TOXOPLASMA (Slide Latex Test)

Diagnostic reagent set (Slide latex tests) for the in-vitro qualitative screening and semi-quantitative determination of anti-toxoplasma antibodies present in infected human serum manually.

REF:V/TO01.025	25 tests	REF: V/TO01.050	50 tests
REF: V/TO01.100	100 tests		

CLINICAL SIGNIFICANCE

Toxoplasmosis is an infectious disease caused by the parasite Toxoplasma Gondii and affects both animals and humans. In humans this infection is usually acquired by ingesting inadequately cooked meat or from feces of infected cats. Approximately 25-50% of the adult population is asymptomatically affected with Toxoplasmosis. Acquired Toxoplasmosis is usually asymptomatic and benign. In pregnant women however, the infection acquires a special significance as the parasite may enter the fetal circulation through placenta and cause congenital Toxoplasmosis. The consequences of congenital Toxoplasmosis range from spontaneous abortion and prematurity to generalized and neurological symptoms. Some infants with congenital Toxoplasmosis may also remain asymptomatic at birth and develop the disease during childhood or adolescence.

METHOD PRINCIPLE

Lab.Vie.Toxo-Latex Test is a rapid slide agglutination procedure, developed for the direct detection of antibodies anti-Toxoplasma in human serum.
The assay is performed by testing a suspension of latex particles coated with antigenic extract of Toxoplasma gondii against unknown samples. The presence or absence of a visible agglutination indicates the presence or absence of anti-Toxoplasma antibodies in the sample tested.

REAGENT COMPOSITION

Reagents:	Composition
Latex Reagent	Latex particles coated with soluble T.gondii antigen, pH 7.5, sodium azide 0.95 g/dl.
Positive Control	Stabilized serum pool containing T.gondii antibodies.
Negative Control	Animal serum negative for T.gondii antigen. Contains 0.95 g/L of sodium azide.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person.
Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the **Lab.Vie**. Toxoplasma reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

Lab.Vie.Toxoplasma reagent is ready-to-use and is stable until expiration date stated on label when properly stored in an upright position and refrigerated at 2-8°C (do not freeze).

Deterioration

The **Lab.Vie**. Toxoplasma reagent can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of the reagent be verified with the positive controls.

SPECIMEN COLLECTION AND PRESERVATION

Fresh serum. Stable 7 days at 2-8°C or 3 months at -20°C. Samples with presence of fibrin should be centrifuged.
Do not used highly hemolized or lipemic samples.

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes
- Centrifuge
- Stop watch
- Variable Micropipettes

ASSAY PROCEDURE

Allow the reagents and samples to reach room temperature. The sensitivity of the test may be reduced at low temperatures. Shake and mix antigens well before dispensing

Qualitative procedure

1. Identify each reaction circle of the slide test to make one positive control, one negative control and the desired number of samples respectively.
2. Place 40 µl of positive control, 40 µl of negative control and 40 µl of patient's serum to be tested onto each reaction circles.
3. Add 20 µl of latex reagent to the reaction circles containing positive controls, negative control and patient's serum.
4. Mix contents of each circle uniformly over the entire circle with separate mixing sticks.
5. Rock the slide gently back and forth, and observe for agglutination macroscopically at 4 minutes.

Semi-quantitative method

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.

Note: This method is recommended for obtaining quick approximate titers only.

READING AND INTERPRETATION

Qualitative procedure	
Positive	Agglutination indicates an antibody concentration more than 4 IU/ml
Negative	No agglutination as indication for the level in the patient's serum less than 4 IU/ml
Semi-Quantitative procedure	
Titer	Is defined as the highest dilution showing a positive result.

The approximate anti-Toxoplasma concentration in the patient sample is calculated as follows: 4 x highest dilution of the serum showing agglutination.

QUALITY CONTROL

The positive controls have been included with the test kit to monitor the performance of the reagent. Good physiological saline may be used as a negative control, if the expected results have not been observed, the reagent should not be used. For more information please contact **Lab.Vie**. technical support.

PERFORMANCE CHARACTERISTICS

Precision (reproducibility and repeatability): Precision of toxoplasma suspensions is 100% (+/- one double dilution).
Analytical sensitivity: 4(3-7) IU/ml
Prozone effect: No prozone effect was detected up to 200 IU/ml
Diagnostic sensitivity: 96 %.
Diagnostic specificity: 89 %.

LIMITATIONS OF PROCEDURE

1. Patients with hepatocellular diseases may result give false positive results.
2. A 25% of serum containing heterofile antibodies may give false positive results.
3. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

EXPECTED VALUES

Up to 4 IU/ml
Each laboratory should establish its own reference range.

REFERENCES

1. Young D.S. Effects of Drugs on Clinical Laboratory Tests, 4th ed. AACC Press (1995).
2. Feldman HA. Hosp. Practice. 4: 64 (1969).
3. Lunde MN at al. The Journal of Parasitology. 53 (5):933 (1967).
4. Desmonts G. and Couvreur J., Toxoplasmosis in Pregnancy and its transmission to the fetus, Bull. N.Y. Acad. Med., 1974:50: 146-159.
5. Ruoss C.F. and Bourne G.L., Toxoplasmosis in Pregnancy, J. Obstet. Gynecol., 1972:79:1115- 1118.

SYMBOLS IN PRODUCT LABELLING			
IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number	⚠	Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		