LOMINA
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Lomina Tetanus Test

[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-TET-Pro /1P or 1B	La-TET--Pro/2B	La-TET--Pro/25B	La-TET-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]

Clostridium tetani is the bacterium that causes tetanus in humans. Clostridium tetani is gram-positive, spore-forming rods that are anaerobic. If they enter the body through a wound, they can multiply and produce a toxin that attacks nerves and affects muscle function. Clostridium tetani toxin binds to the membranes of peripheral nerve cells and inhibits the release of neurotransmitters. Antibodies to tetanus toxin are produced in humans by vaccination with chemically inactivated tetanus toxin (tetanus toxoid). Vaccination is the best way to prevent C. tetani infection in children and adults. In addition, injection of specific and purified anti-tetanus toxin IgG is used to prevent exposure to the toxin during acute infection. Sometimes it is better to know the patient's level of antibodies to tetanus toxin, to assess his or her immune status to determine the need for additional vaccination to provide immunity to tetanus toxin. In emergency situations, it is important for the clinician to know the immune status to make decisions about appropriate anti-tetanus prophylaxis in patients who are at risk of death from Clostridium tetani infection.

[INTENDED USE]

The Lomina Tetanus Test is a rapid chromatographic immunoassay for the qualitative detection of tetanus toxin antibodies in whole blood, serum or plasma to aid in the diagnosis of tetanus toxin infection.

[TEST PRINCIPLE]

The Lomina Tetanus Test is a qualitative membrane immunoassay for the detection of antibodies to tetanus toxin in whole blood, serum or plasma. In this test procedure, anti-human IgG is applied to the test area. During testing, the sample reacts with particles coated with tetanus antigen in the test strip. The mixture of blood/serum/plasma and reagent migrates across the membrane where an immunochemical reaction occurs during capillary migration and reacts with the anti-human IgG antibody in the test area. If the sample contains tetanus antibodies, a coloured line appears in the test area. If the sample does not contain tetanus antibodies, no coloured line appears in the test area, indicating a negative result. As a check on the procedure, a coloured line always appears in the control area to indicate that the correct volume of sample has been added and the membrane has been activated.

[PACKAGE CONTENTS]

1. IVD test strip in plastic cassette
2. Desiccant
3. Lancet for disposable blood sample collection (HTL-Strefa S.A. CE0344; Type Actilance STERILE R nebo wellion MED TRUST CE0197; Type 23G double protection STERILE R)
4. Stabilization fluid (buffer)
5. 15 µl dropper
6. Disinfecting pad (alcohol-based disinfection)
7. 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.
- For professional use only.
- Do not eat, drink or smoke in areas where samples or kits are handled.
- Store in a dry place at 2-30 °C, avoiding areas with excessive humidity.
- If the foil packaging is damaged or has been opened, do not use it.
- This test kit is intended for preliminary testing only.
- Strictly observe the specified time for reading results.
- Use the test only once.
- Do not disassemble or touch the test window of the test cassette.
- Do not freeze or use the kit after the expiry date on the packaging.
- Keep out of the reach of children.
- The used test should be disposed of in accordance with local regulations.

[STORAGE CONDITIONS]

1. The package is stored at a temperature of 2 °C to 30 °C.
2. The ingredients of different batches must not be mixed.
3. The contents of the kit are stable until the expiry date marked on the packaging, the shelf life is set at 18 months (based on stability studies).
4. Prolonged exposure to heat and moisture renders the reagent unusable.

[SAMPLE PREPARATION AND COLLECTION]

The Lomina Tetanus Test can be performed from whole blood, serum or plasma.

Collection of whole blood samples from venepuncture:

- Collect anticoagulant blood sample (sodium or lithium heparin, potassium or sodium EDTA, sodium oxalate, sodium citrate) according to standard laboratory procedures.

Collection of serum/plasma samples:

- Collection of whole blood samples from venepuncture.
- Separate serum or plasma from blood as soon as possible to prevent haemolysis. Use only clear, unhemolyzed samples.

Serum and plasma samples can be stored at 2-8 °C for up to 3 days. For long-term storage, samples should be stored at temperatures below -20 °C. Whole blood collected by venepuncture should be stored at 2-8 °C if the test is to be performed within 2 days of collection. Do not freeze whole blood samples. Warm samples to room temperature before testing. Frozen samples should be thawed completely and mixed well before testing. Samples should not be repeatedly frozen and thawed. If specimens are to be transported, they should be packaged in accordance with local regulations for the transport of etiological agents.

[SAMPLE QUALITY REQUIREMENTS]

1. The sample should be treated with stabilization fluid (buffer) immediately after sample collection. It is recommended to detect immediately after sample collection.
2. Stabilization fluid (buffer) should not be opened until the sample has been applied.
3. Long-term storage of samples is not recommended.

[INSTRUCTIONS FOR USE]

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

1. Warm the bag to room temperature before opening. Remove the test cassette from the sealed bag and use it as soon as possible.
2. 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 25 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. See figure later in the instructions.

For venepuncture of a whole blood sample:

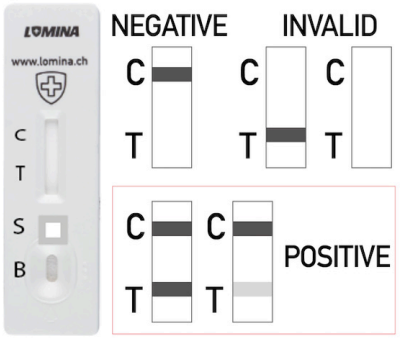
- Hold the dropper vertically and transfer 4 drops of whole blood (approximately 50 µl) into the sample slot (S), then add 2 drops of stabilization fluid (buffer) (approximately 80 µl) into the buffer slot (B) and start the timer. See figure below.

3. Wait for the colored stripe to appear. Read the results after 15 minutes. Do not evaluate the result after 20 minutes.

Note: It is recommended not to use the stabilization fluid (buffer) for more than 6 months after opening the bottle.

[INTERPRETATION OF RESULTS]

- After applying the sample, start the stopwatch, wait 15 minutes without moving the card and then read the result in the „T" section of the test card. The line may appear within a few seconds for strong infections, weaker infections will pull the line a little later.
- The result is interpreted by the presence of a visible line in the „T" area on the body of the test cassette (see figure below), the results of the visual inspection are as follows:



POSITIVE:* Two coloured lines appear. One color line should be in the control area (C) and the other color line should be in the test area (T).*NOTE: The intensity of the color in the test area (T) will vary depending on the concentration of tetanus antibodies present in the sample. Therefore, any shade of colour in the test area (T) should be considered positive.
NEGATIVE: A single colour line appears in the control area (C). No color line appears in the test area (T).
INVALID: No line appears in the control area (C). Insufficient sample volume or improper procedure is the most likely cause of control area failure. Check the procedure and repeat the test with a new cassette. If the problem persists, stop using the test set immediately and contact your local distributor.

[QUALITY CONTROL]

The test includes a procedural check. The colored bar that appears in the control area (C) is an internal procedural check. It confirms sufficient sample volume and correct procedural technique.

[LIMITATION OF INSPECTION METHODS]

1. The Lomina Tetanus Test is intended for in vitro diagnostic use by healthcare professionals only. The test should only be used to detect tetanus antibodies in whole blood, serum or plasma. Neither the quantitative value nor the rate of increase in tetanus antibody concentration can be determined by this qualitative test.
2. The Lomina Tetanus Test only indicates the presence of tetanus antibodies in the sample and should not be used as the sole criterion for the diagnosis of tetanus infection.
3. As with all diagnostic tests, all results must be interpreted in conjunction with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, further testing using other clinical methods is recommended. A negative result in no way excludes the possibility of tetanus infection.
5. The haematocrit of whole blood should be between 25% and 65%.

[SENSITIVITY/SPECIFICITY]

A total of 155 samples were tested using the Lomina Tetanus test (whole blood/serum/plasma) and a commercially available tetanus rapid test, both of which revealed 70 positive results and 85 negative results.

Method		Commercially available Tetanus rapid test		Total
Lomina Tetanus Test	Results	Positive	Negative	
	Positive	69	1	70
	Negative	1	84	85
Total		70	85	155

Sensitivity: 98.6% (95%CI: 92.3%-100%)
Specificity: 98.8% (95%CI*: 93.6%-100%)
Accuracy: 98.7% (95%CI*: 95.4%-99.8%)

[INTERFERENCE FACTORS]

The Lomina Tetanus Test was tested for possible interference with visibly hemolyzed and lipemic samples and serum samples containing high levels of bilirubin. In addition, no interference was observed with samples containing up to 1000 mg/dl haemoglobin; up to 1000 mg/dl bilirubin and up to 2000 mg/dl human serum albumin.

[CROSS-REACTIVITY]

No cross-reactivity was observed for the following substances: HIV, Hepatitis A virus IgG, Pertussis IgG, Treponema pallidum IgG, Mycoplasma pneumoniae IgG, Herpes simplex virus IgG, Diptheria toxoid IgG, Rubella virus, Hepatitis B virus, Varicella zoster virus IgG, EB virus IgG, Cytomegalovirus IgG, Toxoplasma gondii IgG, RF.

[CAUTION!]

- False negative results may occur if the sample is incorrectly 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).
- Do not mix different batches (LOTs) of tests and reagents!
- Read the instructions for use (IFU) carefully before testing and follow the procedures in the manual carefully.
- Apply the test sample to the test card very slowly and follow the exact amounts of sample and reagents indicated! The reaction time of the test is 15 minutes. After the reaction is complete, do not read the result later than 20 minutes. In other words, the result is invalid 20 minutes after loading the test solution.
- The Lomina Tetanus Test is intended for in vitro diagnostic use by healthcare professionals and should only be used for the qualitative detection of the presence of antibodies to tetanus toxin in a sample.
- The intensity of colour or the thickness of a positive streak cannot be considered „quantitative or semi-quantitative".

[SYMBOL INDEX]

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

MANUFACTURER:
LOMINA SUPERBIO a.s.
Na Radosti 184/59, Praha 5,
155 21, CZECH REPUBLIC
www.lomina.ch sales@lomina.ch

CE
REF La-TET-Pro

IVD 2°C 30°C

Date of last revision: 2022/07/14
Version: La-TET-Pro / EN-IFU-1.0