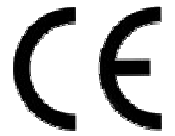


# RA LATEX TEST KIT



## CATALOGUE NUMBER

RA/010  
RA/012

## PRODUCT DESCRIPTION

50 Test Kit  
100 Test Kit

## INTENDED USE

The Plasmatec RA Latex test kit is for the qualitative and semi-quantitative determination of RA in human serum samples.

## WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only

For professional use only

### Health and Safety warnings:

All patient samples and reagents should be treated as potentially infectious and the user must wear protective gloves, eye protection and laboratory coats when performing the test.

Non disposable apparatus must be sterilised after use by an appropriate method.

Disposable apparatus must be treated as biohazardous waste and autoclaved or incinerated.

Spillages of potentially infectious material should be absorbed and disposed of as above. The site of spillage must be sterilised with disinfectant or 70% alcohol.

Do not pipette by mouth.

Control reagents contain human serum. The human serum used has been tested and found to be negative for HIV, HCV and HbsAg. Nonetheless the reagent must be treated as potentially infectious and appropriate precautions should be taken when handling and on disposal. The product also contains aqueous buffer salts including sodium azide as preservative - see material safety data sheet

### Analytical precautions:

Do not modify the test procedure.

Do not dilute or modify the reagents in any way.

Allow all reagents and samples to reach room temperature (18- 30°C) before use.

Resuspend test and control cells gently but thoroughly.

Do not interchange reagents from different kit batches.

## COMPOSITION

### Kit contents:

**Latex reagent** sufficient for 50/100 slide tests (Yellow label). The latex reagent should be well shaken to ensure homogeneity.

**Positive Control** (Red label). This serum is human positive RA serum. This reagent is ready for use and will give positive results when tested with the Plasmatec RA latex test.

**Negative Control** (Blue label). This control is a negative RA control serum. This reagent is ready for use and will give a negative result when tested with the Plasmatec RA latex reagent.

**10x Concentrated Glycine Buffer** (Green label). Add one part to nine parts distilled water before use. On dilution the diluent has a pH between 8.0 and 8.2.

**Pipette/ Stirrers**

**Reusable Agglutination slide.**

**Kit insert.**

## STORAGE AND SHELF LIFE

Store reagents, upright at 2-8°C.

DO NOT FREEZE ANY OF THE REAGENTS

Do not use reagents after the stated expiry date.

Discard reagents if they become contaminated or do not demonstrate the correct activity with controls.

## MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED.

Small glass or plastic test tubes / Serological pipettes

## SPECIMEN AND SAMPLE PREPARATION

Use fresh serum obtained by centrifugation of clotted blood. The sample may be stored at 2-8°C for 48 hours before performing the test. For longer periods of time the serum must be frozen. Haematic, lipaemic or contaminated serum must be discarded.

## PROCEDURE

### Principle

An abnormal protein occurs in the serum of many patients suffering from rheumatoid arthritis. This protein behaves as if it were an IgM antibody directed against determinants of IgG globulins. Detection of the rheumatoid factor protein is of value in the diagnosis of rheumatoid arthritis. Singer and Plotz(1956:1958) described a method of detecting rheumatoid factor using a suspension of fine plastic granules coated with human gamma globulins

which were agglutinated in the presence of rheumatoid factor. The RA latex reagent is a sensitive, standardised preparation of this type, made with a purified human IgG fraction and selected polystyrene latex.

## Qualitative method

1. Allow each component to reach room temperature.
2. Gently shake the latex reagent to disperse the particles.
3. Place a drop of undiluted serum onto the circle of the test slide using the disposable pipettes provided.
4. Add one drop of the latex reagent next to the drop of serum.
5. Using the other end of the pipette (broad end) spread the reagent and serum sample over the entire area of the test circle.
6. Gently tilt the test slide backwards and forwards approximately once every two seconds for two minutes. Positive and negative controls should be included at regular intervals. Both are ready for use and do not require further dilution. At the end of the test rinse the test slide with distilled water and dry. Normal laboratory precautions should be maintained while handling patients samples.

## INTERPRATATION OF RESULTS

Presence of agglutination indicates a level of RF in the sample equal or >8. I.U./ml.

The lack of agglutination indicates a level of RF in the sample of < 8. I.U./ml.

## Semi-quantitative determination

The semi-quantitative test can be performed in the same way as the quantitative test using dilutions of the serum in saline, phosphate buffered saline or glycine saline as follows:-

Dilutions	1/2	1/4	1/8	1/16
Sample serum	100? 1	-	-	-
Saline	100? 1	100? 1	100? 1	100? 1
	?	100? 1 ?	100? 1 ?	100? 1
Volume of sample	50? 1	50? 1	50? 1	50? 1
8xN°. Of dilution	8x2	8x4	8x8	8x16
Mg/I.U./ml	16	32	64	128

Normal Levels :- Adults < 8. I.U./ml

## RESULTS

The titre is expressed as the reciprocal of the highest dilution showing macroscopic agglutination: e.g. if this occurs in dilution 3, the titre is 64.

## INTERPRETATION OF RESULTS

Using a latex test system, positive results are not always found with every case of clinically defined rheumatoid arthritis. The number of positives reported using various types of latex reagent range from 70% to over 90%. False positive results also occur in various pathological conditions including lupus erythematosus, hepatitis, cirrhosis of the liver, lymphomas, scleroderma, and various other infections. The frequency of false positive results is not high even in these conditions but the possibility must be borne in mind when interpreting results.

## PERFORMANCE CHARECTERISTICS

Analytical Sensitivity: 8 (6-16IU/ml)

Prozone effect: No prozone effect detected up to 800IU/ml

Diagnostic Sensitivity: 100%

Diagnostic Specificity: 98.8%

## LIMITATIONS OF THE METHOD

The incidence of false positive results is about 3-5 %. Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive results.

Diagnosis should not be solely based on the results of latex method but also should be complemented with a Waaler Rose test along with the clinical examination.

NB: Results obtained with a latex method do not compare with those obtained with Waaler Rose test. Differences in the results between methods do not reflect differences in the ability to detect rheumatoid factors.

Haemoglobin (10 g/L), bilirubin (20 mg/dL) and lipemia (10 g/L), do not interfere. Other substances may interfere<sup>8</sup>

## INTERNAL QUALITY CONTROL

Positive and negative control sera are provided and should be used to verify the test

# RA LATEX TEST KIT



## REFERENCES

1. Singer J.M., Plotz, C.M. Amer. J. Med. 21:888-895 (1956)
2. Singer J.M., Plotz C.M. Amer. J. Med. Assoc. 168:180 (1958)
3. Dorner R.W. et al. Clinica Chimica Acta. 1987: 167: 1-21
4. Wolfe F. et al. Arthritis and Rheumatism 1991; 34: 951-960

**PRA.V2**

**8/4/03**