Ana-Chek® ASO - LATEX

METHOD – IMMUNO AGGLUTINATION
PRODUCT CODE – LX01

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for determination of antibodies against Streptolysin "O" by Immuno Agglutination method.

CLINICAL SIGNIFICANCE

Streptolysin "O" is a toxic immunogenic exoenzyme produced by haemolytic Streptococci of groups A, C and G. Measuring the ASO antibodies are useful for the diagnostic of rheumatoid fever, acute glomerulonephritis and streptococcal infection. Rheumatic fever is an inflammatory disease affecting connective tissue from several parts of human body as skin, heart, joints etc. and acute glomerulonephritis is a renal infection that affects mainly to renal glomerulus.

PRINCIPLE

The Ana-Chek® ASO-Latex is a slide agglutination test for the qualitative and semi-quantitative detection of anti-streptolysin "O" (ASO) antibodies. Latex particles coated with streptolysin "O" are agglutinated when mixed with samples containing ASO.

REAGENTS

Latex Reagent	-	Latex particles coated with streptolysin O, pH 8.2. Sodium azide 0.95 g/L.
Positive Control	-	Human serum with an ASO conc. 200 IU/mL. 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

Fresh serum. Stable for 8 days at 2-8 ^{0}C or 3 months at -20 ^{0}C. Samples with presence of fibrin should be centrifuged. Do not use highly haemolysed or lipemic samples.

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 ASO-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 ASO concentration equal or greater than 200 IU/mL. The titre, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

CALCULATIONS

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

200 x ASO Titre = IU/mL.

REFERENCE VALUES

Up to 200 IU/mL (adults) and 100 IU/mL (children < 5 years old).

Each laboratory should establish its own reference range.

PERFROMANCE CHARACTERISTICS

1. Analytical sensitivity: 200 (±50) IU/mL, under the described assay conditions.
2. Prozone effect: Not detected up to 1500 IU/mL.
3. Diagnostic sensitivity: 98%.
4. Diagnostic sensitivity: 98%.

INTERFERENCES

Hemoglobin (10 g/L), bilirubin (20 mg/dL), lipemia (10 g/L) and rheumatoid factors (300 IU/mL) do not interfere. Other substances may interfere.

CALIBRATION

The Ana-Chek® ASO-latex sensitivity is calibrated against the ASO international calibrator (WHO).

LIMITATIONS OF PROCEDURE

False positive results may be obtained in conditions such as rheumatoid arthritis, scarlet fever, tonsilitis, several streptococcal infections and healthy carriers. Early infections and children from 6 months to 2 years may cause false negative results.

BIBLIOGRAPHY

1. Haffejee. Quarterly Journal of Medicine 1992. New series 84; 305: 641-658.
2. Ahmed Samir et al. Pediatric Annals 1992; 21: 835-842.
3. Spaun J et al. Bull Wld Hlth Org 1961; 24: 271-279.
4. The association of Clinical Pathologists 1961, Broadsheet 34.
5. Picard B et al. La Presse Medicale 1983; 23: 2-6.
6. Klein GC, Applied Microbiology 1971; 21: 999-1001.

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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GMP
CE