Anti- cyclic citrullinated peptide （Anti- CCP） Assay Kit

Method: Latex Immunoturbidimetric Method

Cat.NO.	Package Size
GS8691M GK8691M	R1: 1×45 ml R2: 1×15 ml
GB8690M GM8691M	R1: 1×45 ml R2: 1×15 ml
GH8691M	R1: 1×45 ml R2: 1×15 ml
GT8691M	R1: 1×45 ml R2: 1×15 ml
GX8691M	R1: 1×45 ml R2: 1×15 ml
GD8691M	R1: 12×3.8 ml R2: 6×2.6 ml

This assay kits apply to biochemistry analyzers: Hitachi7180/7080/7060/7020,AU400/5800/DXC 800, Bayer1800, Dimension RXL Max, TBA40FR,etc. It is recommended that each laboratory should verify the results accordingly before testing.

INTENDED USE

For quantitative determination of Anti- cyclic citrullinated peptide（Anti- CCP） in human blood.

CLINICAL SIGNIFICANCE

Cyclic citrullinated peptide(CCP) antibodies are autoantibodies produced by rheumatoid arthritis (RA) patient that are directed against cyclic citrullinated peptides (CCP). It is an important indicator of early diagnosis RA. The CCP antibody test helps to diagnose early RA: CCP antibodies can be detected as early as several years before the typical clinical symptoms. The sensitivity and specificity of CCP is superior to RF. CCP antibody testing, along with RF, could improve the detection rate of RA.In recent years, the bone destruction of positive patients is more serious than negative patients according to the study. Additionally, high concentrations should suggest poor prognosis and high risk of joint erosion. Thus, it is an reliable indicator of observing patients condition and using of drugs.

ASSAY PRINCIPLE

Agglutination is formed when CCP antibody is reacted with latex particles coated with hypersensitized CCP antigen. The rate of formation is proportional to the concentration of Anti-CCP in the samples and is measured colorimetrically as in increase in absorbance at 546 nm.

REAGENTCOMPOSITON

Contents	Concentration of Solutions
Reagent 1	
Phosphate/NaCl Buffer	0.1 mol/L
Reagent 2	
Latex particles coated with hypersensitized CCP antigen	0.12%

SAMPLE COLLECTION AND PREPARATION

Fresh Serum.
Fasting blood should be taken to centrifuge. Then, pipette the serum for the assay.
Severe lipemia, jaundice, hemolysis, and contaminated samples should be avoid.

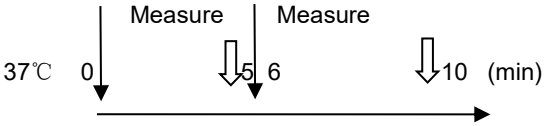
STABILITY AND PREPARATION OF REAGENTS

1. The reagents and controls should be stored at 2-8° C. Do not freeze. The reagents are stable when stored as instructed until the expiration date on the label.
2. Please prevent cross-contamination if opened. The on-board stability is 28 days.

ASSAY PROCEDURE

Test Procedure for Analyzers (Hitachi)
Assay Mode: Two Point End 16-34
Wave length (sub/main): 800/546nm

Sample:5 µl
R1: 150µl R2: 50 µl



CALIBRATION

G-cell CCP Calibrator (GC-CCP) is recommended.

CALCULATION OF RESULTS

$$\text{Concentration} = \frac{\Delta A_{sample}\ /\text{min}}{\Delta A_{calibrator}\ /\text{min}} \times \text{Calibrator value}$$

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QUALITY CONTROL

Gcell CCP Control (GQ-CCP) is recommended as daily quality control sample. Please confirm the values should be within a specific range. If not, Please check:

1. The instrument settings and light source;
2. Reaction temperature;
3. Expiration date of kit and contents.

REFERENCE RANGE

Normal value: 0- 35 U/ mL

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

PERFORMANCE CHARACTERISTICS

PRECISION

The coefficient of variation (CV) for both Intra assay precision and Inter assay precision is below 10%

Intra assay precision		
N=10	Sample 1	Sample 2
Mean(U/L)	19.52	60.55
SD	1.21	1.46
CV(%)	6.1%	2.3%

Inter assay precision			
N=10	Batch 1	Batch 2	Batch 3
Mean(U/L)	21.16	19.94	20.62
$\bar{x}$ (U/L)	20.57		
CV(%)=(Xmax-Xmin)/$\bar{x}$	7.8%		

LINEARITY

Linearity is 5 ～ 100 U/mL. Samples that exceeded the linearity limit (100 U/mL) should be diluted with an equal volume of water. Multiply the result by two.

CORRELATION

Tested the blood samples with Gcell Anti-CCP assay kit (X) and a well-known brand kit (Y) at the same time. The correlation formula is $Y=0.9876X- 5.045$, $R^2 = 0.9803$

INTERFERENCE

The following analytes are tested and not to interfere:

Bilirubin: up to 50 mg/dL

Ascorbic acid: up to 50 mg/dL

Hemoglobin: up to 200 mg/dL

SENSITIVITY

For analytical sensitivity, the absorbance change (△ **A)** should be between 0.1500 ～ 0.4000 under the concentration of 100U/ml.

SAFETY PRECAUTIONS AND WARNINGS

1.For in vitro diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

2.Reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.

3.Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide from building up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

4.Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.

5.Reagents with different lot numbers should not be interchanged or mixed.

REFERENCES

1. MILNE, Ken. Assay method for antibodies against cyclic citrullinated peptide: WO 2009/103988 A1.2009-02-20.

2.Xu Miaogen. The value and application of Anti-CCP antibody in patients with rheumatoid arthritis. J of Radioimmunology 2013，26(6):756-758

3.The meaning of Anti-CCP antibody in patients with rheumatoid arthritis. Chinese Journal of Clinical Laboratory Science, 2004, Vol 22, No.213

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INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by (Expiration date)
IVD	For In-Vitro Diagnostic use only
	Stored at 2-8℃
	Attention: See instruction for use
EC REP	Authorized Representative in the European Company

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