ANTI CCP

(Latex ImmunoturbidimetricMethod)

Intended Use

Anti CCP is intended for in-vitro quantitative detection of present Anti-cyclic ciitrulline peptide antibody (Anti CCP) in human serum samples.

Principle

The Kit adopts the principle of latex enhanced turbidimetric immunoassay, the latex particles coated with cyclocitrulline peptide is used to react with snit-cyclic citrulline peptide antibody in sample to form insoluble immune complex and to give turbidity to the reaction solution. The turbidity of the reaction can reflect the concentration of anti-cyclic citrulline peptide antibody in the sample, and the concentration determined optically by.

Reagent provided

1. R1 – Anti CCP Buffer
2. R2 – Anti CCP Antibody
3. Calibrator

Reagent storage and stability

Reagent and Calibrator are stable till the expiry date stated on the container label.

Specimen collection and preservation

The sample is Serum Samples. Exclusion of contaminated samples and samples of severe hemolysis, lipid and jaundice.

Assay guidelines for Analyzers

Reaction type	Fixed Time- Non linear (Multi standard)
Reaction slope	Increasing
Flow cell Temperature	37°C
Wavelength	578 (546 - 600 nm)
Blank	Distilled water
Delay Time	30 sec.
Read Time	120 sec.
Sample volume	20 µl
Reagent volume	300 µl (R1) + 100 µl (R2)
Calibrator. concentration	As on vial
Factor calculation	-
Linearity	Up to 270U/ml

Assay guidelines for Manual procedure (Multi Point Calibration with 4 Level Calibrator).

Reagents	Calibrator (C)	Test (T)
Anti CCP R1	300 µl	300 µl
Calibrator	20 µl	-
Serum / Plasma	-	20 µl
Anti CCP R2	100 µl	100 µl

1. Read absorbance A1 after 30 seconds (Delay)
2. Read absorbance A2 after 120 seconds (Measuring)

KEE DIAGNOSTICS

.

Calculation

Anti CCP Concentration) = $\frac{\Delta A(T) \times \text{Calibrator Concentration}}{\Delta A(C)}$

Normal Range

Negative	**:** Below 32 U/mL
Weak Positive	**:** 32 – 35 U/mL
Positive	**:** 35 – 75 U/mL
Strong Positive	: Above 75 U/mL

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitation

- The Kit is for in vitro diagnostic use only. Not for use in humans or animals.
- The instructions must be followed to obtain accurate results.
- Do not use the reagents beyond the expiration date.
- Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.

Quality Control

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls.

References

1. Fabiny DL: et al: ClinChem 1971, 17:696.
2. Vasiliades J: et al: ClinChem 1976, 22:1664

Symbols

IVD	In Vitro Diagnostics.		Caution.		Keep away from sun light.		Date of Manufacture.
LOT	Batch No.		Read Instructions.		Fragile.		Product Expiry Date.
CONT	Content.		Storage Temperature.		Keep Dry.		Manufactured By.
REF	Catalogue No.						

KEE DIAGNOSTICS PVT LTD
CIN: U24231DL2004PTC128343 .
A subsidiary of KEE PHARMA LTD
A-8 . 3RD FLOOR. NARAINA INDUSTRIAL AREA, PHASE 2.
NEW DELHI-110028.
W. www.keediagnostics.com
E. info@keediagnostics.com, T. 011 43136000.

KEE DIAGNOSTICS

ISO 9001 : 2015 & ISO 13485 : 2016 Certified Company