Ana-Chek® CRP - LATEX

METHOD – IMMUNO AGGLUTINATION
PRODUCT CODE – LX02

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for determination of C-Reactive Protein (CRP) by Immuno Agglutination method.

CLINICAL SIGNIFICANCE

CRP is an acute-phase protein present in normal serum, which increases significantly after most forms of tissue injuries, bacterial and virus infections, inflammation and malignant neoplasia. During tissue necrosis and inflammation resulting from microbial infections, the CRP concentration can rise up to 300 mg/L in 12-24 hours.

PRINCIPLE

The Ana-Chek® CRP-Latex is a slide agglutination test for the qualitative and semi-quantitative detection of C – Reactive Proteins (CRP) in human serum. Latex particles coated with goat IgG anti-human CRP are agglutinated when mixed with samples containing CRP.

REAGENTS

Latex Reagent	- Latex particles coated with goat IgG anti-human CRP, pH 8.2. Sodium Azide 0.95 g/L.
Positive Control	- Human serum with an CRP conc. >20 mg/L. Sodium Azide 0.95 g/L.
Negative Control	- Protein based with Sodium Azide 1 gm/L.

MATERIALS REQUIRED BUT NOT PROVIDED

Sample Dropper or Micropipette with tips, Stopwatch, Mechanical Rotator of 80-100 r.p.m.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Contamination of the reagent should be avoided.

STORAGE AND STABILITY

All the kit components are ready to use, and will remain stable until the expiration date printed on the label, when stored at 2-8 ^{0}C and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.

Reagent deterioration: Presence of particles and turbidity.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Plasma (using sodium fluoride) is preferred as sample. Sodium fluoride acts as anti-glycolytic agent as well as anticoagulant. Glucose is stable for 24 hours at 2 – 8 ^{0}C and 30 days at -10 ^{0}C in neatly separated plasma or serum.

PROCEDURE

QUALITATIVE METHOD

1. Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 40 µl of the sample and one drop of Positive and Negative controls each into separate circles on the slide.
3. Swirl the CRP-latex reagent gently before using and add one drop (40 µl) next to the sample to be tested.
4. Mix the drop with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

SEMI-QUANTITATIVE METHOD

1. Make serial two-fold dilution of the sample in 9 g/L saline solution.
2. Proceed for each dilution as in the qualitative method.

READING AND INTERPRETATION

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator. The presence of agglutination indicates on CRP concentration equal or greater than 8 IU/mL. The titre, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS

The approximate CRP concentration in the patient sample is calculated as follows:

6 x CRP Titre = mg/L.

REFERENCE VALUES

Up to 6 mg/L.

Each laboratory should establish its own reference range.

PERFROMANCE CHARACTERISTICS

1. Analytical sensitivity: 6 (5-10) mg/L, under the described assay conditions.
2. Prozone effect: Not detected up to 1600 mg/L.

INTERFERENCES

Haemoglobin (10 g/L), Bilirubin (20 mg/dL) and Lipemia (10 g/L) do not interfere. Rheumatoid Factors (100 IU/mL) interfere. Other substances may interfere.

LIMITATIONS OF PROCEDURE

The incidence of false-positive results is about 3-5 %. Individuals suffering from infectious mononucleosis, hepatitis, syphilis as well as elderly people may give positive result.

NOTES

High CRP concentration samples may give negative results (prozone effect). Retest the sample again using a drop of 20 µl volume. The strength of agglutination is not indicative of CRP concentration in the sample tested.

BIBLIOGRAPHY

1. Lars-Olof Hanson *et. al.* Current opinion in infectious diseases1997; 10: 196-201
2. M.M. Pepys. The Lancet 1981; March 21: 653-656.
3. Chetana Vaishnavi. Immunology and Infectious Diseases 1996; 6: 139-144.
4. Yoshitsugy Hokama *et. al.* journal of Clinical Laboratory Status 1987; 1: 15-27.
5. Yamamoto S *et. al.* Veterinary Immunology and Immunopathy 1993; 36: 257-264.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE