

Lomina Toxoplasmosis IgG/IgM Antibody Test

Instructions for use (IFU)

[PACKING DESCRIPTION]

Variants	1 pc in package - box/ pouch	2 pcs in package - box	25 pcs in package - box	50 pcs in package - box
REF	La-TOXO-Pro/1B or 1P	La-TOXO-Pro /2B	La-TOXO-Pro /25B	La-TOXO-Pro /50B
IVD test strip in plastic cassette [pcs]	1	2	25	50
Sterile Lancet [pcs]	1	2	25	50
Stabilization fluid - buffer [pcs]	1	2	25	50
15 µl dropper [pcs]	1	2	25	50
Disinfecting pad [pcs]	1	2	25	50
IFU [pcs]	1	1	1	1

[INTRODUCTION]

T. gondii is an obligate intracellular protozoan with a worldwide distribution. According to serological data, approximately 30% of the population of most industrialized countries is chronically infected with this organism. A number of serological tests for antibodies to *T. gondii* are used to aid in the diagnosis of acute infection and to assess previous exposure to the organism. These tests include the Sabin-Feldman staining test, direct agglutination, indirect haemagglutination, latex agglutination, indirect immunofluorescence and ELISA. More recently, lateral flow chromatographic immunoassays such as the Lomina Toxoplasmosis IgG/IgM Antibody Test have been introduced into clinical practice for the serodiagnosis of *T. gondii* infection.

[INTENDED USE]





The Lomina Toxoplasmosis IgG/IgM Antibody Test is a lateral flow chromatographic test for the simultaneous detection and differentiation of IgM anti-Toxoplasma Gondii (*T. gondii*) and IgG anti-*T. gondii* in human whole blood, serum or plasma. This kit is intended for use as a screening test and as an aid in the diagnosis of *T. gondii* infection. Any reactive sample with the Lomina Toxoplasmosis IgG/IgM Antibody Test must be confirmed by alternative test method(s) and clinical findings.

[TEST PRINCIPLE]

The Lomina Toxoplasmosis IgG/IgM Antibody Test is a lateral flow chromatographic test. The test consists of: 1) a red coloured

conjugate containing recombinant *T. gondii* antigens conjugated to colloidal gold (*T. gondii* conjugates) and conjugates of mouse IgG and gold, 2) a nitrocellulose membrane strip containing two test lines (IgG and IgM lines) and a control line (C line). The IgM line is pre-coated with monoclonal anti-human IgM for the detection of anti-*T. gondii* IgM, the IgG strip is pre-coated with reagents for the detection of anti-*T. gondii* IgG and the C line is pre-coated with goat anti-mouse IgG. After applying an adequate volume of test sample to the test pad, the sample migrates through the strip via capillary action. IgM anti-*T. gondii*, if present in the sample, binds to *T. gondii* conjugates. The immunocomplex is then captured on the membrane by a pre-coated anti-human IgM antibody and forms a red coloured IgM line, indicating a positive test result for *T. gondii* IgM. IgG anti-*T. gondii*, if present in the sample, binds to *T. gondii* conjugates. The immunocomplex is then captured by pre-coated reagents on the membrane and forms a red coloured IgG line, indicating a positive test result for *T. gondii* IgG. Absence of T line in the test area indicates a negative result. The test contains an internal control (control area C) which should show a red coloured line of the goat anti-mouse IgG/mouse IgG-gold conjugate immunocomplex, regardless of the development of the colour of either of the IgG or IgM lines. Otherwise, the test result is invalid and the sample must be retested with a different instrument.

[PACKAGE CONTENTS]

- IVD test strip in plastic cassette
- Desiccant
- Lancet for disposable blood sample collection (HTL-Stréfa S.A. ; Type Actilance  nebo wellion MED TRUST ; Type 23G double protection )
- Stabilization fluid (buffer)
- 15 µl dropper
- Disinfecting pad (alcohol-based disinfection)
- Instructions for use

[NOT INCLUDED IN THE PACKAGE]

Stopwatch/clock for measuring the duration of the test.

[ATTENTION!]

- Please read all information in this package insert before performing the test.
- The Lomina Toxoplasmosis IgG/IgM Antibody Test is intended for in vitro diagnostic use by healthcare professionals and should only be used for the qualitative detection and differentiation of the presence of IgM anti-Toxoplasma Gondii (*T. gondii*) and IgG anti-*T. gondii* in a sample.
- Do not eat, drink or smoke in the area where samples or kits are handled.
- Strictly adhere to the specified time for evaluation of results.
- Do not disassemble or touch the test window of the test cassette.
- Do not freeze or use the kit after the expiration date on the package.
- Keep out of reach of children.
- Used test should be disposed of in accordance with local regulations.
- Do not mix different lots (LOT) of tests and reagents!

[STORAGE CONDITIONS]

- The package is stored at a temperature of 2 °C to 30 °C.
- The contents of the kit are stable until the expiry date marked on the packaging, with a shelf life of 18 months (based on stability studies).
- Prolonged exposure to heat and moisture renders the reagent unusable.

[SAMPLE PREPARATION AND COLLECTION]

- The Lomina Toxoplasmosis IgG/IgM Antibody Test can be performed using whole blood.
- Both finger prick and venous puncture whole blood can be used.
- Collection of finger prick whole blood samples:**
- Wash the patient's hands with soap and warm water or clean them with an alcohol swab. Allow them to dry.
- Massage the hand without touching the puncture site by rubbing the hand down to the tip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe off the first signs of blood.
- Gently rub your hand from the wrist across the palm to the finger to create a round drop of blood at the injection site.
- Warm the specimens to room temperature before testing. Frozen specimens must be completely thawed and mixed well before testing. Blood specimens should not be frozen and thawed more than three times repeatedly.
- If specimens are to be transported, they should be packaged in accordance with federal regulations for transporting etiologic agents.
- EDTA K2, sodium heparin, sodium citrate, and potassium oxalate may be used as anticoagulant tubes for blood sampling.

[APPLICATION PROCEDURE]

Allow the assay, sample and buffer to reach room temperature (15-30°C) before testing.

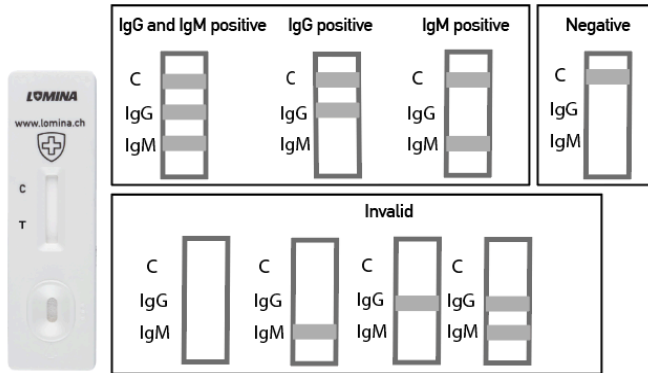
- Warm the bag to room temperature before opening. Remove the test cassette from the sealed bag and use it as soon as possible.
- Place the cassette on a clean, flat surface. For the serum or plasma sample:
 - Hold the dropper in an upright position and transfer 2 drops of serum or plasma (approximately 20 µl) into the sample slot (S) of the test cassette, then add 2 drops of stabilization fluid (buffer) (approximately 80 µl) into the reagent-buffer slot (B) and start the timer.
 - Wait for the coloured line to appear. Evaluate the results after 15 minutes. Do not evaluate the result after 20 minutes.

Note: It is recommended not to use the buffer more than 6 months after opening the vial.



[INTERPRETATION OF TEST RESULTS]

After applying the sample, start the stopwatch, wait 15 minutes without moving the cassette and then read the result. The result is interpreted by the presence of a visible line in the „IgG“ or „IgM“ area on the body of the test cassette (see figure below), the results of the visual inspection are as follows:



IgG POSITIVE:*Two coloured lines appear. One coloured line should always appear in the control area (C) and the other in the IgG test area.

IgM POSITIVE:* Two coloured lines appear. One coloured line should always appear in the control area (C) and the other in the IgM test area.

IgG and IgM POSITIVE:* Three coloured lines will appear. One colored line should always appear in the control area (C) and two lines should appear in the IgG and IgM test areas.

***NOTE:** The intensity of the color in the test line areas may vary depending on the concentration of Lyme antibodies present in the sample. Therefore, any shade of colour in the test line area should be considered positive.

NEGATIVE: A single coloured line appears in the control area (C). No line will appear in the IgG or IgM area.

INVALID: No line will appear in the control area (C). The most likely cause of control line failure is insufficient sample volume or incorrect procedure. Check the procedure and repeat the test with a new test. If the problem persists, stop using the test kit immediately and contact your local distributor.

[LIMITATION OF INSPECTION METHODS]

- When testing for the presence of antibodies to *T. gondii* in whole blood, serum or plasma of individual subjects, the test procedure and interpretation of results must be followed precisely. Failure to follow the procedure may lead to inaccurate results.
- The Lomina Toxoplasmosis IgG/IgM Antibody Test is limited to the qualitative detection of antibodies to *T. gondii* in human whole blood, serum or plasma. The intensity of the test strip does not correlate linearly with the antibody titre of the sample.
- A negative result in an individual subject indicates the absence of detectable antibodies to *T. gondii*. However, a negative test

result does not exclude the possibility of exposure to or infection with *T. gondii*.

- A negative result may occur if the amount of *T. gondii* antibodies present in the sample is below the detection limits of the test or if the detected antibodies are not present at the stage of disease at which the sample was collected.
- Some samples containing unusually high titres of heterophile antibodies or rheumatoid factor may affect the expected results.
- Results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.
- The haematocrit of whole blood should be between 25 % and 65 %.

[PERFORMANCE CHARACTERISTICS]

Performance characteristics for antibody IgM

Method	T.Gondii ELISA (IgM)		Total
	Results		
Lomina Toxoplasmosis IgG/IgM Antibody Test	Positive	47	52
	Negative	3	398
Total		50	450

Sensitivity: 94.0% (95%CI: 83.5%-98.=%)

Specificity: 98.8% (95%CI*: 97.1%-99.6%)

Accuracy: 98.2% (95%CI: 96.5%-99.2%)

Performance characteristics for antibody IgG

Method	T.Gondii ELISA (IgG)		Total
	Results		
Lomina Toxoplasmosis IgG/IgM Antibody Test	Positive	48	54
	Negative	2	396
Total		50	450

Sensitivity: 96.0% (95%CI*: 86.3%-99.5%)

Specificity: 98.5% (95%CI*: 96.8%-99.4%)

Accuracy: 98.2% (95%CI*: 96.5%-99.2%)

[CROSS-REACTIVITY]

Lomina Toxoplasmosis IgG/IgM Antibody Test was tested for HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-HAV IgM, anti-HCV IgG, anti-HIV IgG, anti-RF IgG, anti-Syphilis IgG, anti-H. Pylori IgG, anti-Rubella IgG, anti-Rubella IgM, anti-CMV IgG, anti-CMV IgM, anti-HSV 1 IgG, anti-HSV 1 IgM, anti-HSV 2 IgG and anti-HSV 2 IgM positive samples. The results showed no cross-reactivity.

[INTERFERENCE FACTORS]

The following compounds were also tested using the Lomina Toxoplasmosis IgG/IgM Antibody Test (whole blood/serum/plasma) test and no interference was observed: Acetaminophen: 20mg/

dL, Acetylsalicylic Acid: 20mg/dL, Ascorbic Acid: 2g/dL, Bilirubin: 1000mg/dL, EDTA: 20mg/dL, Glucose: 20mg/dL, Caffeine: 20mg/dL, Gentisic Acid: 20mg/dL, Phenylpropanolamine: 20mg/dL, Salicylic Acid: 20mg/dL, Ethanol: 10%, Phenothiazine: 20mg/dL.

[ANALYTICAL ACCURACY]

Within batch (Intra-Assay): the analytical precision within a batch was determined using 10 replicates for three samples: negative, weak positive and strong positive. Negative, weakly positive and strongly positive values were correctly identified > 99% of the time.

Between batches (Intra-Assay): Inter-batch accuracy was determined by 10 replicates in 3 different batches on the same three samples: negative, weakly positive and strongly positive. Samples were correctly identified > 99% of the time.

⚠ [CAUTION!]

- A negative test result can occur if the antibody level in the sample is below the detection limit of the test.
- False negative results can occur if the sample is improperly collected, transported or handled - in other words, if these instructions for use are not followed.
- If samples are tested later than 1 hour after collection, false results may occur. (Samples should be tested as soon as possible after collection).
- Insert the test sample into the test cassette very slowly and observe the exact amount of sample and reagents!
- The reaction time of the test is 15 minutes. When the reaction is complete, do not read the result later than 20 minutes. In other words, the result is invalid 20 minutes after the test solution has been loaded.
- The intensity of the colour or the thickness of the positive line cannot be considered „quantitative or semi-quantitative“.

[SYMBOL INDEX]

	Consult instructions for use		Caution		Use by date
	In vitro diagnostic medical device		Do not use if package is damaged		Do not re-use/Intended for one use
	Manufacturer		Batch code		Catalogue number
	Keep away from sunlight		Contains sufficient for <n> tests		Temperature limit 2-30 °C
	Keep dry		Sterilised by radiation		

MANUFACTURER:
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REF

La-TOX0-Pro

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