ACCUCARE® Anti-CCP Turbilatex Kit is intended to Quantitative determination of Anti-cyclic citrullinated peptide Antibody (Anti-CCP) in human serum or plasma. Only for In Vitro Diagnostic use

ORDER INFORMATION

REF	Cont.
TCP 20	1 X 20 mL
TCP 40	1 X 40 mL

CLINICAL SIGNIFICANCE

Anti-CCP is a polypeptide segment of cyclic filaggrin, an antibody that is primarily IgG type. It has very high sensitivity and specificity to rheumatoid arthritis (RA). Those RA patients with Anti-CCP positive have more serious bone destruction than Anti-CCP negative persons. RA is a common chronic autoimmune disease.

Method

Latex Enhanced Immunoturbidimetric Method

PRINCIPLE

Anti-CCP in human serum react with latex particle cross-linked cyclic citrullinated peptide and generates insoluble immune complex, thus to change the absorbance of reaction liquid. When antigen quantity is fixed, the absorbance change is positively correlated to the content of Anti-CCP.

REAGENT

Reagent I : PBS Buffer Solution, PEG, Surfactant
Reagent II : Latex particles coated with citrulline peptides BSA PBS buffer Stabilizer

REAGENT PREPARATION

The Reagent is ready to use.

REAGENT STORAGE AND STABILITY

- Unopened reagent: stable for 18 months at 2～8℃, protect from light.

WARNING AND PRECAUTIONS

- Avoid skin and eye contact. Avoid ingestion. If in contact with skin, wash with copious amount of water.
- Avoid mixing used and unused reagents, or the stability will decline.
- Read the instructions carefully and operate strictly according to the instructions.
- When disposing reagents, dilute with copious amount of water
- See specifications for constant value and amount of different batches of calibrator.

WASTE MANAGEMENT

Please refer to local legal requirements.

SAMPLE COLLECTION AND PRESERVATION

- Type of specimen: fresh human serum or plasma without hemolysis
- Collection of specimen: collect veinous blood 3ml placed in a test tube, seal and send for assay in time.
- Interference of specimen: absorbance can be interfered by lipoidemia and hemoysis; re-collect the sample in the above situation.

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 - 28ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	546 nm
Reaction Temperature	37°C
Reaction Type	Fixed time
Reaction Direction	Increasing
Read Time	5 Sec
Cuvette	1 cm light path
Measurement	Against Distilled water
Sample Volume	10 µl
Reagent Volume1	300 µl
Reagent Volume2	100 µl
Blank Absorbance	≤1.6
Incubation	5 minutes
Delay Time	10 Second
Read Time	300 Second
Linearity	10-180 U/ml

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	REAGENT BLANK	CALIBRATOR	SAMPLE
REAGENT I	300 µl	300 µl	300 µl
Cali.(C0,C1,C2, C3,C4,C5,C6)	-	10 µl	-
SAMPLE	-	-	10 µl
Mix well and incubate for 5 mins at 37°C & Immediately Add			
REAGENT II	100 µl	100 µl	100 µl
Mix well, and read the absorbance immediately A1 and after 5 minutes A2 of the sample addition.			

LINEARITY

Linearity Range: 10-180 IU/ml

REFERENCE VALUES

Serum / Plasma	≤17 IU/ml

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- When the concentration of the samples ≥1000 IU/ml, more than the detection limit, it should be diluted by saline for many times.
- Only when using this kit, the matching calibration product is used in the applicable inspection system.
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INTERFERENCE

- The linearity of this kit depends on the ratio of samples and reagents, reducing the amount of specimens can increase linearity, but decrease the reagent sensitivity. Excessive samples size will affect the standard curve.
- The first material should be performed 40 seconds after the addition of R2, and the second material is performed 300 seconds after the addition of R2.
- When used for diagnostics and therapeutic purposes, the results of this test should always be combined with history, symptoms and other clinical outcomes for patients explained.

BIBLIOGRAPHY

1. Mori, Others: Testing and Technology, 16,641-644 (1988)
2. ERCNNA, THE IMMUNOTURBIDIMETRIC MEASUREMENT OF IMMUNOGLOBULIN G, Clin, CHEM1990, 71 (3): 1410-1458
3. Guiding Principles for the Compilation of National Practice Rules for Clinical Laboratory (Third Edition) and Instructions for Diagnostic Reagents.

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

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