Lepzi®

Women's Health

HCG Test

- Quantitative detection of Human Chorionic Gonadotrophin (hCG) in female urine
- Healthcare Professional Use Only-used with Lepzi Colloidal Gold Analyser
- Easy to use Point of Care and near patient test
- For use in pregnancy assessment

Human Chorionic Gonadotrophin

Human Chorionic Gonadotrophin (hCG) is a glycoprotein secreted by placental trophoblast cells.

Embryo formation occurs following fertilization and implantation. During the development of the foetus, the placental syncytiotrophoblast cells produce a large amount of hCG which present in maternal blood and are excreted into urine.

Urine hCG levels rapidly increase from 1 to 2.5 weeks of gestation, peak at the 8th week of pregnancy, decrease to moderate levels by the 4th month of pregnancy, and remain detectable until the end of pregnancy.

HCG is a useful biomarker for pregnancy detection and can also act as a useful aid for the clinician in suspecting pregnancy issues such as ectopic pregnancy.

Product Performance

- **Test sample:** Fresh Urine
- **Test Range:** 10-5000 mIU/ml
- **Precision:** CV ≤15%

Results Interpretation

HCG levels in female ≥25 mIU/ml are an indication of pregnancy.

In normal pregnancy, hCG can be detected as early as 6 days following conception with concentrations doubling every 32-48h, peaking in excess of 100,000 mIU/ml in approximately 10 to 12 weeks.

Results in just 10 minutes

CE BG/CA01/MD-0056 IVD REF LD_BG014 12 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 0056/ 01.11.2021

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-48631/13.10.2021.

REGISTER

Medical device:
LEPZI ® HCG Test

EDMS code: 12.70. 05.02
GMDN code: 33819

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* ...-0056...../.....01.11.....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-48631/13.10.2021 г.

РЕГИСТРИРАМ

Медицинско изделие:

LEPZI® HCG Тест
LEPZI® HCG Test

EDMS код: 12.70.05.02
GMDN код: 33819

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

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