CE IVD

Anti-CCP

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF IF1029 for Getein1100
IF3029 for Getein1180
IF2029 for Getein1600

INTENDED USE

Anti-CCP Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of anti-CCP 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

Anti-CCP is an autoantibody that synthesizes cyclic citrulline polypeptide (CCP) as antigens. Anti-CCP mainly consists of IgG and it can be used for the early diagnosis of RA due to its high sensitivity and specificity to the disease. Currently, it is believed that the sensitivity of Anti-CCP to RA diagnosis is 50%-78% with a specificity of 96%. The positive rate of early RA patients is 80%. Meanwhile, radiological examination results show that patients with positive Anti-CCP have significantly more severe joint injuries than those with negative Anti-CCP. Therefore, Anti-CCP as a prognostic indicator can play an important role in monitoring the development and progression of rheumatoid arthritis disease. In addition, Anti-CCP is a sensitive indicator for differentiating invasive and non-invasive RA.

PRINCIPLE

The test kit adopts an indirect sandwich method to quantitatively detect the concentration of Anti-CCP in human serum, plasma and whole blood samples.
After the sample has been added to the test card, the fluorescence latex-labelled CCP antigen combined with Anti-CCP in sample and forms a marked antigen-antibody complex. The complex moves to the detection area by capillary action. Then it is captured by Anti-human IgG antibody coated on the detection area of nitrocellulose membrane, forming a CCP-Anti-CCP-Anti-human IgG complex. The complex generates fluorescent signal and the intensity increases in proportion to the amount of Anti-CCP in sample. Then test card is inserted into Getein1100/Getein1180 Immunofluorescence Quantitative Analyzer or automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100, Getein1180 and Getein1600), the concentration of Anti-CCP in sample will be measured and displayed on the screen. The result will be stored in Getein1100/Getein1180/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1180 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein Anti-CCP 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 Anti-CCP 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 which is coated with fluorescence latex-labelled CCP antigen, nitrocellulose membrane (the test line is coated with Anti-human IgG antibody and the control line is coated with polyclonal goat anti chicken IgY 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
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months.
Use the test card for Getein1100/Getein1180 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°C 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 get 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°C and 6 months at -20°C before testing. Whole blood samples should not be frozen and can be stored at 2~8°C 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.

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 ***100 μL*** of sample mixture into the sample port on the test card.
7. ***Reaction time: 15 minutes***. Insert the test card into Getein1100 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 Getein1180:

8. Confirm SD card lot No.in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
9. Enter testing interface of Getein1180.
10. Remove the test card form the sealed pouch immediately before use. Label the test card with patient or control identification.
11. Put the test card on a clean table, horizontally placed.
12. Using sample transfer pipette, deliver ***10 μL*** of sample into one tube of sample diluent, mix gently and thoroughly. Then drop ***100 μL*** of sample mixture into the sample port on the test card.
13. ***Reaction time: 15 minutes***. Insert the test card into Getein1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shoe on the screen and printed automatically.

For Getein1600:

14. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
15. Put the sample diluent at the correct position of Getein1600.
16. 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 display the result automatically.

NOTES

1. It is required to perform “SD card” calibration when using a new batch of kits for Getein1100/Getein1180.
2. It is suggested to calibrate once for one batch of kits for Getein1100/Getein1180.
3. Make sure the test card and the sample insertion are correct and complete.

TEST RESULTS

Getein1100/Getein1180/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/Getein1180/Getein1600.

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

EXPECTED VALUE

The expected normal value for Anti-CCP is determined by testing samples from 282 apparently healthy individuals. The upper 99.0th percentile value is 25.0 U/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	10.0-400.0 U/mL
Lower Detection Limit	≤10.0 U/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

1. Ishigooka, Nozomi, Fujii Takao, et al. Predicting factors for disappearance of anti-mutated citrullinated vimentin antibodies in sera of patients with rheumatoid arthritis [J]. Modern rheumatology, 2020, 30(3):450-457
2. Tülay Kars Fertelli. Effects of Education About Rheumatoid Arthritis and Sexuality on the Sexual Problems of Women With Rheumatoid Arthritis [J]. Clinical Nursing Research, 2020, 29(3):189-199
3. Verheul M K, Bhringer S, Mam V D, et al. The combination of three autoantibodies,ACPA,RF and antiCarP antibodies is highly specific for rheumatoid arthritis:implications for very early identification of individuals at risk to develop rheumatoid arthritis [J]. Arthritis and Rheumatism, 2018, 70(11):1721-1731
4. Shakiba Yadollah, Koopah Susan, Jamshidi Ahmad Reza, et al. Anti-cyclic citrullinated peptide antibody and rheumatoid factor isotypes in Iranian patients with rheumatoid arthritis: evaluation of clinical value and association with disease activity [J]. Iranian Journal of Allergy, Asthma and Immunology, 2014, 13(3):147-156.

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 15223-1:2021.

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
Σ	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		

Thank you for purchasing Anti-CCP Fast Test Kit (Immunofluorescence Assay).

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

Version: WIF106-S-02

Getein Biotech, Inc.
Add.: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054