TURBICHEM ANTI CCP

(Turbidimetry Method)

KIT NAME	KIT SIZE	CAT. NO
Turbichem - ANTI CCP	1 x 40 ml	TACP01040M

GENUINE BIOSYSTEM

INTRODUCTION

The Anti CCP assay is intended for invitro quantitative detection of present Anti-cyclic citrulline peptide antibody (Anti CCP) in human serum samples.

METHOD PRINCIPLE

The kit adopts the principle of latex enhanced turbidimetric immunoassay, the latex particles coated with cyclocitrulline peptide is used to react with anti-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

KIT CONTENTS

R1 - Anti CCP Buffer	1 x 30 ml
R2 - Anti CCP antibody	1 x 10 ml
R3 - Calibrator	1 vial

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 10 days on board the analyser at 2-10°C. Protect from light and avoid contamination.

WORKING REAGENT PREPARATION AND STABILITY

Assay can be performed with use of separate R1-Anti CCP and R2-Anti CCP reagents of 3 parts of R1-Anti CCP with 1 part of R2-Anti CCP. Avoid foaming.

CONCENTRATIONS IN THE TEST

R1 - Tris buffer solution.
R2 - Latex suspension, Anti CCP antibody

WARNINGS AND NOTES

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

ADDITIONAL EQUIPMENT

- Automatic analyzer or photometer able to read at 570 nm
- Thermostat at 37ºC
- General laboratory equipment

SPECIMEN

The sample is Serum Samples.

Exclusion of contaminated samples and samples of severe hemolysis, lipid and jaundice.

PLOTTING OF MULTIPOINT CURVE

The Turbichem Anti CCP is based on Non-Linear Reactions, hence it is strongly recommended to run Multi-standard mode to plot the Multi-point curve to have better accuracy and precise result.

Serial Dilution Step

	1st	2nd	3rd	4th	5th
Calibrator	100 µl	50 µl from 1st Tube	50 µl from 2nd Tube	50 µl from 3rd Tube	50 µl from 4th Tube
Normal Saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dillution	Neat	1/2	1/4	1/8	1/16

PROCEDURE

These reagents may be used both for manual assay Sample Start and in several automatic analyzers. Applications for them are available on request.

Wavelength 570 nm
Temperature 37°C
Cuvette 1 cm

Pipette into the cuvette:

Reagent	Calibrator (C)	Test (T)
R1 Anti CCP Buffer	150 µl	150 µl
Calibrator	5 µl	
Sample	-	5 µl
Bring up to the temperature of determination. Then add		
R2 - Anti CCP Anitbody	150 µl	150 µl

Mix well, after about 10 sec. (37°C) read the absorbance A1 of the test (T) and calibrator (C) against air or water. After exactly 180 secs. (for all temperature) read the absorbance A2 of the test (T) and calibrator (C). Calculate ΔA/min. (A2 - A1) for the test and calibrator.

CALCULATION

Anti CCP concentration = ΔA (T) / ΔA(C) x calibrator concentration

REFERENCE VALUES

<35 U/mL

It is recommended for each laboratory to establish its own reference ranges for local population.

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

PERFORMANCE CHARACTERISTICS

- **Linearity :** 5~200 U/mL
- **Precision :** Within Run: CV≤60%;
- **Ability:** hemogloin<3.0g/L, bilirubin <342umol/L, triglycerides <11.3mmol/L, RF <500 IU/ml.

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1. Adam S.S., Key N.S., Greenbery C.S. D-dimer antigen: current concepts and future prospects. Blood 113 (13): 2878-87.
2. Gaffney, P.J. Distinction between Fibrinogen and Fibrin Degradation Products in Plasma. Clin. Chem. Acta. 65 (1): 109-115; 1975.
3. Rylatt, D.B., et al. An Immunoassay for Human D-DImer using Monoclonal Antibodies. Thromb. Res. 31(6): 767-778; 1986.
4. Smith, R.T.,e.tal.Fibrin Degradation Products in the Postoperative Period. Evaluation of a New Latex Agglutination Method. Am. J. Clin. Pathol. 60(5): 644-647; 1973

SYSTEM PARAMETERS

Method	End Point)
Wavelength	570 nm
Zero Setting	Distilled Water
Temperature Setting	37° C
Incubation Temperature	37° C
Incubation Time	----
Delay Time	10 secs
Read Time	180 secs
No. of Reading	2
Interval Time	----
Sample Volume	5 ul
Reagent Volume	200ul
Standard Concentration	Refer Calibrator Vial
Units	mg/L
Factor	----
Reaction Slope	Increasing
Linearity	5 ~ 200 U/mL

IVD CE

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