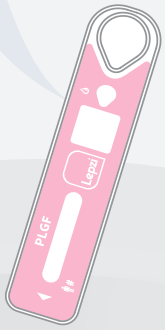
Lepzi®

Women's Health

PLGF Test

- Quantitative detection of Placental Growth Factor (PLGF) in whole blood or plasma samples (EDTA)
- Aid in the diagnosis of preterm pre-eclampsia in pregnant women
- Healthcare Professional Use Only-used with Lepzi Reader
- Easy to use Point of Care and near patient test



Placental Growth Factor

Placental Growth Factor (PLGF) is produced by the placenta and circulates at high concentration in normal pregnancy.

In pre-eclampsia, there is increased expression of soluble fms-like tyrosine kinase-1 (sFlt1) which binds to circulating PLGF, and results in significantly decreased levels of PLGF.

In pregnant women with pre-eclampsia PLGF levels are abnormally low compared to women with a healthy pregnancy of approximately the same gestational age.

PLGF is lower in severe pre-eclampsia compared with mild pre-eclampsia.

Placental Growth Factor (PLGF) testing is used as an aid in the diagnosis of preterm pre-eclampsia in women presenting with signs and symptoms of pre-eclampsia between 20-and 35-weeks of gestation.

Pregnant women with suspected or confirmed preterm pre-eclampsia and a low circulating level of PLGF are at increased risk for adverse maternal and perinatal outcome.

Product Performance

- **Test sample:** Whole blood or Plasma
- **Test Range:** 12-3000 pg/ml
- **Precision:** CV ≤10%

Results Interpretation

- When PLGF is ≥100 pg/ml, the result indicates normal placental function.
- When PLGF is <100 pg/ml, the result indicates abnormal placental function.

Results in just 15 minutes

CE BG/CA01/MD-0041 IVD REF LD_BG002 25 tests 2℃ 8℃

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 0041/ 29.09.2021

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-41681/31.08.2021 and subsequent letter with entry No ИАЛ-45245/23.09.2021.

REGISTER

Medical device:
LEPZI ® PLGF Test

EDMS code: 12.70. 05.90
GMDN code: 56619

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* ....0041...../.....29.09.....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-41681/31.08.2021 г.и последващо писмо с вх. № ИАЛ-45245/23.09.2021 г,

РЕГИСТРИРАМ

Медицинско изделие:

LEPZI® PLGF Тест
LEPZI® PLGF Test

EDMS код: 12.70.05.90
GMDN код: 56619

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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