

TOXO LATEX KIT

REF: 729 001 100 test
REF: 729 002 200 test

INTENDED USE

For qualitative and semi-quantitative detection of *Toxoplasma gondii* antibodies in serum

BACKGROUND

Toxoplasma gondii is a specific protozoa in the genus *Toxoplasma*. Toxoplasmosis, the disease of which *T.gondii* is the causative agent, is usually minor and self-limiting. The disease may also have serious effects on a fetus whose mother first contracts the disease during pregnancy.

PRINCIPLE

Toxo latex consists of an aqueous suspension of polystyrene particles coated with soluble purified antigens from *Toxoplasma gondii*. If specific antibodies are present in the sample a clear visible agglutination will appear

MATERIALS PROVIDED

Spectrum TOXO latex kit contains the following components :

- **Toxo Latex Reagent :**
Latex particles coated with soluble *T.gondii* antigen, pH,7.5 sodium azide 0.95 g/dL.
- **Toxo Positive Control.**
- **Toxo Negative Control.**
- **Test slide.**
- **20 G dispensing needle (20 µl/drop)**

STORAGE & STABILITY

The reagents are stable up to the expiration date specified when stored at 2 – 8 °C.

PRECAUTIONS AND WARNINGS

All human blood components used to prepare controls have been tested for Hepatitis B surface antigen (HBsAg) and HTLV-III antibodies by FDA approved procedure and found to be non-reactive. No known test method for HBsAg or HTLV-III antibodies offers total assurance that a human derived product will not transmit hepatitis or HTLV-III virus. The user is therefore cautioned to handle reagents as if being capable of transmitting these diseases.

SPECIMEN COLLECTION AND PRESERVATION











Use only fresh serum specimens , plasma samples are not suitable for the test. Serum samples can be stored for 24 hrs at 2 – 8 °C, for longer Storage it is recommended to store the samples at -20 °C Haemolysis should be avoided.

PROCEDURES

A) Qualitative

1. Bring reagents to room temperature.
2. Dispense 40µl of sample onto a single circle on the test slide.
3. Repeat step 2 for the positive and negative controls.
4. Spread the sample of each test specimen over the entire test circle.

SYMBOLS IN PRODUCT LABELLING

	Authorised Representative		Use by/Expiration Date
	For in-vitro diagnostic use		CAUTION. Consult instructions for use
	Batch Code/Lot number		Manufactured by
	Catalogue Number		(Xi) - Irritant
	Consult instructions for use		Temperature Limitation

5. Shake the Toxo Latex reagent well.
6. With the needle suck up reagent sufficient to the testing requirements.
7. Dispense one free-fall drop (20 µl) of the Latex reagent on each test circle containing specimen.
8. Mix well and rotate slide slowly.
9. After 4-6 minutes check for agglutination .

B) Semi-Quantitative Test

1. Make serial two fold dilutions of the sample in normal saline solution.
2. Proceed for each dilution as in the qualitative method.

Results and Interpretation

Negative result:

No agglutination of the latex particles suspension within 4-6 minutes.

Positive result:

An agglutination of the latex particles suspension will occur within 4-6 minutes, indicating an antibody concentration equal or more than 4 IU/mL.

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

TOXOPLASMA Ab CONCENTRATION

Approximate anti-*Toxoplasma* concentration in the patient sample is calculated as follows: $4 \times \text{anti-Toxo Titer} = \text{IU/mL}$

Performance Characteristics

All the performance characteristics are found in the corresponding Technical Report and available on request

SENSITIVITY

The Sensitivity of the Kit is 4 IU/mL (3-6 IU/mL) under the recommended assay condition.

REFERENCE VALUE

Up to The 4 IU/mL

REFERENCE

1. Young DS Effects of drugs on clinical laboratory test 4th ed. AACC Press,1995.
2. Jacobs L.ADV Parasitol 1973;11;631-669
3. Ruoss CF at al .The Journal of Obsterics and Gynecology of the British Commonwealth 1972 ;79:1115-1118

ORDERING INFORMATION

CATALOG NO	QUANTITY
729 001	100 test
729 002	200 test