LOMINA
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IVD CE

Lomina HCG Pregnancy Enhanced Sensitivity Test

Instructions for use (IFU)

[PACKAGING SPECIFICATION]

Variants	1 pc in package - box/pouch	2 pcs in package - box	25 pcs in package - box	50 pcs in package - box
REF	La-HCG-Pro /1B or 1P	La-HCG-Pro /2B	La-HCG-Pro /25B	La-HCG-Pro /50B
TIVD test srtip [pcs]	1	2	25	50
Desiccant [pcs]	1	2	25	50
IFU [pcs]	1	1	1	1

[INTRODUCTION]

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced and developed by the placenta shortly after fertilization. In a normal pregnancy, hCG can be detected in both urine and serum or plasma as early as 7 to 10 days after conception. The level of hCG continues to rise very rapidly, often exceeding 100mIU/ml by the first missed menstrual period and peaking in the range of 100,000-200,000mIU/ml at approximately 10-12 weeks of pregnancy. The occurrence of hCG in both urine and serum or plasma soon after conception and its subsequent rapid increase in concentration during early gestational growth makes it an excellent marker for early detection of pregnancy.

[INTENDED USE]

The Lomina HCG Pregnancy Enhanced Sensitivity Test is a rapid chromatographic immunoassay for the quantitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

[TEST PRINCIPLE]

The Lomina HCG Pregnancy Enhanced Sensitivity Test is a rapid one-step lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test uses a combination of antibodies including a monoclonal anti-hCG antibody that selectively detects elevated levels of hCG. The test is performed by adding urine to a hydrophilic stick and obtaining the result from coloured lines.

[PACKAGE CONTENTS]

1. Test strip
2. Desiccant
3. Instructions for use

[NOT INCLUDED IN THE PACKAGE]

- Stopwatch/clock for measuring the duration of the test
- Container for urine

⚠ [ATTENTION!]

- Please read all information in this package insert before performing the test.
- The Lomina HCG Pregnancy Enhanced Sensitivity Test is intended for in vitro diagnostic use by healthcare professionals and should only be used for the qualitative detection of the presence of human chorionic gonadotropin in a sample.
- Do not eat, drink or smoke in the area 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.
- Strictly observe the specified time for sample reading.
- Use the test only once.
- Do not disassemble or touch the test window of the test cassette.
- The kit should not be frozen or used beyond 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 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).
3. Do not freeze.

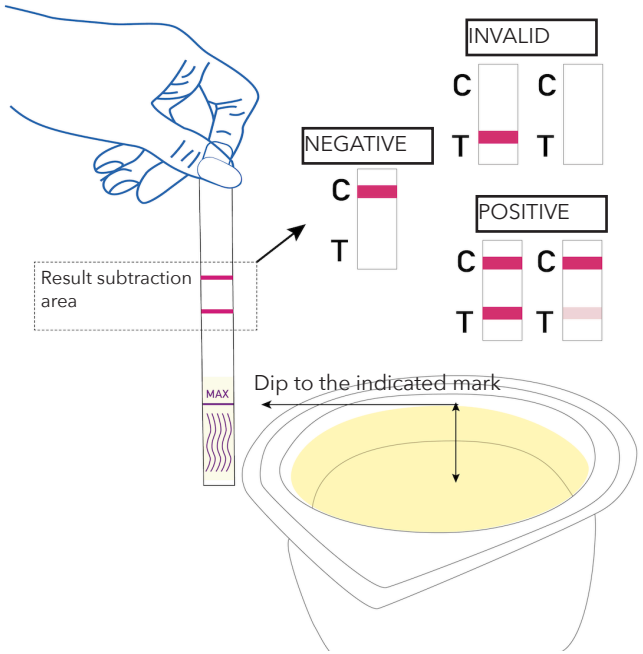
[SAMPLE COLLECTION AND PREPARATION]

Urine analysis: The urine sample must be collected in a clean, dry container. A morning urine sample is preferred as it generally contains the highest concentration of HCG; however, urine samples collected at any time of the day may be used. Urine samples that show visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear sample for testing.

Sample Storage: Urine samples may be stored at 2-8°C for up to 48 hours prior to testing. For longer storage, samples can be frozen and stored below -20°C. Frozen samples should be thawed and mixed before testing. Samples should not be refrozen and thawed repeatedly.

[INSTRUCTIONS FOR USE]

1. Remove the strip from the bag and test it immediately, within one hour at the latest.
2. Set the test strip to insert the absorbent tip into the urine stream, or insert the absorbent tip (≥2/3) into the urine in a clean cup for at least 15 seconds.
3. Then place the test strip on a clean, flat surface and start the timer.
4. Read the result after 3 minutes; do not interpret the result after 10 minutes.



[INTERPRETATION OF TEST RESULTS]

After applying the sample, start the stopwatch, wait 3 minutes without handling the test strip and then read the result in the test area „T". The result is interpreted by the presence of a visible line in the control area (C) on the test strip (see figure below), the results of the visual inspection are shown on the first page of this manual:

POSITIVE

Two distinctive coloured lines appear. One line should be in the control area (C) and the other in the test area (T). One line may be lighter than the other; they do not have to match. This result means that you are probably pregnant.

NEGATIVE

One colored line will appear in the control area (C). No line appears in the test area (T). This result means that you are probably not pregnant.

INVALID

The result is invalid if no coloured line appears in the control area (C), even if a line appears in the test area (T). The most likely cause of the control area failure is insufficient sample volume or incorrect procedure. Check the procedure and repeat the test with a new test strip. If the problem persists, stop using the test kit immediately and contact your local distributor.

[LIMITATION OF INSPECTION METHODS]

There is a possibility that this test may give false results.

1. Drugs that contain hCG (e.g. Pregnyl, Profasi, Pergonal, APL) may give a false positive result. Alcohol, oral contraceptives, painkillers, antibiotics or hormone therapies that do not contain hCG should not affect the test result.
2. Very dilute urine samples, as shown by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine sample should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50mIU/ml) are present in urine samples shortly after pregnancy. However, because a significant number of first trimester pregnancies end from natural causes, a weakly positive test result should be confirmed by retesting a first morning urine sample collected 48 hours later.
4. This test may give false positive results. There are a number of diseases (trophoblastic diseases and diseases of certain non- trophoblastic tumours, including testicular cancer, prostate cancer, breast cancer and lung cancer) that cause elevated hCG levels. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been excluded.
5. This test may give false negative results. False negative results may occur if the hCG level is below the sensitivity level of the test. If pregnancy is suspected, a sample of the first morning urine should be collected 48 hours later and tested. If pregnancy is suspected and the test continues to give negative results, see a doctor for further diagnosis.
6. This test provides a presumptive diagnosis of pregnancy. A confirmed diagnosis of pregnancy should be made by a physician only after evaluation of all clinical and laboratory findings.

[QUALITY CONTROL]

The test includes a procedural check. A coloured line appearing in the control line area (C) is considered an internal procedural check. It confirms sufficient sample volume, sufficient membrane drainage and correct procedural technique. Control standards are not included in this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify that the test was performed correctly.

[SENSITIVITY/SPECIFICITY]

108 samples (confirmed by a commercially available product) were used in the clinical study. The results are shown in the table below.

Method		Commercially available product		
Lomina Pregnancy Enhanced Sensitivity Test	Results	Positive	Negative	Total
	Positive	231	0	231
	Negative	0	377	377
Total		231	377	608

Sensitivity: 100% (95.0%CI: 98,42%-100%)
Specificity: 100% (95.0%CI: 99,03%-100%)
Accuracy: 100% (95.0%CI: 99,40%-100%)

[CROSS-REACTIVITY]

No cross-reactivity has been demonstrated with these substances:
hFSH, LH, hTSH.

[INTERFERENCE FACTORS]

No interference with the following substances has been detected: Acetoaminophen, Acetoaceto Acid, Ascorbic Acid, Atropine, Acetosalicylic Acid , Albumin, Bilirubin, Caffeine, Codeine , Ephedrine, EDTA, Ethanol, Gentisic Acid, Glucose, Hemoglobin, Methadone, Methanol, Phenylpropanolamine, Phenothiazine, Salicylic Acid.

⚠ [CAUTION]

- 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).
- The reaction time of the test is 3 minutes. After the reaction is complete, do not read the result later than 10 minutes. In other words, the result is invalid 10 minutes after the test solution is loaded.
- The intensity of the color or the thickness of the positive strip 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				

MANUFACTURER:
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CE

REF
La-HCG-Pro

IVD 2°C 30°C

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