Lepzi®

Women's Health

FSH Test

- Quantitative detection of Follicle-Stimulating Hormone (FSH) in female urine
- Aid in the diagnosis and evaluation of the female menstrual cycle in relation to menopause onset and infertility assessment
- Healthcare Professional Use Only-used with Lepzi Colloidal Gold Analyser
- Easy to use Point of Care and near patient test

Follicle-Stimulating Hormone

Follicle-Stimulating Hormone (FSH) regulates the development of the follicles in the ovary which eventually leads to release of the egg at ovulation.

The levels of FSH reflect the responsiveness of follicle development and FSH levels rise as the ovary becomes less responsive during perimenopause onset and the transition to menopause.

FSH levels become elevated above normal menstrual cycle levels and can help to determine whether a woman is in perimenopause.

The Lepzi FSH Test is a rapid immunoassay for the quantitative detection of FSH in urine to aid in evaluation of the female menstrual cycle related to menopause onset and infertility assessment.

Product Performance

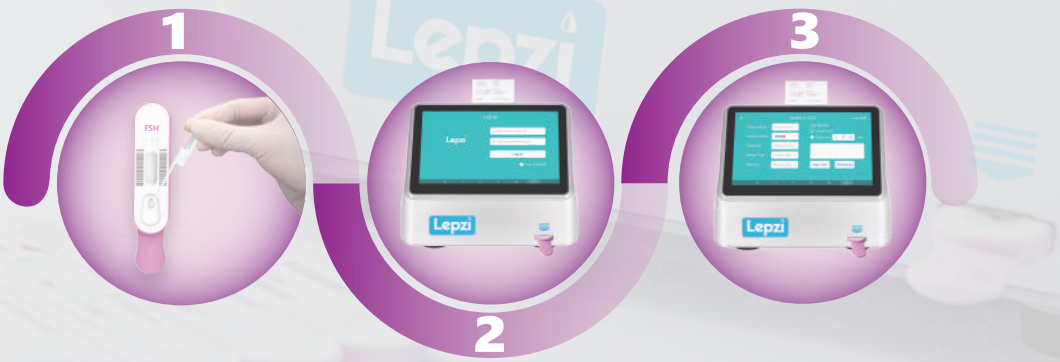
- **Test sample:** Fresh Urine
- **Test Range:** 10-200 mIU/ml
- **Precision:** CV ≤10%

Results Interpretation

FSH levels depend upon the day of the cycle in which the test is performed. FSH can be higher at ovulation.

At the lower end the level can be <5mIU/ml. FSH levels consistently >30 mIU/ml are typical of perimenopause and postmenopause.

Results in just 10 minutes



CE BG/CA01/MD-0029 IVD REF LD_BG030 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 0029/ 11.08.2022

We, pursuant to Article 6, item 1 of the Medical Devices Act, in connection with Article 28, paragraph 1 of Medical Devices Act, submitted application with entry No ИАЛ-21739/20.05.2022 and subsequent letter with entry No ИАЛ-31148/18.07.2022.

REGISTER

Medical device:
FSH Test Kit (Follicle stimulating Hormone Test Kit)
for determination follicle-stimulating hormone in female urine

EDMS code: 12.70. 05.01
GMDN code: 65840

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* ..0029...../..11.08.....2022 *г.*

На основание чл. 6, т. 1 от ЗМИ, във връзка с чл. 28, ал. 1 от ЗМИ, подадено заявление с вх. № ИАЛ-21739/20.05.2022 г. и последващо писмо с вх. № ИАЛ-31148/18.07.2022 г.

РЕГИСТРИРАМ

Медицинско изделие:

FSH Тест Кит (Follicle stimulating Hormone Test Kit)
за определяне на фоликулостимулиращ хормон в женска урина

EDMS код: 12.70. 05.01
GMDN код: 65840

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

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