SPECTRUM

The Creative Approach To Bioscience

TOXO LATEX KIT

A rapid latex agglutination test for qualitative and semi- quantitative detection of Toxoplasma gondii antibodies in serum

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

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Temperature Limitation
IVD	For in-vitro diagnostic use		Use by/Expiration Date
LOT	Batch Code/Lot number		CAUTION. Consult instructions for use
REF	Catalogue Number		
	Consult instructions for use		Manufactured by

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 an-tibodies 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.
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 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: 4xanti-Toxo Titer= IU/mL

SENSITIVITY

The Sensitivity of the Kit is 4 IU/mL (3-6 IU/mL) under the recomended asay 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

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CE ISO 13485

IFUFIB07 Rev.(1), 20/10/2011

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