MISPA-i_2 AGAPPE

RF

15 Tests, 30 Tests
12009034, 12009003

Intended Use
This reagent is intended for *in vitro* quantitative determination of Rheumatoid factor in Serum.
-Nephelometry methodology
-Linear up to 100 IU/mL
-No sample dilution required
-Ready to use reagents
-No calibration required
-Lower Detection Limit of 10 IU/mL

Clinical Significance
Rheumatoid Factor (RF) is an auto antibody against human IgG commonly seen in serum of patients with rheumatoid arthritis. The measurement of RF value is useful in evaluating the diagnosis, effects of therapy and prognosis of RA, systemic lupus erythematosus, Chronic hepatopathy etc.

Principle
When a sample containing rheumatoid factor is added to denatured human IgG which has been sensitizied to latex particles, antigen-antibody reaction occurs leading to agglutination. The agglutination is proportional to the quantity of RF in the sample.

Kit Components

Reagent/ Component	Product Code 12009034	Product Code 12009003	Description
RF R1	1 x 3.8 mL	1 x 6.8 mL	Glycine Buffer Solution
RF R2	1 x 2.3 mL	1 x 3.8 mL	Latex suspension coated with denatured human IgG

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request.

Reagent Preparation
RF R1 & R2 Reagents are ready to use

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2 - 8^{o}C.

Open Vial Stability
Once opened the reagents are stable for 60 days. .
The validity of the smart card will be up to 60 days from the date of insertion and activation of the card in Mispa *i2*.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Protein Control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
Bring the reagents to room temperature (RT) before use.
To avoid contamination, use provided cuvettes and pipette tips for dispensing the reagent & sample. Close reagent bottles immediately after use.Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.
This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Fresh serum (Do not use haemolized or lipemic sample

Interferences
No interference for

Bilirubin up to	20 mg/dL
Haemoglobin up to	10 g/dL
Lipids up to	10 g/L

Materials provided
RF R1& R2 Reagents
Smart Card, Cuvettes & Pipette Tips

Test Procedure
The test procedure and the calibration data is provided in the smart card along with the kit. Insert the smart card and follow the instructions.
Step 1:
Insert card to card reader slot & display will prompt to add R1+Sample
Step 2:
Pipette 200 µL R1 & 20 µL sample to cuvette & place the cuvette into cuvette holder.
Step 3:
After incubation display will prompt to add R2
Step 4:
Pipette 100 µL R2 using attached sensor pipette to the cuvette
Step 5:
The result will show in the display and print out

Calibration
The calibration data is incorporated in the smart card and hence no calibration is required.

Quality Control
It is recommended to use Agappe Protein Control (Bi Level) (Product Code: 11614007) to verify the performance of the assay. Each laboratory has to establish its own internal quality control scheme and procedure for corrective action, if control do not recover within the acceptable range.

Reference Range
It is recommended that each laboratory should establish its own reference values.
The following value may be used as guide line.
Serum up to 18 IU/mL
Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance
1. Linearity
The reagent is linear up to 100 IU/mL.
If the concentration is greater than linearity (100 IU/mL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.
2. Comparison
A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.9569 and a regression equation of y = 0.9835x.
3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 3	Level 1	Level 3
n	20	20	20	20
Mean (IU/mL)	23.96	39.04	24.89	40.86
SD	0.98	2.16	1.04	1.25
CV(%)	4.10	5.42	4.19	3.07

Accuracy (IU/mL)		
Control	Expected Value	Measured Value
Control Level 1	23.8 ± 4.8	23.4
Control Level 3	37.9 ± 7.6	39.2
Protein Control	28.5 ± 7	28

4. Sensitivity
Lower detection Limit is 10 IU/mL

Bibliography
1. Frederick, Wolfe *et al.* ; Arthritis and Rheumatism 1991: 34; 951-960

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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REV. NO.: ADL/IFU/RF/I2/R03

CE ISO 9001:2015
EN ISO 13485:2016