# RF (RHEUMATOID FACTOR) VISILATEX – SLIDE ASSAY

| CAT NO | DESCRIPTION | PACK SIZE |
|---|---|---|
| LATRF01 | RF VISILATEX (FULL KIT – Latex Reagent, Positive, Negative Controls, Stirrers & Reusable Slides) | 100T |
| LATRF02 | RF VISILATEX (FULL KIT – Latex Reagent, Positive, Negative Controls, Stirrers & Reusable Slides) | 150T |
| LATRF03 | RF VISILATEX – LATEX REAGENT ONLY | 1x4ml (100T) |

## Intended Use:

RF Visilatex is a rapid slide agglutination procedure intended to be used for the direct detection and semi quantitation of Rheumatoid Factor (RF) in human serum. This reagent is for In vitro diagnostic use by trained professionals only.

## Summary and Principle:

A suspension of latex particles coated with human gamma globulin is added to a test sample. The presence or absence of a visible agglutination indicates the presence or absence of RF in the samples tested.

## Reagent Composition:

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| **RF Latex Reagent** | **Polystyrene Latex particles coated with human gamma globulin stabilized in a buffered saline solution.** |
| | **Sodium azide 0.95g/l** |
| **Positive Control** | **Serum base with RF activity equivalent to > 30 IU/ml** |
| **Negative Control** | **Serum base with preservative** |

## Warnings and Precautions:

- The reagent contains Sodium azide. Do not allow contact with skin or mucous membranes.
- Source components of human origin have been tested and found to be negative for the presence of antibodies to HIV 1+2 and HCV and for HBsAg. However, control material should be handled as potentially infectious.

## Reagent Preparation and Stability:

Unopened reagents are stable up to expiry when stored at 2 - 8°C.
The reagents and controls are provided liquid stable. Once opened store at 2 - 8°C tightly capped. Do not freeze.

## Materials required but not provided:

Pipettes, Saline solution (0.9% NaCl for semi quantitation), mechanical rotor adjustable to 100 rpm.

## Specimen Collection:

Collect clear serum by separation after standard venepuncture technique. Samples that cannot be tested immediately may be stored at 2 - 8°C for up to 1 week. For longer term storage keep serum samples at -20°C for up to 3 months.
Before use, bring all samples to room temperature (+25°C)

## Procedure:

### Qualitative Assay:

1. Ensure that the test reagents and the samples are at room temperature.
2. Mix the Latex reagent gently by aspirating and expulsion of the reagent using the dropper several times.
3. Place 1 drop of serum (40 µl) in one of the circles on the card. On separate circles dispense 1 drop of Positive Control and Negative Control.
4. Add 1 drop (40 µl) of RF Latex reagent to each circle next to the sample to be tested.
5. Mix the contents of each circle with a disposable stirrer while spreading over the entire area enclosed by the ring. Use separate stirrers for each mixture.
6. Rotate the slide by means of a mechanical rotor (100 rpm) for a period of 2 minutes.
7. Observe immediately under a suitable light source for any degree of agglutination.

### Interpretation:

- Non-Reactive: Smooth suspension with no visible agglutination as shown by Negative Control.
- Reactive: Any degree of agglutination visible macroscopically.

### Semi-Quantitative Assay:

1. For each sample to be tested pipette 40 µl of 0.9% saline into each of the circles (6 circles) of a reaction card. Do not spread the saline.
2. To circle 1 add 40 µl of sample. Mix well by repeated aspiration and expulsion and transfer 40 µl of the mixture to the saline solution in the second circle. Mix as above.
3. Continue with the 2-fold serial dilutions up to the last circle and discard 40 µl from the last circle. Final sample dilutions will be 1/2, 1/4, 1/8, 1/16, 1/32, 1/64.
4. Test each dilution as described in the steps 4-7 for the qualitative assay.

### Interpretation:

- Non-Reactive: Smooth suspension with no visible agglutination as shown by Negative Control
- Reactive: Any degree of agglutination visible macroscopically. If the highest dilution is still reactive, repeat the test starting with a 1/16 dilution. As the diluent, use a 1/50 dilution of Negative Control serum in 0.9% saline solution to make the new dilution series starting at 1/16. The approximate RF level present in the sample may be obtained by multiplying the titre of the last positive dilution by the minimum detectable unit. (analytical sensitivity)

## Expected Values:

70-80% of patients with a clinical diagnosis of rheumatoid arthritis are seropositive for rheumatoid factor. Positive results were seen for nearly all patients with variants of rheumatoid arthritis such as Sjorgen's Syndrome and Felty's Syndrome. A positive result can be expected in less than 5% of healthy individuals while in the population aged 60 years and older as many as 30% may be seropositive using latex tests for the detection of rheumatoid factor.

## Quality Controls:

Positive and Negative controls should be run following the steps outlined in the qualitative assay. The Positive Control should produce clear agglutination. If it does not, discard the kit and use a fresh one for further assays.

## Performance Characteristics:

- The minimum detectable limit (analytical sensitivity) is ~8 IU/ml as tested against a RF International Calibrator (NIBSC 64/002).
- Diagnostic Specificity: 100%.
- No prozone effect was observed up to 1500 IU/ml.
- Haemoglobin < 10 g/l, bilirubin < 20 mg/dl and lipaemia < 10 g/l do not interfere with the assay. Other substances may interfere.

## Limitations:

- Positive reactions do occur in conditions other than rheumatoid arthritis such as mononucleosis, hepatitis, syphilis, various other infections and in elderly patients. When tested by the quantitative test, however, most of these specimens give very low results.
- A positive result from this test should not be used as the sole criteria for diagnosis, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

## Note:

- The sensitivity of the test may be reduced at low temperatures. The best results are achieved at 15 - 25°C.
- Delays in reading the results may result in over-estimation of the antibody present. Do not interpret results after 2 minutes.
- Titres obtained with the latex agglutination test do not compare with titres obtained with the Waaler-Rose test.

Differences in titre do not reflect a difference between methods in the ability to detect rheumatoid factors.

## Sources of Error:

- Bacterial contamination of controls and specimens as well as freezing and thawing of the latex reagent may lead to false positive results.
- Traces of detergent in the test cards may give false positive results. Wash used cards first under tap water until all reactants are removed and then with distilled water. Allow to air dry, avoiding the use of organic solvents as they may impair the special finish on the slide.
- The RF latex antigen must not be used beyond its expiry date because prolonged storage can affect the sensitivity of the suspension.

## References:


1. Dorner RW et al. Clinica Chemica Acta, 1987; 167: 1-21.
2. Wolfe F et al. Arthritis and Rheumatism, 1991; 34: 951-960.
3. Shmerling R et al. The American Journal of Medicine, 1991; 91: 528-534.
4. Young D.S.et al., Effect of Drugs on Clinical Laboratory Tests, 4th ed., AACC Press Washington DC 1995.


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| REF | Catalogue number | | Temperature limitation |
| | Consult instructions for use | LOT | Batch code |
| IVD | *In vitro* diagnostic medical device | | Use by Date |
| | Manufacturer | | |

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