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UROBEST®

RT-PCR assay for the diagnosis and surveillance of bladder cancer from urine

Description of the Assay

UROBEST addresses the need for a cost-effective non-invasive assay for diagnosis and surveillance of bladder cancer. It is based on a **clinically validated** signature of ten differentially-expressed genes and displays **superior performance** (sensitivity **80%;** specificity **94%;** AUC **0.91**) to other molecular markers in the market. The validation study also demonstrated the excellent performance of additional of 2, 5 and 12-gene panels, both in European and Chinese populations. UROBEST® is a registered trademark in Spain.

The Opportunity

Bladder cancer is among the five most common malignancies worldwide being responsible for 3% of all cancer deaths in males and 1% in females. If detected early, 5-year survival is high (94%), but **>70%** of diagnosed patients will **relapse** within this period, with 20% progressing to muscle invasive cancer (T2 or higher). High prevalence, survival and relapse rates combine to make BC one of the **most expensive** cancers to treat and monitor.

The gold standard diagnostic tool is combined cystoscopy and cytology which is costly and highly invasive requiring transurethral access and presenting the risk of important complications and discomfort to patients. Because clinical symptoms are not useful in predicting progression, surveillance requires frequent cystoscopies, on average in excess of 13 per patient following initial diagnosis and treatment.

A clear opportunity exists to replace surveillance, and eventually initial examinations, with a cost-effective and non-invasive procedure.

Format and Clinical Performance

The current assay is based on a validated panel of 10 differentially expressed genes employing RT-qPCR on spontaneous urine samples [1-4]. To date, around 2.400 samples have been analysed.

Clinical results on **525 patients** after a prospective multinational blinded validation study have demonstrated that our single non-invasive test yields **80% sensitivity** and **94% specificity** vs. 80% sensitivity and 90% specificity for combined invasive and costlier cystoscopy and cytology [5]. This performance is superior to that of competing biomarkers in the market (NMP22, Alere or BTA Stat, Polymedco) as well as being significantly cheaper than FISH-based tests (UroVysion, Abbott). These results have been validated in an independent Asian cohort (N=389)..

Partnering Information

UROBEST® is not yet commercially available. For more information on the diagnostic test or on partnering opportunities, please contact us.

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Publications

1. Mengual L, Burset M, Ars E, Ribal MJ, Lozano JJ, Miñana B, Sumoy L, Alcaraz A. ***Partially degraded RNA from bladder washing is a suitable sample for studying gene expression profiles in bladder cancer***. Eur Urol 2006, 50(6);1347-56. PMID: 16815626.

2. Mengual L, Burset M, Marin-Aguilera M, Ribal MJ, Alcaraz A. ***Multiplex preamplification of specific cDNA targets prior to gene expression analysis by TaqMan Arrays.*** BMC Research Notes 2008, 1:21. PMID: 18710479.

3. Mengual L, Burset M, Ars E, Lozano JJ, Villavicencio H, Ribal MJ, Alcaraz A. ***Expression profiling of bladder cancer by DNA microarrays allows the identification of non-invasive diagnostic markers***. J Urol 182:741-8,2009. PMID: 19539325.

4. Mengual L, Burset M, Ribal MJ, Ars E, Marín-Aguilera M, Fernández M, Ingelmo-Torres M, Villavicencio H, Alcaraz A. ***Gene expression signature in urine for diagnosis and aggressiveness assessment of bladder urothelial carcinoma.*** Clin Can Res. 2010 May 1;16(9):2624-33. PMID: 20406841.

5. Mengual L, Ribal MJ, Lozano JJ, Ingelmo-Torres M, Burset M, Fernández PL, Alcaraz PL, ***Validation study of a non-invasive urine test for diagnosis and prognosis assessment of bladder cancer. Evidence for improved models.*** J Urol. Vol. 191, 261-269, January 2014

6. Ribal MJ, Mengual L, Lozano JJ, Ingelmo-Torres M, Palou J, Rodríguez-Faba O, Witjes JA, Van der Heijden AG, Medina R, Conde JM, Marberger M, Schmidbauer J, Fernández PL, Alcaraz A. ***Gene expression test for the non-invasive diagnosis of bladder cancer: A prospective, blinded, international and multicenter validation study***. Eur. J Cancer. 2016 Feb; 54:131-8

7. Han C, Mengual L, Kang B, Lozano JJ, Yang X, Zhang C, Alcaraz A, Liang J, Ye D. **Validation of Urine-based Gene Classifiers for Detecting Bladder Cancer in a Chinese Study.** J Cancer. 2018 Aug 6; 9(17): 3208-3215.

Intellectual Property

Fina Biotech owns two patent families protecting the diagnostic method, in the EU, USA, Canada and Japan. Please do not hesitate to contact us if you require further information about intellectual property.

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