Chuangxingwell

CE

Anti-CCP Rapid Test Kit
Package Insert

For quantitative determination of IgG class auto antibodies against cyclic citrullinated peptides in Human Serum and Plasma or whole blood samples.
For in vitro diagnostic use only.

IVD

INTENDED USE

Anti-CCP Rapid Test Kit is intend-ed 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 lgG 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 cassette, the fluores-cence 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 captu「ad by Anti-human lgG antibody coated on the dete-ction area of nitrocellulose membrane, forming a CCP-Anti-CCP-Anti-human lgG complex. The complex generates fluorescent signal and the intensity increases in proportion to the amount of Anti-CCP in sample. Then test cassette is inserted into Fluorescence Immunoassay Analyzer, the concentration of Anti-CCP in sample will be measured and displayed on the screen. The result will be stored in Fluorescence Immunoassay Analyzer and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

MATERIALS AND COMPONENTS

Materials provided with the test kits:

Package specifications: 25 tests/box, 10 tests/box

1) Anti-CCP test Cassette in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) Package insert: 1 piece/box
5) SD card: 1 piece/box

A test Cassette 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 lgG antibody and the control line is coated with polyclonal goat anti chicken lgY antibody), absorbent paper and liner.

Sample diluent composition: Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

Note: Do not mix or interchange different batches of kits.

Material Required But Not Provided:

Fluorescence Immunoassay Analyze

Specimen Collection Containers

Centrifuge

Timer

STORAGE AND STABILITY

Store the test cassette at 4-30°C with a valid period of 24 months.

The test cassette must remain in the sealed pouch until use. Use the test Cassette within one hour once the foil pouch is opened.

Do not freeze.

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 cassette if the foil pouch or the cartridge is damaged.
5. Do not open pouches or the cassette until ready to perform the test.
6. Do not reuse the test cassette.
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 antico-agulant 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

Refer to Immunofluorescence Analyzer User Manual for the complete instructions on use of the Test. The test should be in room temperature.

1. Allow the test cassette, specimen and reagent to reach room temperature (15 - 30 °C) prior to testing.

2. Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.

3. Remove the test cassette from the sealed pouch immediately before use. Label the test cassette with patient or control identification.

4. Put the test cassette on a clean table, horizontally placed.

5. Use sample transfer pipette to deliver **10μL** 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 cassette.

6. Incubate at room temperature for 15 minutes.

7. After 15 minutes, insert the test device immediately into the Fluorescence Immunoassay Analyzer and read results.

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.
3. Make sure the test cassette and the sample insertion are correct and complete.

TEST RESULTS

Results read by Immunofluorescence Analyzer.

The result of test for Anti-CCP is calculated by Immuno-fluorescence Analyzer and display the result on the screen. For additional information, please refer to the user manual of Immunofluorescence Analyzer.

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 applicablity 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. Tulay Kars Fertelli .Effects of Education About Rheumatoid Arthritis and Sexuality on the Sexual Problems of WomenWith 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 antibodiesis 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.

Index of Symbols

	Caution	IVD	In Vitro Diagnostic Medical Device
	Manufacturer		Date of Manufacture
	CE Marking		Do Not Re-use
	Keep Dry		Keep Away From Sunlight
LOT	Batch Code		Do Not Use if Package is Damaged
REF	Catalogue Number		Contains Sufficient for <n> Tests
	Use-By Date		Temperature Limit
EC REP	Authorized representative in the European Community		

Manufacturer
Jinan Chuangxingwell Biotech Co., Ltd.
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