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CE IVD

RF
Fast Test Kit
(Immunofluorescence Assay)

Instructions for Use

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). For professional and laboratory use only.

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, and IgM is the main type of RF. 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. RF is mainly used in the clinical diagnosis of RA. RF has a positive detection rate of 80% in RA patients. 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.

PRINCIPLE

RF Fast Test Kit (Immunofluorescence Assay) 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 fluorescently labelled RF antigen 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 coated on the detection area of nitrocellulose membrane, forming a double-antigen complex. The fluorescence intensity of the test line increases in proportion to the amount of RF in sample. Fluorescent signals intensity can be analyzed by applicable device thus the RF in sample be detected quantitatively.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1200/Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
RF test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10 tubes	25 tubes	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

*RF test card

A test card consists of: Fluorescently labelled RF antigen, RF antigen.

** Sample diluent

(1)Sample diluent for Getein 1100/Getein 1160/Getein 1180 in each tube mainly consists of: phosphate buffer (20 mmol/L), NaN_3 (<0.1%).

(2)Sample diluent for Getein 1200/Getein 1600 is an independent packing box mainly consists of:

-Phosphate buffer (20 mmol/L), NaN_3 (<0.1%) (25 mL/bottle for Getein 1200, 30 mL/bottle for Getein 1600),

-Box with pipette tips (96 tips/box),

-Mixing plate (1 piece/box).

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

-For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

-For test card of Getein 1200/Getein 1600: 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.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional and laboratory use only, not for near-patient test and self-testing.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches until performing the test.
5. Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
6. It is recommended that operators take necessary self-protection measures (work clothes, goggles and disposable gloves, etc) when touching kits or samples.

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. It is recommended to test the sample within 4 hours after collection. Stable in serum and plasma for 7 days at 2~8°C and 3 months at -20°C. Stable in whole blood for 3 days when stored at 2~8°C.
5. Refrigerated or frozen sample should be reached to room temperature before testing. Frozen samples must be completely thawed, rewarmed and evenly mixed. Serum and plasma samples can be freeze and thawed twice at most.
6. Sample volume (for Getein 1100/Getein 1160/Getein 1180): 10 μL

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

(1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.

(2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).

(3) Remove the test card from the sealed pouch before use. Horizontally place the test card.

(4) Deliver 10 μL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 μL of sample mixture into the sample well on the test card.

(5) ***Reaction time: 10 minutes***. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

(1) Confirm SD card lot No. in accordance with test kit lot No. It is required to perform "SD card" calibration when using a new batch of kits.

(2) Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).

(3) Remove the test card from the sealed pouch before use. Horizontally place the test card.

(4) Deliver 10 μL of sample into one tube of sample diluent using disposable pipet or pipette, mix gently and thoroughly. Then drop 100 μL of sample mixture into the sample well on the test card.

(5) Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (10 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1200/Getein 1600:

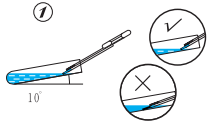
1. Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card (SD card) which can calibrate automatically.
2. Place the sample diluent at the correct position in Getein 1200/Getein 1600.

3. Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 will do the testing and print the result automatically.

Note:

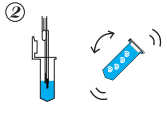
1. It is required to perform “SD card” calibration when using a new batch of kits for Getein 1100/Getein 1160/Getein 1180.
2. The directions for using disposable pipet are as follows:

Directions to use disposable pipet

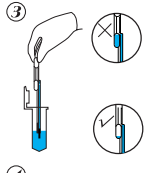


Insert the disposable pipet into the sample tube, gently touch the liquid surface with the capillary tip, and draw the sample.

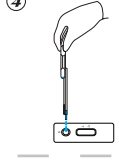
Note: Do not immerse the exhaust pipe below the liquid level.



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, gently squeeze the suction bulb to perform 2-3 aspiration washing cycles, then mix the dilution manually.



Insert the disposable pipet (including the exhaust tube) into the dilution liquid, firmly squeeze the suction bulb to aspirate the mixed sample.



Squeeze the suction bulb and drop the mixed sample vertically into the sample well on the test card.

RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

Others:

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

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

Interferent	Concentration (Max)
Triglyceride	10 g/L
Bilirubin	0.2 g/L

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
Limit of Detection	≤10.0 IU/mL
Within-Run Precision	≤10%
Between-Lot Precision	≤15%

REFERENCES

1. Eberhardt KB, Truedson L, Pettersson H, et al. 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.
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 anticitrullinated 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 RF Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more detail in the European Standard EN ISO 15223-1:2021.

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

Thank you for using RF Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

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Catalogue number	Applicable analyzer	Package specification
IF1075-10T	Getein 1100	10 T/kit
IF1075	Getein 1100	25 T/kit
IF5075-10T	Getein 1160	10 T/kit
IF5075	Getein 1160	25 T/kit
IF3075-10T	Getein 1180	10 T/kit
IF3075	Getein 1180	25 T/kit
IF4075	Getein 1200	2*24 T/kit
IF4075-96T	Getein 1200	2*48 T/kit
IF2075	Getein 1600	2*24 T/kit
IF2075-96T	Getein 1600	2*48 T/kit