CE IVD

RF

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF **IF1075 for Getein1100**
IF2075 for Getein1600

INTENDED USE

RF Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of rheumatoid factor (RF) in serum, plasma or whole blood samples. The test is designed to aid in the diagnosis of autoimmune diseases, such as rheumatoid arthritis (RA).

SUMMARY

Rheumatoid factor is an autoantibody targeting the Fc fragment of human or animal denatured IgG molecule. RF mainly includes four types of IgM, IgG, IgA and IgE. IgM is the main type of RF, and this test kit mainly detects this type. Under the direct stimulation of denatured IgG or Epstein-Barr virus, B cells in patients with rheumatoid arthritis will synthesize RF in large quantities. On the contrary, in healthy people, there are few clones of B cells that produce RF, and the soluble factors secreted by monocytes can inhibit the production of RF, which is generally difficult to be detected. Positive RF is one of the criteria for RA classification by the American College of Rheumatology, but positive RF is not the sole basis for the diagnosis of RA. RF has a positive detection rate of 80% in RA patients, 20-50% in patients with systemic lupus erythematosus, Sjogren's syndrome and dermatomyositis, and even 5% in the normal elderly population.

PRINCIPLE

The test kit adopts a double-antigen sandwich method to quantitatively detect the concentration of RF in human serum, plasma and whole blood samples.
After the sample has been applied to the test card, the fluorescence latex-labelled RF antigen Ⅰ binds with RF in sample and forms a marked antigen-antibody complex. The complex moves to the detection area by capillary action, then it is captured by RF antigen Ⅱ coated on the detection area of nitrocellulose membrane, forming a double- antigen complex. The complex generates a fluorescent signal and the intensity increases in proportion to the amount of RF in sample.
Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/ automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of RF in sample will be measured and displayed on the screen. The value will be stored in Getein1100/ Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein RF test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card: 1 piece/box
2. A kit for Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein RF test cards
2) User manual: 1 piece/box
Materials required for Getein1600:
1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box
3. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad ,nitrocellulose membrane (one end of the membrane is coated with fluorescence latex-labelled RF antigen Ⅰ, the test line is coated with another RF antigen Ⅱ and the control line is coated with polyclonal goat anti human IgG antibody),absorbent paper and liner.
4. Sample diluent composition:
Phosphate buffered saline, proteins, detergent, preservative, stabilizer.
Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100 within one hour once the foil pouch is opened.
For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.
Store sample diluent at 0~30℃ with a valid period of 24 months.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch or the cartridge is damaged.
5. Do not open pouches or the cartridge until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. ***Serum, plasma or whole blood*** samples can be used for the test. Other body fluids and samples may not give accurate results. Samples should be free of hemolysis.
2. Venous blood should be collected under aseptic conditions; serum or plasma is preferred for testing.
3. Heparin, sodium citrate or EDTA can be used as the anticoagulant for plasma and whole blood samples.
4. The test should be performed at room temperature within 4 hours after sample collection.
5. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2 ~ 8℃ and 6 months at -20℃ before testing. Whole blood samples should not be frozen and can be stored at 2 ~ 8℃ for 3 days. Do not heat inactivated samples or use hemolyzed blood samples.
6. Refrigerated or frozen sample should be reached to room temperature before testing. Frozen samples must be completely thawed, rewarmed and evenly mixed. Avoid multiple freeze-thaw cycles.
7. Sample volume (for Getein1100):***100 μL***

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature before test.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
4. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver ***10 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100μL*** of sample mixture into the sample port on the test card.
7. ***Reaction time: 10 minutes.*** Insert the test card into Getein 1100 and click on “Start” icon (for Android Getein1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

1. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
2. Put the sample diluent at the correct position of Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein 1100.
3. Make sure the test card and the sample insertion are correct and complete.

TEST RESULTS

Getein1100/ Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/ Getein 1600.

Others: Samples whose concentration exceeds the upper limit should be diluted no more than 4 times.

EXPECTED VALUE

The expected normal value for RF is determined by testing samples from 282 apparently healthy individuals. The upper 97.5th percentile value is 15.9 IU/mL.

It is recommended that each laboratory determine the applicability of the reference value through experiments and establish its own reference ranges if necessary.

PERFORMANCE CHARACTERISTICS

Measuring Range	10.0-640.0 IU/mL
Lower Detection Limit	≤10.0 IU/mL
Within-run Precision	≤10%
Between-run Precision	≤15%

LIMITATIONS

1. Bilirubin and triglyceride in the sample may interfere with the test results, and the maximum allowable concentrations are 0.1 mg/mL and 10 mg/mL respectively.
2. The test results of this kit are for clinical reference only, and should not be used as the sole criteria for clinical diagnosis. It is recommended to conduct a comprehensive analysis on the condition in combination with symptoms/signs, history and other laboratory tests.

REFERENCES

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2. Kolarz B, Podgorska D, Podgorski R. Insights of rheumatoid arthritis biomarkers.[J]. Biomarkers : biochemical indicators of exposure, response, and susceptibility to chemicals,2020: 1-34.
3. Nithya L, Jeremy S, Lauren J, et. al. Combination of anti-citrullinated protein antibodies and rheumatoid factor is associated with increased systemic inflammatory mediators and more rapid progression from preclinical to clinical rheumatoid arthritis[J]. Clinical Immunology,2018,195: 119-126.
4. Veerle I, Xavier B, Daniël B, Ellen DL. Prevalence and clinical correlates of rheumatoid factor and anticitrullinated protein antibodies in patients with idiopathic inflammatory myopathy[J]. RMD Open,2018,4(2):.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on the test kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
Σ	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged
REF	Catalogue number		

Thank you for purchasing RF Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

Version: WIF82-S-02

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