TOXOPLASMA LATEX

In Vitro **diagnostic (IVD)**

Latex agglutination slide test for the qualitative and semi-quantitative determination of specific antibodies in the serum of Toxoplasmic patients

I. INTRODUCTION AND INTENDED USE

Toxoplasmosis is an infectious disease affecting both animals and humans, which is caused by the protozoan parasite *Toxoplasma gondii,* obligate intracellular parasite common among mammals and birds. Toxoplasma gondii usually lives in the intestinal tract of the cat, who gets infected by eating the flesh of small rodents. The cat is the animal reservoir for the reproduction of the protozoan, as in his intestines Toxoplasma carries out its cycle of sexual reproduction. The oocysts pass in the feces of cats and can be ingested by another animal or rarely man, who thus represent its intermediate host. Acquired toxoplasmosis is usually asymptomatic and benign. Adults, depending on the geographical area and age, would contain antibodies in more that 50% of cases, being protected to a new infection. In its congenital form may be devastating, causing mental retardation, ocular disease, and death in newborn. In adults, the parasite may be responsible for some forms of eye disease; individuals with impaired immunologic competence are also at serious risk. Infection in pregnant women acquires a special significance as the parasite may enter the fetal circulation through the placenta and causes congenital toxoplasmosis especially during the first trimester of pregnancy. The consequences range from spontaneous abortion, early delivery or fetal death.

II. PRINCIPLE OF THE TEST

The Toxoplasma latex is a slide agglutination test for the qualitative and semi-quantitative detection of anti-toxoplasma antibodies. Latex particles coated with soluble *Toxoplasma gondii* antigen are agglutinated when mixed with samples containing antibodies anti-Toxoplasma.

III. REAGENTS AND MATERIALS

Each kit contains:

1. Toxoplasma latex. Suspension of polystyrene particles coated with soluble purified antigens from Toxoplasma gondii.
2. Positive Control. **C**ontrol ready for use, containing antibodies anti-Toxoplasma at concentration > 4 IU/ml.
3. Negative Control. Control ready for use, not reactive with the latex reagent.
4. Instruction for use.

REQUIRED MATERIALS (NOT SUPPLIED)

Mechanical rotator with adjustable speed at 80-100 r.p.m.
Timer

IV. SPECIAL PRECAUTIONS

- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices.
- Wear gloves when handling the samples.
- Never use reagents from another lot.
- Discard the reagents if its are contaminated with bacteria or mould.
- The reagents' quality cannot be guaranteed beyond their shelf-life date or if the reagents are stored under inappropriate conditions.

V. STORAGE

Store at refrigerated temperature (2-8ºC). The test is stable through the expiration date printed on the packaging label. The kit must not be frozen.

VI. SAMPLE STABILITY

Serum sample: 7 days at 2-8 ºC, 3 months at –20ºC.

VII. PROCEDURES AND INTERPRETATION OF RESULT

Allow the serum samples and reagents to reach to room temperature (15-30ºC) prior to testing and mix latex reagent gently before use..

Qualitative test:

Distribute in the different areas on the slide:	Sample	Positive control	Negative control
Sample	50 µl	---	---
Positive control	---	1 drop	---
Negative control	---	---	1 drop
Latex	25 µl	25 µl	25 µl
Mix with the sticks and spread the fluid over the entire area of the cell. Til the slide back and forth slowly for **4 minutes**. Observe under artificial light.			

Agglutination indicates a Toxoplasma antibodies content higher than 10 IU/ml. Sera with positive results in the qualitative test should be retested with semiquantitative test.

Semi-quantitative test:
Prepare dilutions of the sample with saline buffer as indicated in the following table:

Dilutions	---	1:2	1:4	1:8	1:16	1:32
Serum Toxoplasma IU/ml	10	20	40	80	160	320

Follow the methods of qualitative test.
The titre is given by the last dilution with visible agglutination.
If positive results are obtained through dilution 1:32, prepare further two-fold serial dilution in saline and retest.

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VIII. DIAGNSTIC MEANING

Negative reaction: it should be interpreted as absence of specific anti-Toxoplasma antibodies; in case of pregnant women, the presence of IgM should be investigated; it is advisable to repeat the test with another sample of serum 2 or 3 weeks later, to observe the possible evolution of antibody titre and a possible seroconversion.

Positive reaction at 1:4 to 1:8 dilutions: it should be interpreted as absence of residual antibodies; in case of pregnant women, the presence of IgM should be investigated; it is advisable to repeat the test with another sample of serum 2 or 3 weeks later, to observe the possible evolution of titre.

Positive reaction at 1:8 to 1:32 dilutions: it should be interpreted as suspect of incipient Toxoplasmosis; investigate the presence of IgM; repeat the test with another sample of serum 2 or 3 weeks later, to observe the possible evolution of antibody titre; an increase of at least two dilutions regarding the sample, should be considered indicative of acute Toxoplasmosis.

Positive reaction of titre 1:32 or more: it should be interpreted as suspect of an evolutive acute Toxoplasmosis; investigate the presence of IgM and confirm with a second sample 2 or 3 weeks later.

IX. PERFORMANCES

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

Prozone effect: Up to 200 IU/mL. Occasionally a prozone effect may be observed with strong positive sera. Therefore in these cases 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: 96.1%

Diagnostic specificity: 89.6%

X. NOTES

Results obtained on sample have to be always compared with results obtained on control.

The positive control shows the agglutination within 4 min.

The negative control may shows a light granulation without any agglutination within 4 min.

Lipemic or contamined sera may cause false positive results.

The latex reagent and the control sera contain sodium azide as preservative. Do not swallow. Avoid contact with skin and mucous membranes.

All reagents of human source have been tested for HBsAg and HIV antibody and found to be negative. However the material should still be regarded as potentially hazardous.

If the test area of the slide is hydrorepellent clean it with alcohol.

As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

The components of this I.v.D. are tested always each other without verify the compatibility with components produced by others manufacturers. Is not excluded that these components can be used with components of same chemical composition but produced by others manufacturers, but there is not an experimental evidence of this compatibility.

The kit must be used by clinical test trained personnel only.

XII. BIBLIOGRAPHY

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2. Feldman HA. Hosp. Practice 1969; 4: 64-72.
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4. Lunde MN at al. The Journal of Parasitology 1967; 53 (5): 933-936.
5. Kwantes W at al. Journal of Clinical Pathology 1772; 25: 359.
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CONTENT

	UB80900 (62 test)	UB80910 (125 test)	UD80911 (controls)
Latex (black cap)	1 x 1.6 ml	1 x 3.2 ml	
Positive Control (red dropper)	1 x 0.5 ml		1 x 0.5 ml
Negative Control (green dropper)	1 x 0.5 ml		1 x 0.5 ml
Slide with 6 test areas	4 items		
Sticks	3 items		

IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (DXXX)		Fabbricante
	Consult Instructions for Use		Use By (year/month)	REF	Catalogue number		Do not reuse
	Keep dry		Fragile, handle with care	NON STERILE	Non-sterile		Keep away from heat

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