**Expected values**

Establishing «normal values» for rheumatoid factor is difficult since its presence has little diagnostic value if it is not accompanied by signs that suggest the existence of rheumatoid arthritis.

In at least 70-80% of patients with rheumatoid arthritis the existence of rheumatoid factor can be proved through significant titers. The higher titers are usually related with the most serious cases of rheumatoid arthritis. The remaining patients are considered seronegative having rheumatoid factor titers falling in the normal range or not detectable by conventional tests.

In approximately 3-5% of the normal population there can be found rheumatoid factor at low titers. This proportion increases with the age of the population being studied.\(^2\)

**Performance characteristics**

Sure-Vue® RF was evaluated by comparison with a commercially available latex test (samples 1/6 diluted). A total of 192 serum samples from hospital patients were tested following the qualitative test. This study demonstrated a 91.7% agreement between the tests. The discrepant results were subsequently re-analyzed by means of a quantitative latex enhanced turbidimetric method being their titers between 10 and 30 IU/mL.

In a second study the Sure-Vue® RF was compared to another commercially available latex test (undiluted samples). A total of 223 serum samples were tested including random patients samples from a hospital and stored samples previously known to be positive for rheumatoid factor. This study demonstrated a 96.0% agreement between both tests. The discrepant sera exhibited borderline results.

A panel of 10 positive serum samples was tested on three consecutive days using the semi-quantitative test. The results of the study indicate that Sure-Vue® RF in-house reproducibility (within one dilution) was 100%.

**References**

Storage
The reagents will remain stable through the expiration date shown on the label, if stored between 2 and 8°C. Do not freeze. The reagents can be damaged by improper handling, especially temperature extremes. Checking with the positive and negative controls provided will permit detection of reagents deterioration.

The reagents should not be used after the expiration date shown on the label.
The latex reagent, once shaken, must be uniform without visible clumping. When stored a slight sedimentation may occur and should be considered normal.

Do not use reagents if they become contaminated.
The reagent dropper dispenses drops of 50 µL ± 10%. The dropper must be held perpendicular to the slide surface and a single drop allowed to fall. Do not use another dropper without previously checking the volume of the drop.

Interpretation of the results
The presence of agglutination indicates a content of rheumatoid factor in the serum equal to or greater than 10 IU/mL.
The absence of agglutination indicates a content of rheumatoid factor in the serum of less than 10 IU/mL.

POSITIVE REACTIONS:
- Large clumping with clear background.
- Moderate clumping with fluid slightly opaque in background.
- Small clumping with opaque fluid in background.

NEGATIVE REACTIONS:
No visible clumping, uniform suspension.

Semi-quantitative test
Allow reagents and samples to reach room temperature (20 to 30°C).
Preparation of two-fold serial dilutions of the serum on the slide (see the descriptive diagram for the technique):
- Place 50 µL of normal saline on slide sections 2 through 6.
- Using an automatic pipette, place 50 µL of the serum onto slide section 1 and 50 µL directly into the drop of normal saline on slide section 2.
- Using the same pipette take in and release several times the mixture made on section 2 and transfer 50 µL of the mixture to section 3. Repeat in this manner serially through section 6, discarding 50 µL from section 6.

Material required but not provided
- Normal saline (0.9% NaCl, only for semi-quantitative test).
- Automatic pipettes.
- Disposable stirrers.
- Rotator.
- Timer.

Sample collection
Use fresh serum collected by centrifuging clotted blood. If the test cannot be performed on the same day, the serum may be stored between 2 and 8°C for no longer than 8 days after collection. For longer storage, store samples frozen (-20°C).

It is not necessary to inactivate the serum.

As in all serological tests, hemolytic, lipemic or turbid sera may cause incorrect results and should not be used.

Do not use plasma.

Procedure
PREVIOUS MANIPULATIONS
- Before performing a set of determinations it is advisable to check the latex reagent with each of the controls, positive and negative, included in the kit.
- Both controls should be used following the steps outlined in the QUALITATIVE TEST.
- The reaction between the positive control and the reagent should show a clear agglutination, different from the uniform appearance of the negative control. If no agglutination takes place, the test should be repeated, and the kit discarded if there is no positive reaction.

QUALITATIVE TEST
- Allow reagents and samples to reach room temperature (20 to 30°C).
- Gently shake the reagent vial to disperse and suspend the latex particles in the buffer solution. Vigorous shaking should be avoided.
- Place 50 µL of the serum onto one section of the disposable slide.
- Place one drop of reagent next to the drop of serum.
- Mix both drops with a stirrer covering the whole surface of the slide section.
- Gently rotate the slide for 2 minutes manually or on a rotary shaker set at 80-100 rpm.
- Look for the presence or absence of agglutination after the aforementioned period of time.

Interpretation of the results
The approximate titer will correspond to the highest serum dilution that still presents a clearly visible agglutination (see diagram).

Limitations of the procedure
- Reading of the results after more than 2 minutes may give false positive results.
- The strength of agglutination is not necessarily indicative of relative rheumatoid factor concentration.
- Since increased levels of rheumatoid factor may accompany certain acute immune responses such as infectious mononucleosis, certain diseases such as sarcoidosis, systemic lupus erythematosus and Sjögren’s syndrome and may also be found in a considerable percentage of elderly individuals, the interpretation of the clinical significance of a positive test result must be made with caution. Less commonly, a positive test may result in situations where chronic inflammatory disease is suspected, such as bacterial endocarditis, tuberculosis, leprosy, etc.1,5
- Certain patients with rheumatoid arthritis may show negative results for rheumatoid factor.1,9