procedure as for the sample, and determine the anti-lipid antibody titer from the change of turbidity.

Assessment of Assay Results

1. Assessment of assay results

When the result obtained by using this kit is ≥ 1 R.U. [Note2], the sample is judged to be positive.

[Note2]: R.U. (RPR units) is based on the WHO Standard (The International Standard for Syphilitic Human Serum [first international standard preparation] established in 1958): 1 R.U. is equal to 0.4 IU. One R.U. is equivalent to the value obtained by using the RPR card method.

2. When the assay result is positive, perform further tests and interpret the results by other related tests, and take the symptoms into consideration.

3. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results. Do not make a diagnosis based on the results obtained with this kit alone.

4. Serum (plasma) samples from patients in the early stage of the antibody response or with impaired antibody production due to compromised immune function may contain a low antibody titer and the test may be negative.

5. Nonspecific reactions may occur when serum (plasma) samples from patients with autoimmune diseases are tested. Clinicians should make a comprehensive clinical decision by also assessing the results of other tests and the patient's symptoms.

6. Caution must be exercised, because false-positive assay results may be obtained with serum (plasma) samples from patients who have received blood products containing immunoglobulins.

7. Pay attention to the prozone phenomenon (hook effect), since it generally may occur in immune responses.

Performance

1. Performance

When used in accordance with the standard testing method specified by the manufacturer, the performance of this product is as follows.

1) Sensitivity
   The change of turbidity (ΔAbs) per 1 R.U. of syphilis anti-lipid antibody is ≥ 0.0100 higher than that (ΔAbs) under blinded conditions.
2) Accuracy
   Proceed with control serum that has a known syphilis anti-lipid antibody titer: the result is within the range from 80–120% of the known antibody titer.
3) Within-run reproducibility
   Test each of 2 types of control serum with different syphilis anti-lipid antibody titers 10 times simultaneously: the coefficient of variation (CV) of the measurements is ≤ 15%.
4) Measurement range[2)]
   The measurement range of this kit is 0.2–8 R.U. (on Hitachi 7170 automated analyzer). If the syphilis anti-lipid antibody titer in a sample exceeds 8 R.U., dilute the sample with physiological saline or another suitable reagent and perform re-measurement.

2. Correlation[1), 2)]

1) Serum N=82 r=0.909 y=1.01x+0.35
   Control method: Approved in vitro diagnostic (RPR card method)
2) Plasma N=88 r=0.995 y=1.03x+0.05
   Control method: This product (Comparison with serum samples obtained simultaneously)

Precautions for Use or Handling

1. Handling (to Ensure Safety)

1) All samples used in the test should be handled as a material possibly infected with viruses such as HIV, HBV, or HCV or other pathogens. The ingredient of the RPR Standard Serum is human-derived. The Standard Serum has been confirmed to be negative for HIV antibody, HBs antigen, and HCV antibody. However, the presence of pathogens (including those mentioned above) cannot be excluded, so it should be handled with care using disposable gloves, protective glasses, and a gown in the same way as the samples. To prevent infection, avoid mouth pipetting.
2) Do not eat, smoke, apply cosmetics, or touch contact lenses in the assay area where samples and reagents are being handled.
3) Buffer Solution, Latex Suspension, and RPR Standard Serum contain sodium azide at a concentration of 0.1% or lower as a preservative. If any of these reagents accidently comes into contact with the eyes or skin, implement first-aid measures such as rinsing the area with water and seek medical treatment if necessary.
4) To prevent transmission of infection from spilled samples or solutions containing samples, wipe the spilled area thoroughly with sodium hypochlorite solution at a concentration of 0.1% or more.

2. Precautions for use

1) This product should be stored as directed. Avoid freezing. Do not use any reagent that has been stored under conditions other than those specified (such as in a freezer) or has expired.
2) Do not combine or mix different lots of the Buffer Solution or Latex Suspension.
3) Prepare a new calibration curve for each assay. Do not change the bottle or lots of Buffer Solution or Latex Suspension during the assay.
4) Use the thermostat of the analyzer to ensure even distribution of the reaction temperature.
5) Check the reagent bottle and its label before use. Do not use the reagent if the label has peeled off or if it is smudged or illegible.

3. Precautions for Disposal

1) Sterilize or disinfect any waste created during the assay in the same way as for the samples and reagents. Such waste should be disposed of in accordance with the regulations established by each prefecture, such as the Waste Disposal and Public Cleansing Act and the Water Pollution Prevention Act.
2) Dispose of the used containers as medical or industrial waste in accordance with the regulations for handling medical or industrial waste.
3) The reagents contain sodium azide that may react with lead or copper pipes and produce highly explosive metallic azide. When washing

reagents off the skin or if reagents are accidentally discarded, take appropriate measures (e.g., flush copiously with water).

Storage and Shelf Life

1. Storage temperature: Store at 2–8 °C (avoiding freezing)
2. Shelf life: 6 months (indicated on the outer box and the container)

Packaging

1. MEDIACE RPR (A)

Reagent name	Package contents
Buffer Solution	2 × 18 mL
Latex Suspension	1 × 12 mL

2. MEDIACE RPR (M)

Reagent name	Package contents
Buffer Solution	1 × 60 mL
Latex Suspension	1 × 20 mL

Constituent reagents are available in other configurations. For further details, contact SEKISUI MEDICAL CO., LTD.

3. Sold separately

Reagent name	Package contents
RPR Standard Serum (5 concentrations)	1 × 1 mL × 5 concentrations

References

1) Osato K. et al.: Japanese Journal of Sexually Transmitted Infections, 13, 124–130, 2002. Japanese.
2) In house data, SEKISUI MEDICAL CO., LTD.

Contact

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