Anti-cyclic citrullinated peptide semi-quantitative assay kit (Colloidal Gold)

Read the package insert carefully and completely before performing the assay. Follow the instructions and do not modify them. Only by strict adherence to these instructions, the erroneous results can be avoided and the optimal performance of Hotgen Anti-cyclic citrullinated peptide semi-quantitative assay kit (Colloidal Gold) achieved.

INTENDED USE

This kit is used for semi-quantitative measurement of human anti-cyclic citrullinated peptide antibody (Anti-CCP) in serum and plasma employing colloidal gold immunochromatography as an aiding tool for diagnosis of rheumatoid arthritis (RA).

SUMMARY

Rheumatoid arthritis (RA) is one of the most common autoimmune diseases. It is characterized by a progressive inflammation of the joints, leading to gradual damage and loss of their function. Early diagnosis of RA and immediate onset of an appropriate treatment is essential for prevention of complete joint damage. In addition to rheumatoid factors, autoantibodies against citrullinated antigens (ACPA) have proven to be valuable tools for the serological diagnosis of early RA. They have become a critical component of the new 2010 ACR criteria for the classification of RA, and account for three of the six points required to verify a diagnosis of RA.

Anti-CCP antibodies are highly sensitive and specific for RA. Studies show Anti-CCP test demonstrates an outstanding sensitivity of over 80% and a specificity of over 96%.

Anti-CCP detects autoantibodies very early – sometimes even years before symptoms become evident. Persons without symptoms but with an increased Anti-CCP antibody titre is at high risk for future RA development. Furthermore, a positive result is predictive for a severe course of RA. Therefore Anti-CCP is an effective tool for rapid and precise routine

PRINCIPLE OF THE ASSAY

The kit employs colloidal gold immunochromatography. When specimen is added to the sample cavity, capillary effect causes the fluid to flow to the other end of the NC membrane of the test cassette, Anti-CCP (if present) in the specimen first binds to a colloidal gold CCP conjugate. As the mixture moves along the NC membrane to the test region (T line) it binds to a mouse anti human antibody that is immobilized on the membrane resulting in the formation of a red line. The mixture continues to move to the control area (C line) where it forms a red colored band, indicating that the test results are valid.

The color intensity of the red T line is proportional to the Anti-CCP concentration in the specimen, which is assessed after comparison with the reference card provided with the kit.

The result is reported in four concentration intervals: less than 25RU/mL, between 25 and 100RU/mL, between 100 and 400RU/mL, and more than 400RU/mL.

COMPONENTS

Name	Quantity	Mark
Test cassettes	40 set	packed in 40 foil pouches
Sample diluent	6mL×1bottle	
Colorimetric card	40pcs	
User manual	1pcs	

Materials required but not provided: Pipette and equipment for collection of samples; Tubes, tips, etc.

SPECIMEN COLLECTION AND STORAGE

1. Use plasma or serum sample. Separate plasma or serum within 24 hours after blood collection and samples may be stored refrigerated (2-8°C) for as long as one week or at -20°C or below for longer time.
2. Do not freeze and thaw sample more than once.
3. Highly lipemic and haemolysed samples are not suitable for this assay and should not be used.

STORAGE AND STABILITY

The unopened kit should be stored under 4-30℃ and under this condition the kit can be used until the expiry date labeled on the kit which normally lasts for 18 months from date of manufacture.

The sample dilute can be stored at 4-30℃ for 30 days after opening.

PRECAUTIONS AND SAFETY

This test is for *In Vitro Use Only* IVD

FOR PROFESSIONAL USE ONLY

- All the waste and sample should be treated in case of transmitting disease and must be properly disinfected (autoclaving is preferred) before disposal.
- Allow the test cassette to reach room temperature (about 15-30 minutes) before opening the pouch.
- Once taking the cassette out of the pouch, carry out your testing as early as possible (no more than 30 minutes) to avoid moisture. The nitrocellulose membrane can absorb water, which can affect the test chromatography performance.
- Add too much or not enough sample on the cassette could affect the test results.
- Make sure that the cassette is placed on flat surface during the testing.
- Result should be read immediately after 15 minutes of incubation; Result got after 30 minutes is invalid. Do not read the results in dim light.
- Make sure that the test is within the indicated validity.
- Do not use materials past expiration date.
- If automatic pipette is used, calibrate it frequently to assure the accuracy of dispensing. Use different disposal pipette tips for each specimen in order to avoid cross-contaminations.
- Do not modify the test procedure.
- Do not reuse the test cassettes.
- Invalid result should be repeated test.
- Blood that has been chemically treated, heated, diluted, or otherwise modified may give inaccurate results.
- Test cassette should be used within 30 minutes after taken out from the airtight protective package.
- Test result should be interpreted considering all other laboratory results and clinical situation of the patient.

PROCEDURE

1. Equilibrate the test cassette, sample diluent and sample to room temperature (20-25℃).
2. Rip off the aluminium foil packaging and place the test cassette on an even lab platform.
3. Write sample ID on the plastic case of the test cassette.

4. Add 10μL sample immediately followed by addition of 2 drops (or 80μL using a pipette) of sample diluent to the sample cavity of the test cassette.
5. Incubate for 15 minutes at room temperature.
6. Read result and assess the value interval by comparing the color intensity of the T line with the colorimetric card.

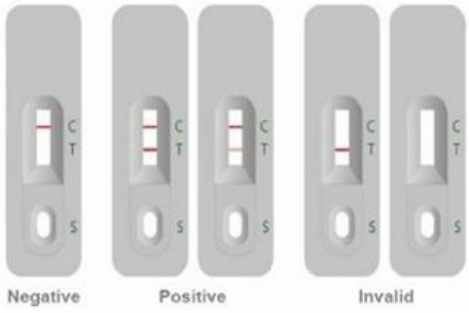
INTERPRETATION OF RESULTS

Quality Control: One red band will always appear in the Control Zone (C) indicating the validity of the test. If no red control band appears, the test is invalid - discard the test and repeat with new sample and new strip.

Positive Results: One red band in the Test Zone (T) indicates that Anti-CCP has been detected with this test, comparing with colorimetric card in order to define Anti-CCP concentration range.

Negative Results: Comparing with colorimetric card, the T color lighter than 25 color is negative results within 15 minutes in the test. However, this does not exclude the possibility from rheumatoid arthritis.

The positive result obtained with this test alone cannot be the final diagnosis of rheumatoid arthritis. Any positive results must be interpreted in conjunction with the patient clinical history and another laboratory testing results. Follow-up and supplementary testing of any positive samples with other analytical system (e.g. ELISA or PCR) is required to confirm any positive results.



INTERPRATATION OF TESTING RESULT

Reference range: <25RU/mL

Note: The reference range may vary depending on different group of people and different clinical situations. Therefore these ranges are given for reference only. Each laboratory should establish its own reference values.

Note: Test should be regarded as invalid if purplish color does not appear at C line after 15 minutes of incubation and the sample should be assayed again.

PERFORMANCE CHARACTERISTICS

1. Limit of detection: 25RU/mL
2. Specificity: Cross-reactivity evaluation result: sample containing 95 RU/mL RF was tested with the results no more than 25RU/mL.

LIMITATIONS

1. This test is semi-quantitative and can only give the concentration interval rather than exact concentration of Anti-CCP in the specimen.
2. A negative test result of Anti-CCP can not rule out rheumatoid arthritis disease completely.
3. Test result is used for reference only and diagnosis should be made in consideration of other clinical findings.
4. Result should be read immediately after 15 minutes of incubation; Result got after 30 minutes is invalid.

REFERENCES

[1] A.J.W. Zendman, W.J.van Venrooij, G.J.M. Pruijn. Use and signific ance of anti-CCP auto antibodies in rheumatoidarthritis.Rheurnatology,20 06,45:20-25.

[2].Huang Yi, Gao Fei, Yang Xiaodong. Correlation between level of anti-cyclic citrullinated peptide antibody and joint erosion severity of rheumatoid arthritis patients. Journal of Fujian Medical University. 2006,40(2):175-176.

[3]Aletaha D, et al. Rheumatoid arthritis classification criteria:An American College of Rheumatology/European League Against Rheumatism collaborative initiative. Arthritis & Rheumatism 62 (9):2569-2581, 2010.

[4]Pruijn GJ, Wiik A, van Venrooij WJ. The use of citrullinated peptides and proteins for the diagnosis of rheumatoid arthritis. Arthritis Res Ther 12 (1):203, 2010.

[5]Snir O, Widhe M, Hermansson M, von Spee C, Lindberg J, Hensen S, Lundberg K, Engstrom A, Venables PJ, Toes RE, Holmdahl R, Klareskog L, Malmstrom V. Antibodies to several citrullinated antigens are enriched in the joints of rheumatoid arthritis patients. Arthritis Rheum 62 (1):44-52,

[6]Moran RF, Peisheng Mo. Quality control in laboratory management and basic statistics. China Journal of Medical Diagnostics. 1996,19:49-51.

	Use By	LOT	Batch
	Content Sufficient For <n> Tests		Instructions
	Temperature limitation	REF	Catalog Number
	Manufacturer		Do not reuse
CE	CE Marking – IVDD 98/79/EC	EC REP	Authorized representative in the European Community

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