LOMINA
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Lomina Strep A 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-StrepA--Pro/1P or 1B	La-StrepA--Pro/2B	La-StrepA--Pro/25B	La-StrepA-Pro /50B
IVD test strip in plastic cassette [pcs]	1	2	25	50
Scrubbing swab [pcs]	1	2	25	50
Extraction reagent 1 [pcs]	1	2	25	50
Extraction reagent 2 [pcs]	1	2	25	50
Empty extraction tube [pcs]	1	2	25	50
Dropper 25 µl [pcs]	1	2	25	50
IFU [pcs]	1	1	1	1

[INTRODUCTION]
Streptococcus pyogenes is a Gram-positive coccus that contains Lancefield group A antigens that can cause serious infections such as pharyngitis, respiratory infections, impetigo, endocarditis, meningitis, puerperal sepsis and arthritis. Failure to treat these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess. Traditional procedures for identifying group A streptococcal infection include isolation and identification of viable organisms. The Lomina Strep A Test is a rapid test that qualitatively detects the presence of Strep A antigens in throat swab specimens and provides results within 5 minutes. The test uses antibodies specific for whole-cell Lancefield group A streptococci to selectively detect Strep A antigens in throat swab samples.

[INTENDED USE]
The Lomina Strep A Test is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigens from throat swab samples to aid in the diagnosis of group A streptococcal infection.

[TEST PRINCIPLE]
Lomina The Lomina Strep A Test is a qualitative membrane immunoassay for the detection of the carbohydrate antigen Strep A in throat swabs. The membrane is pre-coated with anti-StrepA antibody in the test area. During testing, the sample reacts with the anti-StrepA coated particle. The mixture of sample and reagents migrates across the membrane where an immunochemical reaction occurs during capillary migration and reacts with the anti-StrepA on the membrane to form a colored line. The presence of the coloured line in the test area indicates a positive result, while its absence indicates a negative result. As a check on the procedure, a colored line always appears in the control area, indicating that the correct volume of sample has been added and membrane activation has occurred.

[PACKAGE CONTENTS]
1. IVD test strip in plastic cassette
2. Scrubbing swab for sample collection CE 0197
3. Desiccant
4. Extraction reagent 1 - red (BUFFER 1)
5. Extraction reagent 2 - colourless (BUFFER 2)
6. Empty extraction tube
7. Dropper 25 µl
8. Instructions for use

[NOT INCLUDED IN THE PACKAGE]
- Stopwatch/clock for measuring the duration of the test

⚠ [ATTENTION !]
- Please read all information in this IFU before performing the test.
- The Lomina Strep A Test is intended for in vitro diagnostic use by healthcare professionals and should only be used for the qualitative detection of Strep A.
- Do not eat, drink or smoke in the area where samples or kits are handled.
- Strictly observe the specified time for evaluation of results.
- Do not disassemble or touch the test window of the test cassette.
- The kit must not be frozen or used after the expiry date stated 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, with a shelf life of 18 months (based on a stability study).
4. Prolonged exposure to heat and moisture renders the reagent unusable.

[SAMPLE PREPARATION AND COLLECTION]
1. Collect the sample using a swab from the throat with the sterile swab included in the kit. Transport swabs containing modified Stuart or Amies medium can also be used with this product. Swab the back of the pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.
2. Testing should be done immediately after sampling. Swab samples may be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8°C.
3. If culture is desired, lightly swirl the tip of the swab onto a Group A Selective Blood Agar (GAS) plate before using the swab in the Lomina Strep A test.

[SAMPLE QUALITY REQUIREMENTS]
1. **The sample should be treated with preservative solution (buffer) immediately after sample collection. It is recommended to detect immediately after sample collection.**
2. Reagent bottles should not be opened until the sample has been applied.
3. Long-term storage of samples is not recommended.

[*Swab manufacturer's details]
STERILE EO
Jiangsu Rongye Technology Co.,Ltd.
TouQiao Town, Yangzhou City, Jiangsu, China
MDD Annex V, Notified: TUV Rheinland LGA Products GmbH CE 0197, Certificate Nr: SX-60148419-001 and future revisions.

[SENSITIVITY/SPECIFICITY]

Method		GAS		Total
Lomina Strep A Test	Results	Positive	Negative	
	Positive	116	9	125
	Negative	6	395	401
Total		122	404	526

Sensitivity: 95.1% (95%CI: 89.6%-98.2%)
Specificity: 97.8% (95%CI: 95.8%-99%)
Accuracy: 97.2% (95%CI: 95.3%-98.4%)

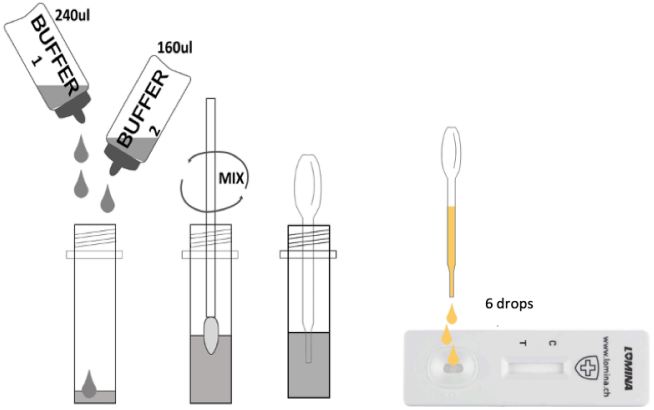
[ANALYTICAL ACCURACY]
Within batch (Intra-Assay): The analytical precision within a batch was determined using 10 replicates for three samples: negative, weak positive and strong positive. Negative, weakly positive and strongly positive values were correctly identified >99% of the time.
Inter-batch (Intra-Assay):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

[APPLICATION PROCEDURE]

Allow the test, reagents, swab sample and/or controls to reach room temperature (15-30 °C) before testing

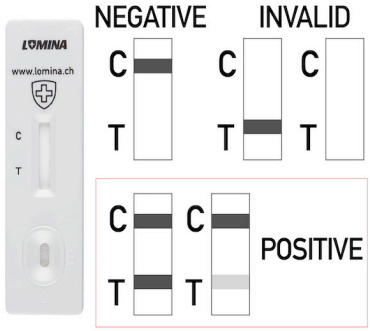
1. Remove the test cassette from the sealed foil bag and use it as soon as possible. For best results, perform the test immediately after opening the foil pouch.
2. Hold the bottle of extraction reagent 1 (BUFFER 1) upright and add 6 full drops (approximately 240 µl) of extraction reagent 1 to the empty attached extraction tube. Extraction Reagent 1 is red in colour. Hold the bottle of extraction reagent 2 (BUFFER B) upright and add 4 full drops (approximately 160 µl) of extraction reagent 2 to the same tube. Mix the solution by gently rotating the extraction tube. The addition of extraction reagent 2 to extraction reagent 1 changes the colour of the solution from red to yellow.
3. Immediately place the swab in the extraction tube, mix the swab vigorously 15 times and leave the swab in the extraction tube for 2 minutes.
4. While you are removing the swab, press the swab against the side of the tube so that most of the fluid remains in the tube. Discard the swab.
5. Prepare the dropper and place the test cassette on a clean, flat surface.
6. Add 6 full drops of the extracted solution (approximately 150 µl) to the sample port in the test cassette and start the timer. Avoid trapping air bubbles in the sample opening. Wait for the colour to appear. Read the result after 10 minutes; do not interpret the result after 20 minutes. See figure below.

- **Note: It is recommended not to use extraction reagents more than 30 days after opening the vial.**



[INTERPRETATION OF TEST RESULTS]

1. After applying the sample, start the stopwatch, wait 10 minutes without handling the cassette and then read the result in the „T" area of the test cassette. The line may appear within a few seconds for strong concentrations, weaker concentrations will pull the line out a little later.
2. The result is interpreted by the presence of a visible streak in the „T" area on the body of the test cassette (see figure), the results of the visual inspection are as follows:



POSITIVE:* Two coloured lines appear. One colour line should be in the control area (C) and the other colour line should be in the test area (T).*NOTE: The intensity of the colour in the test area (T) will vary depending on the concentration of present substance in the sample. Therefore, any shade of colour in the test area (T) should be considered positive.
NEGATIVE: A single coloured line appears in the control area (C). No coloured line appears in the test area (T).
INVALID: No line appears in the control area (C). The most likely cause of the control area failure is insufficient sample volume or an incorrect procedure. 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.

[LIMITATION OF INSPECTION METHODS]

1. The accuracy of the test depends on the quality of the swab sample. False negative results may be the result of improper sample collection or storage. A negative result may also be obtained from patients at the onset of disease due to low antigen concentration.
2. The test does not distinguish asymptomatic carriers of group A streptococcus from persons with infection. If clinical signs and symptoms do not match the results of the laboratory test, a control cell culture is recommended.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should be made by the physician after evaluation of all clinical and laboratory findings.

[INTERFERENCE FACTORS]

No interference with the following substances was found: Group B Streptococcus, Group F Streptococcus, Streptococcus pneumoniae, Streptococcus mutans, Staphylococcus aureus, Corynebacterium diphtheria, Candida albicans, Enterococcus faecalis, Neisseria meningitidis, Neisseria sicca, Branhamella catarrhalis, Group C Streptococcus, Group G Streptococcus, Streptococcus sanguis, Staphylococcus epidermidis, Serratia marcescens, Klebsiella pneumoniae, Bordetella pertussis, Neisseria gonorrhea, Neisseria subflava, Hemophilus influenza, Pseudomonas aeruginosa.

⚠ [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 (LOT) of tests and reagents!
- Apply the test sample to the test card very slowly and observe the exact amounts of sample and reagent!
- The reaction time of the test is 10 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
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 EO	Sterilised by ethylene oxide		

MANUFACTURER:
LOMINA SUPERBIO a.s.
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155 21, CZECH REPUBLIC
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CE

REF
La-StrepA-Pro

IVD 2°C 30°C

Date of last revision: 2022/07/15
Version: La-StrepA-Pro / EN-IFU-1.0