TOXO VISILATEX – SLIDE ASSAY

CAT NO	DESCRIPTION	PACK SIZE
LATTOX2	TOXO VISILATEX (Latex Reagent, Positive and Negative Controls, Pipettes, Stirrers and Reusable Slides)	50 T
LATTOX3	TOXO VISILATEX (Latex Reagent, Positive and Negative Controls, Pipettes, Stirrers and Reusable Slides)	100 T

Intended Use:

Toxo Visilatex is a slide agglutination test for the qualitative and semi-quantitative detection of anti-toxoplasma antibodies. This reagent is for In vitro diagnostic use by professionals only.

Summary and Principle:

Toxoplasmosis is an infectious disease affecting both animals and humans, caused by the protozoan parasite toxoplasma gondii. Acquired toxoplasmosis is usually asymptomatic and benign. Adults depending on the geographical area and age would have antibodies in more than 50% of the cases, being protected to a new infection. In its congenital form the infection causes mental retardation, ocular disease and death in new born. Infection in pregnant women acquires a special significance as the parasite may enter the foetal circulation through the placenta and causes congenital toxoplasmosis especially during the first trimester of pregnancy. The consequences can be spontaneous abortion and prematurity with visceral and neurological symptoms in the foetus.

A suspension of latex particles coated with antigenic extract of Toxoplasma gondii is added to a test sample. The presence or absence of visible particle agglutination indicates the presence or absence of anti-toxoplasma antibodies in the samples tested.

Reagent Composition:

Toxo Visilatex Reagent	**Polystyrene Latex particles coated with antigenic extract of T. gondii in a buffered saline solution. pH 7.5**
	Sodium Azide 0.95 g/l
Positive Control	**Serum Base with anti-Toxoplasma antibody concentration > 4 IU/ml. Contains Sodium Azide 0.95 g/l**
Negative Control	**Serum base without anti-Toxoplasma antibody concentration. Contains Sodium Azide 0.95 g/l**

Warnings and Precautions:

- The reagent contains sodium azide. Do not allow contact with skin or mucous membranes.
- Components of different human origin have been tested and found to be negative for the presence of antibodies to HIV 1+2 and HCV as well as for HBsAg. However, controls should be handled as potentially infectious. Wear suitable protective gloves.

Reagent Preparation and Stability:

Unopened reagents are stable up to expiry when stored at 2 - 8ºC.

Once opened the reagents are stable up to expiry when stored tightly capped and stored at 2 - 8ºC. Do not freeze. Mix thoroughly before use.

Specimen Collection:

Collect clear serum by standard venepuncture technique. Samples that cannot be tested immediately can be stored up to 2 days at 2 - 8ºC or stored up to 3 months at -20ºC.

Procedure:

Qualitative Assay:

1. Ensure that the reagents and the samples are at room temperature before starting the test.
2. Mix the Latex reagent by gentle inversion of the reagent vial several times.
3. Place 1 drop of serum (50 µl) in one of the circles on the card. On separate additional circles place 50 µl of Positive Control and Negative Control.
4. Add 25 µl of Toxo Visilatex reagent to each circle next to the sample to be tested.
5. Mix the contents of each circle with a disposable stirrer while spreading over the entire area enclosed by the ring. Use separate stirrers for each mixture.
6. Rotate the slide by means of a mechanical rotor (80-100 rpm) for a period of 4 minutes.
7. Observe immediately under a suitable light source for any degree of agglutination. Do not interpret results after 4 minutes

Semi-Quantitative Assay:

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

Interpretation:

Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.

The presence of agglutination indicates an anti-Toxoplasma antibody concentration equal to or greater than 4 IU/ml.

The titer, in the semi-quantitative method, is defined as the highest dilution showing a positive result.

Calculations:

The approximate anti-Toxoplasma concentration in the patient sample is calculated as follows:

4 x Titer = IU/ml

Quality Controls:

Positive and Negative Controls are recommended to monitor the performance of the assay, as well as providing comparison wells for a better results interpretation.

All reaction mixture appearances different from the Negative Control circle, should be considered as a positive result.

Reference values:

Up to 4 IU/ml.

Each laboratory should establish its own reference range.

Performance Characteristics:

Analytical sensitivity: 4 (3-7) IU/ml, under the described assay conditions.

Prozone effect: Not observed up to 1000 IU/ml. Occasionally a prozone effect may be observed with strong positive sera. Therefore, where a suspected case of toxoplasmosis gives a negative result, the test should be repeated using 1/5 serum dilution in NaCl 9 g/l.

Diagnostic sensitivity: 100%

Diagnostic specificity: 84.2%

Interferences:

Haemoglobin (10 g/l), bilirubin (20 mg/dl), lipemia (10g/l), and rheumatoid factor (1000 IU/mL) do not interfere. Other substances may interfere.

Limitations:

-False positive results may be obtained with hepatocellular diseases. Approximately 25% of sera containing heterophile antibodies may give false positive results.

-All positive sera should be tested with a confirmatory test.

-Clinical diagnosis should not be made on findings of this single test result but should integrate both clinical and laboratory data available.

References:

1. Jacobs L, ADV Parasitol. 11:631-669 (1973).
2. Feldman HA Hosp Practice 4:64-72 (1969)
3. Ruoss CR et al. The Journal of Obstetrics and Gynecology of the British Commonwealth, 79: 1115-1118 (1972)
4. Lunde MN et al. The Journal of Parasitology. 53 (5): 933-936 (1967).
5. Kwantes W a al. Journal of Clinical Pathology 25: 359 (1772)
6. Young DS. Effects of Drugs on clinical laboratory tests, 4th ed AACC Press (1995)

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		

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