BTA Test

- Qualitative detection of Bladder Tumour Antigen (BTA) Complement Factor H in urine
- Aid in the assessment and diagnosis of patients with suspicion of urinary tract lesions or bladder cancer, including post operative follow up for recurrence
- Near patient test - no need to outsource testing to an off-site laboratory
- Single use, visual read, Point Of Care test
- Healthcare Professional Use Only

Bladder Tumour Antigen

Bladder Tumour Antigen, BTA (also known as Complement Factor H) is a single use colloidal gold immunoassay test intended for qualitative detection of BTA in urine.

Cancer of the bladder, also known as urological cancer or urinary bladder cancer, is the 10th most common cancer in the world, and its incidence is steadily rising worldwide most common in the elderly, with smoking being a major risk factor.

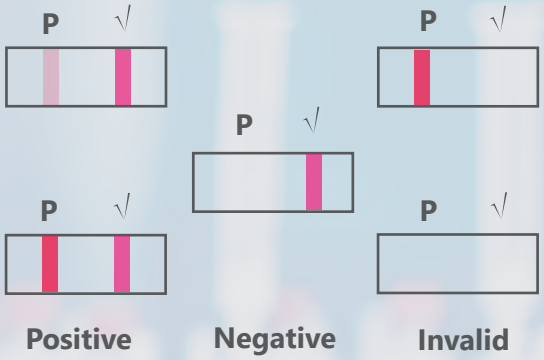
90% of bladder cancer cases arise from these urothelial cells, mostly in the bladder but on rare occasions in the urinary tract.

Bladder Tumour Antigen (BTA) in urine is a sensitive marker and has been used as an adjunct to cystoscopy in the diagnosis and follow-up of patients with bladder cancer.

Product Performance

- Sensitivity: 90.5%
- Specificity: 78.7%

Results Interpratation



Results in just 5 minutes

CE BG/CA01/MD-0001 IVD REF LD_BG006 20 tests 2°C 30°C

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 0001/ 04.01.2022

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-60940/21.12.2021.

REGISTER

Medical device:
LEPZI® BTA Test

EDMS code: 12.70.03.01
GMDN code: 54560

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 ..0001...../...04.01....2022 г.

На основание чл. 6, т. 1 от ЗМИ, във връзка с чл. 28, ал. 1 от ЗМИ и подадено заявление с вх. № ИАЛ-60940/21.12.2021 г.

РЕГИСТРИРАМ

Медицинско изделие:

LEPZI® BTA Тест
LEPZI® BTA Test

EDMS код: 12.70.03.01
GMDN код: 54560

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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