TOXO LATEX

REF. 360 03 002 100 test

IVD

Intended use

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

Introduction

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

Reagents and Materials provided

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.
• Test slide.
• 20 G dispensing needle (20 µl/drop)

Warnings and Precautions

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.

Reagents Preparation and storage

The reagents are stable up to the expiration date specified when stored at 2 – 8 °C.Once opened, the opened vial is stable for 6 months at the specified temperature.

Specimen collection and preparation

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.

Procedure

A) Qualitative
1. Bring reagents to room temperature.
2. Dispense 40 µl 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 (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: 4xanti-Toxo Titer= IU/Ml

Sensitivity

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

Expected Value

Up to 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

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use
LOT	Batch code/Lot number
REF	Catalogue Number
	Consult instruction for use
	Temperature Limitation
	Used by/Expiration day
	CAUTION .Consult instruction for use
	Manufactured by

Spectrum For Diagnostic Industries - Free Zone
Ismailia Free Zone, Block 5 .
Cairo- Port said Avenue.
Tel: +2 064 3488 013 - +2 064 3488 014 Fax: +2 064 3488 015
www.sdi-fz.com