Lepzi®

Women's Health

LH Test

- Quantitative detection of Luteinising Hormone (LH) in female urine
- Healthcare Professional Use Only-used with Lepzi Colloidal Gold Analyser
- Easy to use Point of Care and near patient test
- Aid in the detection of ovulation

Luteinising Hormone

Immediately prior to ovulation, the body produces a large amount of Luteinising Hormone (LH) from the pituitary gland which triggers the release of a mature follicle (egg) from the ovary. This "LH surge" signals that ovulation is likely to take place in the next 24-36h.

LH levels are known to be elevated in conditions such as polycystic ovarian syndrome (PCOS).

Levels of LH depend upon the day of the cycle in which the test is performed.

The Lepzi LH Test is a rapid immunoassay for the quantitative detection of LH in urine to aid in evaluation of the female menstrual cycle related to ovulation.

It is important to note that the LH surge and ovulation may not occur in all menstrual cycles.

Product Performance

- **Test sample:** Fresh Urine
- **Test Range:** 10-200 mIU/ml
- **Precision:** CV ≤10%

Results Interpretation

- Elevated urinary LH levels are ≥25 mIU/ml and indicate ovulation may occur soon.
- When the test result is >200 mIU/ml, it is recommended to go to the hospital for further follow up examination.

Results in just 10 minutes

CE BG/CA01/MD-0054 IVD REF LD_BG016 30 tests 2℃ 30℃

Lepzi Diagnostika Ltd., 111 "Tsarigradsko Shose" Blvd, Sofia 1784, Bulgaria
www.lepzi.com enquiries@lepzi.com +359-897-289-089

Please refer to Instruction For Use for full test information.

Translation from Bulgarian language.
/Form of Bulgarian Drug Agency/

REGISTRATION CERTIFICATE
No BG/ CA01/ MD 0054/ 28.10.2021

We, pursuant to Article 6, item 1 of the Medical Devices Act, in connection with Article 28, paragraph 1 of Medical Devices Act and application with entry No ИАЛ-48633/13.10.2021.

REGISTER

Medical device:
LEPZI ® LH Test

EDMS code: 12.70. 05.04
GMDN code: 54255

Category and ***category code***: ***In vitro diagnostic devices - 06***

Group: **Others**

LEPZI DIAGNOSTIKA LTD
UIC: 206039179
Mladost District
No 111 – B Tsarigradsko Shose Boulevard, Office No 1.17
Sofia 1784
(Manufacturer)

The manufacturer is responsible for the design, manufacture and control of the registered medical device and its evaluation in accordance with the essential requirements of the Medical Devices Act and its implementing acts, according to Directive 98/79/EC.

This medical device registered under Article 31 of the Medical Devices Act, at the Bulgarian Drug Agency.

BOGDAN KIRILOV MASTER OF PHARMACY /signature, stamp/
Executive Manager

I, the undersigned Kristina Karabelyova do hereby certify that this is a true and correct translation I have made from Bulgarian into English of the document attached hereto. The translation includes 1 /one/ page.

Translator: Kristina Karabelyova

РЕПУБЛИКА БЪЛГАРИЯ
Изпълнителна агенция по лекарствата
REPUBLIC OF BULGARIA
Bulgarian Drug Agency

УДОСТОВЕРЕНИЕ ЗА РЕГИСТРАЦИЯ

№ *BG/CA01/MD* ...0054...../...28.10.....**2021 г.**

На основание чл. 6, т.1 от ЗМИ, във връзка с чл. 28, ал.1 от ЗМИ и подадено заявление с вх. № ИАЛ-48633/13.10.2021 г.

РЕГИСТРИРАМ

Медицинско изделие:

LEPZI® LH Тест
LEPZI® LH Test

EDMS код: 12.70.05.04
GMDN код: 54255

Категория и код на ***категорията***: ***Ин витро диагностични изделия- 06***
Група: **Други**

ЛЕПЦИ ДИАГНОСТИКА ЕООД
ЕИК: 206039179
р-н „Младост“
бул. Цариградско шосе“ № 111-Б, офис № 1.17
гр. София 1784
(Производител)

Производителят е отговорен за проектирането, производството и контрола на регистрираното медицинско изделие/я и оценката му в съответствие със съществените изисквания на Закона за медицинските изделия и актовете по неговото прилагане, които въвеждат Директива 98/79/ЕС.

Медицинското изделие е вписано в регистъра по чл. 31 от Закона за медицинските изделия, при Изпълнителната агенция по лекарствата.

МАГ.- ФАРМ. БОГДАН КИРИЛОВ
Изпълнителен директор

ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВАТА * РЕПУБЛИКА БЪЛГАРИЯ *

София 1303, ул. Дамян Груев № 8, тел.: (02) 8903555, факс: (02) 8903434
8, Damyan Gruev Str., 1303, Sofia, Bulgaria, tel: + 359 2 8903555, fax: + 359 2 8903434,
e-mail: bda@bda.bg