Mast Group Ltd.
Mast House, Derby Road,
Bootle, Merseyside, L20 1EA
United Kingdom
Tel: + 44 (0) 151 472 1444
Fax: + 44 (0) 151 944 1332
email: sales@mast-group.com
Web: www.mast-group.com

EC REP **Mast Diagnostica GmbH**
Feldstrasse 20
DE-23858 Reinfeld
Germany
Tel: + 49 (0) 4533 2007 0
Fax: + 49 (0) 4533 2007 68
email: mast@mast-diagnostica.de
Web: www.mast-group.com

Mast Diagnostic
12 rue Jean-Jacques Mention
CS91106, 80011 Amiens, CEDEX 1
France
Tél: + 33 (0) 3 22 80 80 67
Fax: + 33 (0) 3 22 80 99 22
email: info@mast-diagnostic.fr
Web: www.mast-group.com

MAST®ALEX RA80

RST601 / RST602

Intended use
A rapid slide latex agglutination test kit for the determination of Rheumatoid Factor (RF) in human serum samples.

FOR IN VITRO DIAGNOSTIC USE ONLY

Contents
The MAST®ALEX RA80 kit RST601 is for 100 tests and contains the following components:
1. Latex Reagent. Ready to use 4.1 mL. Contains latex particles sensitised with purified human IgG fraction and less than 0.1% sodium azide as preservative.
2. Positive Control. Ready to use. 0.5 mL. Contains less than 0.1% sodium azide as preservative.
3. Negative Control. Ready to use. 0.5 mL. Contains less than 0.1% sodium azide as preservative.
4. 18 disposable 6-place test cards.
5. 100 single use disposable plastic pipette/stirrers.
6. Instruction Leaflet.

MAST®ALEX RA80 Latex Reagents are also available as a separate item for 500 tests as product code **RST602**.

Stability and storage
Store unopened at 2 to 8°C in an upright position until the expiry date shown on the pack label. Once opened, MAST®ALEX RA80 should be stored at 2 to 8°C and may be used until the expiry date given on the label. **Do not freeze any of the reagents.**

Warnings and precautions
For *in vitro* diagnostic use only. Observe approved biohazard precautions and aseptic techniques. To be used only by adequately trained and qualified laboratory personnel. Each donor used in the preparation of materials of this kit was tested by FDA methods for the presence of HbsAg and antibodies to HIV and HCV and found to be negative. Sterilise all biohazard waste before disposal. Sodium azide preservative may be toxic if ingested and may react with lead and copper plumbing to form highly explosive salts. Always dispose of by flushing to drain with plenty of water. Refer to Product Safety Data sheet.

Materials required but not provided
Standard microbiological supplies and equipment such as small glass or plastic tubes and pipettes.

Procedure
A. Sample preparation
Use fresh serum samples obtained by centrifugation of clotted blood. Serum samples may be stored at 2 to 8ºC for up to 48 hours or frozen for longer term storage.

B. Qualitative Procedure
1. Allow the MAST®ALEX RA80 reagents to equilibrate to room temperature before use.
2. Gently shake the latex reagent to suspend the particles. Avoid frothing.
3. Place one drop of undiluted serum onto a circle of the reaction card using the disposable pipettes provided.
4. Add one drop of Latex Reagent onto the same circle of the reaction card near the drop of serum sample using a dropper pipette.
5. Using the other end of the pipette (broad end) mix and spread the reagent and serum sample over the entire area of the test circle. Gently tilt the test slide backwards and forwards approximately once every two seconds for two minutes.
6. Read the result at two minutes, note the result and dispose of the test card safely.

C. Semi-quantitative Procedure
A semi-quantitative procedure can be performed as for the qualitative test using 50 µL amounts of doubling dilutions of the serum prepared in 0.85% w/v saline or phosphate buffer (PBS), as detailed in the table below:

Serum dilution	N	1:2	1:4	1:8	1:16
µL of serum	100	100			
µL of diluent	-	100	100	100	100
Mix serum/diluted serum + diluent and transfer	-	^	100 ^	100 ^	100
8x dilution no.	8x1	8x2	8x4	8x8	8x16
Titre - IU/mL	8	16	32	64	128

Interpretation of results
Qualitative Procedure – A positive result is indicated by visible agglutination of the latex particles and indicates a level of RF in the sample equal to or greater than 8 I.U./mL.
A negative reaction indicated by a milky appearance without any visible agglutination of the latex particles indicates a level of RF in the sample less than 8 I.U./mL.

Semi-quantitative Procedure – Interpret as for the qualitative procedure. 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 IU/mL (see table above).

Limitations of use
Highly lipaemic, haematic or contaminated samples should be avoided.
When 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.

Quality control
It is recommended that quality control should be performed with the Positive and Negative Controls provided to verify that the latex reagents are working correctly, and should be used at regular intervals. Both controls are ready to use and do not require further dilution. The latex reagents should show strong agglutination within 2 minute. Also periodically check that latex reagents give correct results with known reference serum samples. Check for signs of deterioration. Do not use reagents if they are contaminated or cloudy.

References
Bibliography available on request.

IFU162 GB 08/20 V7