Instruction for Rheumatoid Factor (RF) Detection Kit (Nephelometry)

【Product Name】

Generic name: Rheumatoid Factor (RF) Detection Kit (Nephelometry)
Trade name: RF
English name: Rheumatoid Factor (RF) Detection Kit (Nephelometry)

【Package】

Specification 1: 25T/kit	REF: 32026006
Specification 2: 2×25T/kit	REF: 32080006
Specification 3: 50T/kit	REF: 32027006
Specification 4: 100T/kit	REF: 32028006
Specification 5: 150T/kit	REF: 32029006
Specification 6: 200T/kit	REF: 32030006
Specification 7: 250T/kit	REF: 32031006
Specification 8: 300T/kit	REF: 32032006

【Intended Use】

For in vitro quantitative determination of Rheumatoid Factor (RF) content in human serum or plasma.

【Test Principle】

Couple the human γ globulin onto the latex particles, which will have an agglutination reaction with the RF in the sample and form an antigen-antibody complex. With a certain amount of antigen, the turbidity is in direct proportion to the RF of the sample. By detecting the reaction change at specific wavelengths and referring to the multi-point calibration curve, the RF content of the sample can be calculated. The reagents are pre-calibrated, each specific calibration curve has been recorded into the magcard, and each detection kit is allocated with one magcard.

【Main Compositions】

1. Buffer solution: phosphate buffer 20mmol/L, sodium chloride 15.8g/L
2. Antiserum: 3-hydroxymethyl aminomethane - hydrochloric acid (Tris - HCl) 20mmol/L, latex particles coupled with human γ globulin 1.5g/L
3. Magcard: polyvinyl chloride (PVC) plastic
4. Stirrer: stainless steel

【Accessories Required But Not Provided】

1. Pipettor
2. Pipettor tips
3. Reaction cup

【Storage and Validity Period】

The sealed detection kit can be stored at 2-8℃ for 12 months. Do not freeze. Once opened, the reagents stored at 2-8℃ are stable for 30 days.

【Applicable Instruments】

Applicable for PA50&PA54 Specific Protein Analyzer and PA120&PA200 Fully-auto Specific Protein Analyzer manufactured by Genrui Biotech Inc. to quantitatively test RF in human serum or plasma.

【Sample Requirements】

The optimal sample is fresh non-hemolyzed serum or anticoagulant heparin plasma. The fresh serum will be released from the condensation of blood clots, plasma is obtained by centrifugation. RF in the sample can be stored at 2-8℃ for 3 days.

Samples with clear interferent should eliminate the interferent and resample.

【Test Methods】

Bring all reagents to room temperature (18-25℃) before the use.

1. Test methods for PA50&PA54 Specific Protein Analyzer

1) After startup, the instrument displays the main measurement interface, select the test item and sample type at the item column (After the confirmation, it will default to this item and sample type in the future.).
2) Click “LOT” at the batch No. column to enter the card-swiping interface. Put the corresponding magcard onto the magnetic induction area, when a “di” sound heard, the magcard was successfully swiped, and the interface returns to the main measurement interface. For the same batch of reagents, no need to swipe the card again.
3) The instrument interface prompts “Input Cup!”.
4) Take out one cuvette, put one stirrer into it, then use the pipettor to accurately add in 300μl buffer solution, then add in 5μl sample.
5) Put the cuvette into the test channel, the instrument automatically stir for one time.
6) The instrument prompts “Please Add Antiserum”, then use the pipettor to accurately add in 100μl antiserum.
7) Immediately press the corresponding channel’s start button, the instrument will stir automatically. When the test finished, the instrument will automatically display and print the test result.
8) After the test, take out the cuvette, the instrument prompts “Input Cup!”, do the next test.

2. Fully-auto specific protein analyzer (PA120, PA200) detection methods are as follows

1) Login fully-auto specific protein analyzer PA120, PA200 PC software, put the magcard onto the magnetic induction area, the instrument will prompt the card is successfully swiped, for the same batch of reagents, only swipe the card once.
2) Login the main measurement interface, apply for testing according to the items and sample types to be tested.
3) Put the test sample in place, then put the corresponding reagents at the specified locations and start the test, the instrument will automatically aspirate all the test samples and complete the measurement process. After the test is completed, you can view the measurement results and print the test results.
4) Please refer to PA120, PA200 manual for detailed description of instrument operation method.

【Reference Value】

Reference range: 0-20IU/mL

【Explanation for the Test Results】

Rheumatoid Factor (RF) is one kind of non-specific immunoglobulin existed in the sample, which is produced by human body as one kind of antibody aiming at the degenerated immunoglobulin (IgG). It combines with IgG to form an immune complex which distributes everywhere of the human body, this is one of the significant factors for causing local arthropathy and joint outside manifestation. Also existed in patients with dermatomyositis, scleroderma, chronic active hepatitis, etc..

Calculation method: Fitting the standard multi-point calibration curve by appropriate mathematical model (nonlinear) such as Logit / Log. Sample concentration value is obtained by calibration curve.

【Calibration and QC】

1. Calibration

Use the appropriate RF calibrator (recommended brand of Randox or other approved brands) and the calibration period is 30 days. Recalibration is needed when replacing the batch number of reagents.

2. QC

It is recommended to use QC with normal and pathological values to do the indoor quality control, the tested control value should be within the definite limits, if the value is out of control, the laboratory should take appropriate corrective measures.

3. QC Solution (optional)

3.1 Product Name: RF QC

3.2 Package Specification

0.2ml/bottle

3.3 Intended Use

Intended for in vitro diagnostic use in the quality control of diagnostic assays.

3.4 Main Composition: RF antigen

3.5 Storage and Validity Period

The QC can be stored for 12 months at 2-8℃. It is stable for 30 days at 2~8℃ once opened.

3.6 Target and Limitation

Please refer to the label.

3.7 Test Method

The test procedure is same as sample test, please refer to the sample test method above.

【Limitations for the Test Results】

The diagnosis and treatment cannot only depend on this test result, please consider the clinical history and other laboratory test results at the same time. It is suggested that each laboratory builds up its own reference range based on its own patient group.

If the sample's test result is beyond the linearity range, please use distilled water to dilute the sample with integral multiples and re-test. The result should multiply the dilution times.

【Product Performance Indicators】

1. Analysis sensitivity: ≤ 3IU/mL
2. Linearity range: 3-160IU/mL, determination indicator: r ≥ 0.990
3. Measurement precision:

Repeatability: CV ≤ 5%, relative deviation of Detection Kit's inter batches (R) ≤ 5%

4. Accuracy: Bias% ≤ ±10%
5. Specificity:

When add in free bilirubin ≤ 684μmol/L, hemoglobin ≤ 5g/L, triglyceride ≤ 11.3mmol/L, the test result Bias% ≤ ±10%

【Precautions】

- Only used for in vitro diagnostic, please refer to the Operation Manual.
- Do not use the expired reagents. Shake the antiserum reagent well before use.
- Do not use reagents of different batches together.
- The waste solution after reaction contains both human and animal derived materials, should be treated as a potential source of infection.

【Labels】

Label	Meaning
	Date of manufacture
	In vitro diagnostic medical device
	Manufacturer
	Biological risks
	Batch code
	Temperature limit
	Use-by date
	Authorized representative in the European Community
	Volume
	Consult instructions for use
	Do not re-use
	Keep away from sunlight
	Contains sufficient for <n>tests
	Catalogue number
	CE Marking

【Reference】

Eberhard K B, Truedson L,Pettersson H, etal. Disease activity and joint damage progression in early rheumatoid arthrits: relation to IgG、IgA and IgM rheumatoid factor [J]. Ann Rheum Dis, 1990, 49(11): 906

【Manufacturer】

Genrui Biotech Inc.

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【Medical Devices' Manufacturing Permit No.】

Guangdong SFDA (State Food and Drug Administration) authorized Medical Device Manufacturing Permit No. 20041046

【Medical Devices' Product Registration】

Certificate No.

Guangdong SFDA 2014.2400507 (**Approved**)

【Product Standard Code】

YZB/Guangdong --- *0605-2014*

【Instruction Approved and Revised Date】

Approved date: February, 23th, 2018

Revised date: October, 08th, 2018

【Guarantee and Technical Support】

If invalid message repeats or need technical support, please contact Genrui Customer Service and Support Center.