

Press release

May 18th, 2016

Biofina Diagnostics S.L has recently attended the 111th American Urological Association's Annual Meeting (AUA2016) held in San Diego, California, from the 6th until the 10th of May.

Dr. Mengual has presented a poster titled *"Prospective, blinded, international and multicenter validation of a gene expression test for the non-invasive diagnosis of bladder cancer"*. This poster includes performance results of UROBEST, our bladder cancer diagnostic kit tested in a prospective validation study performed in 5 European centers (N=525), as well as the results from a reproducibility study performed in an Asian population (N=69) in collaboration with the Fudan University Shanghai Cancer Center and the Institut Mérieux Laboratory. Performance has been proved to be comparable to that achieved with the current invasive diagnostic method (cystoscopy and cytology) achieving 80% sensitivities and specificities over 90% for all the gene signatures in the European Study. In the Asiatic cohort study, with a smaller sample of patients (N=69), 84% sensitivity and 90% specificity have been achieved. UROBEST has proven to have a significantly better performance in the NMIBC HG tumors which are those clinically most relevant for the urologists, as discussed personally with them. For all the risk groups, UROBEST's performance has been significantly higher to that of the cytology.

The poster has been on display in the *Science and Technology Hall* starting Saturday, May 7th until Tuesday, May 10th. Several diagnostic companies and key opinion leaders in Urology from USA and Europe have had the opportunity to discuss results with the author.

The use of spontaneous urine samples processed and a simple, objective and well-established technology like RT-qPCR turns the test into a non invasive alternative tool to the current gold-standard.

Biofina Diagnostics S.L. (www.biofinadx.com) is a new corporate vehicle incorporated to further develop and take UROBEST to the market, a bladder cancer non-invasive diagnostic test based on RT-qPCR technology. The company holds the exclusive exploitation and commercialization rights on Fina Biotech's patents (www.finabiotech.es) protecting the diagnostic method. UROBEST has already been validated in clinical studies in more than 1.000 patients and has proven to have better sensitivity and specificity than competitive products (10-gene signature results: SN=80% and SP=94%). UROBEST® is a registered trademark in the Spanish Patent and Trademark Office (OEPM).