UROMONITOR

Non-Invasive Bladder Cancer Surveillance

Try Uromonitor®

Uromonitor®

Painless and Non-invasive
Based on a simple urine analysis, reducing the number of recurrent cystoscopies.

Ultra Sensitive
Based on the analysis of highly specific molecular biomarkers through real-time PCR.

Clinically Tested
Presenting sensitivity of up to 100% and specificity of up to 96.2%, independently of tumor grade or stage.

Fast and Simple
We provide the results in 2-5 business days. Urine collection and filtration can be done at home and the filter mailed for analysis.

Hospital Implementation
The shipment of IVD Uromonitor® kits for implementation in hospitals and diagnostic centers is accompanied by technical support and training.

CE Marking
Uromonitor® is a product that complies with European legislation and standards.

EAU Guidelines
Urinary Biomarkers are now on the EAU Guidelines for NMIBC follow-up.

About the test

Uromonitor® is a highly sensitive IVD test, developed and patented by researchers from Ipatimup and U-Monitor (Portugal), specialists in biomarkers in the field of cancer biology and molecular genetics.

It is based on the detection of molecular biomarkers present in bladder cancer tumor cells found in urine.

Validated in samples from patients followed in national and international centers, under surveillance for non-muscle invasive bladder cancer (NMIBC).

Uromonitor® value lies not only on the non-invasive nature of the test but also on the ultra sensitive detection of a set of mutations, highly prevalent in NMIBC, that include mutations in the TERTp, FGFR3 and KRAS genes, through Real-time PCR.

It is the ideal complement in the follow-up of patients under surveillance for non-muscle invasive bladder cancer recurrence, allowing the reduction of the number of cystoscopies performed by the patient.

Contact us for more details!

www.uromonitor.com

info@uromonitor.com
P: +351 227 662 332
M: +351 938 804 174
M: +351 965 057 980

UROMONITOR
Rua Alfredo Allen nº 455/461
4200-135 Porto, Portugal

About us

U-Monitor is specialized in the development of non-invasive diagnostic tools detecting disease-associated biomarkers in the field of cancer and molecular genetics. Our main R&D activity has been focused on bladder cancer and as result of that, we have launched Uromonitor®. We are now present in the main European markets, Africa, Middle East, Asia and North and South America.

Uromonitor®

Need

Bladder cancer (BCa) affects around 500 000 people worldwide each year. After diagnosis and surgery, there is a 40-50% chance of tumor recurrence, so these patients undergo regular and long-lasting surveillance**.** It is estimated that **1 million bladder cancer patients are under follow-up worldwide**. Current **follow-up** of patients with a history of BCa **consists of regular cystoscopies in combination with urine cytology**. Follow-up programs should be maintained years following diagnosis and can even span throughout life, which leads to high costs, making BCa one of the most expensive cancers in terms of follow-up. Another drawback of the current follow-up is **the invasive nature of the cystoscopy procedure and the low sensitivity of urine cytology**, particularly in low-grade non-muscle invasive BCa.

Description

Uromonitor® is a highly sensitive non-invasive IVD test, validated and published in international urological publications based in thousands of samples, from patients followed in national and international centers, under surveillance for non-muscle invasive Bca. The test is based on the **detection of molecular biomarkers present in bladder cancer tumor cells found in urine**. It is the ideal ancillary method in the **follow-up of patients under surveillance for non-muscle invasive BCa recurrence**, allowing to reduce the number of patients that undergo cystoscopies. **Uromonitor® kit** is composed by three sub-units, **incluiding all the tools and reagents needed for sample processing and analysis**. Uromonitor® value lies not only on the non-invasive nature of the test as well on the **ultra sensitive detection of a set of mutations, highly prevalent in BCa**, that include mutations in the TERTp, FGFR3 and KRAS genes, **through Real-time PCR.**

Clinical Performance

The test has been validated in a clinical context and the clinical validation results published in international peer-reviewed journals (Batista R. *et al*, 2019, Sieverink C. *et al*, 2020 and Nessn A. *et al*, 2023). The use of **Uromonitor® to monitor recurrence in patients with non-muscle invasive BCa showed a sensitivity, specificity, PPV, and NPV of 93.1-100%, 85.4-96.2%, 66.7-79.4%, and 95.3-100%, respectively**. The latter contrasts with urine cytology that displayed sensitivity, specificity, PPV, and NPV of 26.3%, 90.9%, 62.5%, and 68.2%, respectively.

Uromonitor®'s potential to be used at initial diagnosis is under testing. In a pilot cohort of initial diagnosis cases. Uromonitor® based on preliminary results, showed a sensitivity, specificity, PPV, and NPV of 93.3%, 80%, 87.5%, and 88.9%, respectively.