LOMINA
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IVD CE

Lomina Male Fertility 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-SPER-M-Pro/1P or 1B	La-SPER-M-Pro/2B	La-SPER-M-Pro /25B	La-SPER-M-Pro /50B
IVD test strip in plastic cassette [pcs]	1	2	25	50
Sperm transfer dropper [pcs]	1	2	25	50
Stabilization fluid [pcs]	1	2	25	50
IFU [pcs]	1	1	1	1

[INTRODUCTION]

The concentration of sperm or SP-10 protein is one of the main factors that doctors use to diagnose male infertility. There are many reasons why a man may be infertile and therefore unable to fertilize a woman's egg during reproduction. One of the main and most common reasons is abnormally low production of viable sperm. Other reasons may be excessive production of inactive, weak or deformed sperm cells, high amounts of other cells in the semen that prevent fertilization, or other physiological factors. Normal sperm cell production may also be disrupted by medical or physical conditions, including high stress, recent high fever or illness experienced within two months prior to testing, and sudden dietary changes. Performing this initial screening test will show if there is a low amount of sperm production. Up to 15% of couples experience infertility, which is defined as not becoming pregnant after one year of unprotected, well-timed intercourse. And for 40% of couples experiencing infertility problems, male infertility is the main cause. Because low sperm count is the leading cause of male infertility, an important first step in determining the cause of infertility is to test the sperm count.

[INTENDED USE]

The Lomina Male Fertility Test is an in vitro diagnostic test based on the principle of rapid chromatographic immunoassay, which is designed to qualitatively detect the acrosomal protein SP-10, found on sperm, to estimate sperm concentration in human semen above or below 15 million/ml. Sperm concentration can be used to assist in the diagnosis and observation of the therapeutic effect of male infertility and can provide guidance for reproductive planning.

[TEST PRINCIPLE]

The Lomina Male Fertility Test detects the acrosomal protein SP-10, which is found on sperm. SP-10 is a protein specific to male sex cells and is not found in other cells. This test is very specific for sperm and is now used to estimate the concentration of sperm in semen as an aid in determining the causes of infertility. The Lomina Male Fertility Test detects SP-10 and gives a positive result if the sperm concentration in the semen is greater than 15 million/ml - the level internationally recognised as the minimum sperm level for normal fertility. A low sperm concentration would mean less likelihood of conception It would be advisable to see a specialist doctor who can advise you on what can be done to improve sperm concentration.

[PACKAGE CONTENTS]

1. Testovací páska v plastové kazetě
2. Desiccant
3. Sperm transfer dropper 25µl
4. Stabilization fluid (buffer)
5. Instructions for use

[NOT INCLUDED IN THE PACKAGE]

- Stopwatch/clock for measuring the duration of the test.
- Sperm collection container.

[ATTENTION !]

- Please read the instructions for use carefully and completely before testing.
- ⚠ he Lomina Male Fertility Test is an in vitro diagnostic test intended for professional use by healthcare professionals and should only be used to qualitatively detect the presence of acrosomal protein SP-10 in a sample.
- This kit can only be used as an in vitro diagnostic test using human semen as a sample and cannot be used with samples of other body fluids.
- The sample should be collected within 3-7 days after the last ejaculation, semen obtained less than 3 days or more than 7 days will affect accuracy.
- Collection containers should be clean, dry, watertight and free of media, preservatives and cleaning agents.
- Semen liquefaction is the process by which semen rapidly changes from a jelly-like appearance to a liquefied state. Freshly collected samples are usually liquefied within 60 minutes, and failure to liquefy within 60 minutes indicates an abnormal result.
- Once the test cassette packaging has been opened, it should be used as soon as possible to avoid prolonged exposure to air, which could cause the test to malfunction.
- Strictly observe the specified time for evaluation of results.

[STORAGE CONDITIONS]

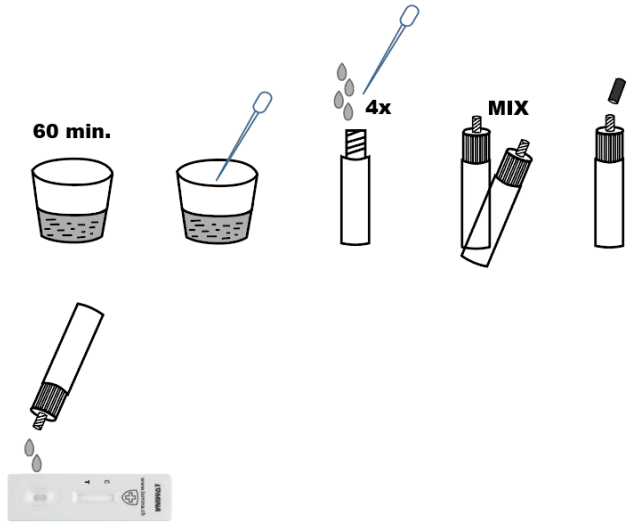
1. The package is stored at a temperature of 2 °C to 30 °C.
2. The ingredients of different batches must not be mixed.
3. The contents of the kit are stable until the expiry date marked on the packaging, with a shelf life of 18 months (based on stability studies).
4. Prolonged exposure to heat and moisture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

[SAMPLE PREPARATION AND COLLECTION]

1. Before testing, it is important that the subject abstain from any sexual activity for 3-7 days. This will ensure that sperm volume and quality are at their peak and the test will then be an accurate determination of sperm concentration.
2. When masturbating, semen should be collected directly into the semen collection container.
3. Care should be taken to ensure that the collected semen is not contaminated by touching hands or tissues or other materials.
4. Shake the semen evenly in the semen collection container and allow it to stand at room temperature for 1 hour until the semen liquefies. Do not use semen stored for more than 12 hours after liquefaction.

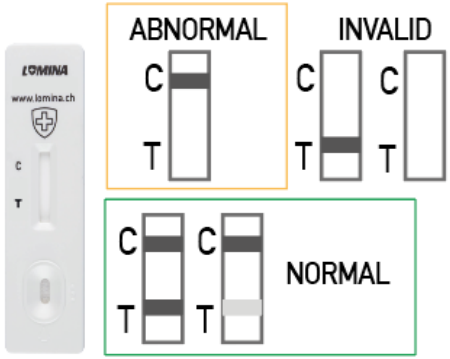
[APPLICATION PROCEDURE]

1. Remove the test cassette from the foil bag and place it horizontally on a flat surface.
2. The semen sample is collected in a clean and dry container.
3. The sample is then allowed to stand for 60 minutes until the semen is completely liquefied.
4. Using a dropper, transfer 4 drops (0.1ml) of liquefied semen into the stabilization fluid (buffer) vial.
5. Mix the semen sample and stabilization fluid (buffer) in the vial well by turning the vial upside down 5-10 times.
6. Hold the vial of diluted solution upright and open the cap of the tube. Transfer 2 full drops of diluted sample (approximately 80 µl) from the tube into the sample area (S) of the test cassette, then start the timer. Avoid trapping air bubbles in the sample well (S). See figure below.
7. Evaluate the results after 5 minutes of sample drip. Do not evaluate the results after 10 minutes!



[INTERPRETATION OF TEST RESULTS]

1. After applying the sample, start the stopwatch, wait 5 minutes without handling the cassette and then evaluate the result in the „T" area of the test cassette.
2. The result is interpreted by the presence of a visible strip in the „T" area on the body of the test cassette (see figure below), the results of the visual inspection are as follows:



NORMAL:* Two coloured lines will appear. One colored line should be in the control area („C") and the other apparent colored line should be in the test area („T"). This result indicates that the concentration of SP-10 protein is within normal limits, i.e., greater than 15 million/ml.*Note: The intensity of the color of the line in the test area („T") will vary depending on the concentration of SP-10 protein present in the sample. Therefore, any shade of color in the test area (T) should be considered normal.

ABNORMAL: A single color line will appear in the control area (C). No color band appears in the test area (T). This result indicates that the concentration of SP-10 protein is below the 15 million/ml threshold; therefore, the concentration is abnormal.

INVALID: The control line does not appear. The most likely cause of the control line failure is insufficient sample volume or an incorrect procedure. Check the procedure and repeat the test with a new kit. If the problem persists, stop using the test kit immediately and contact your local distributor.

Note: If the results are considered questionable or inaccurate for any reason, the test should be repeated with a different test kit. However, the subject must not ejaculate during any sexual activity for 6 days before performing the second test. If the second test is still abnormal, the results should be consulted with a medical professional - specialist.

[LIMITATION OF INSPECTION METHODS]

1. The Lomina Male Fertility Test is designed for in vitro qualitative estimation of SP-10 protein concentration, or sperm concentration in human semen.
2. Sperm concentration is only one of the important components of fertility testing. However, other semen tests such as motility and morphology, as well as ovulation in women, are also important. For cases of infertility, other tests should also be considered.
3. It is recommended to use fresh samples. Any lubricants or lotions taken and semen obtained from condoms will affect the test results.

[INTERFERENCE FACTORS]

The analytes were spiked with 80µl of the interfering substances below at a starting concentration of 1% and then spiked to 80µl of the abnormal sample (<12 million/ml) or normal sample (≥15 million/ml). Samples were tested in triplicate with 3 batches of test kits. A: Moxifloxacin, B: Cephalosporins, C: Fluoroquinolones, D: Clomifene Citrate Capsules, E: Testosterone. F: Testosterone Enanthate, G: Methyltestosterone Tablets.

Abnormal sample:

Lot#	A	B	C	D	E	F	G
SAP17080001-T	-	-	-	-	-	-	-
SAP17080002-T	-	-	-	-	-	-	-
SAP17080003-T	-	-	-	-	-	-	-

Normal sample:

Lot#	A	B	C	D	E	F	G
SAP17080001-T	+	+	+	+	+	+	+
SAP17080002-T	+	+	+	+	+	+	+
SAP17080003-T	+	+	+	+	+	+	+

[SENSITIVITY/SPECIFICITY]

The Lomina Male Fertility Test was evaluated on samples obtained from a population of individuals with normal and abnormal SP-10 protein concentrations. Comparison was made with a commercially available rapid test for SP-10 concentration.

Method		Commercially available SP-10 Rapid Test		Total
Lomina Male Fertility Test	Results	Normal	Abnormal	
	Normal	51	1	52
	Abnormal	1	59	60
Total		52	60	112

Sensitivity: 98.1% (95%CI:*89.7%-99.9%)

Specificity: 98.3% (95%CI:*91.1%-99.9%)

Accuracy: 98.2% (95%CI:*93.7%-99.8%)

[CAUTION!]

- False negative/positive or false normal/abnormal 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 lots (LOT) of tests and reagents!
- Read the instructions for use (IFU) carefully before testing and follow the procedures in the manual carefully.
- Pour the sample solution into the test cassette very slowly and observe the exact amount!
- The reaction time of the test is 5 minutes. Once the reaction is complete, do not evaluate the result later than 10 minutes. In other words, the result is invalid 10 minutes after application of the sample solution.
- The intensity of the colour or the thickness of the positive strip cannot be considered as „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				

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CE

REF La-SPERM-Pro

IVD 2°C 30°C

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