

Press release

March 30th, 2019

FINA BIOTECH has successfully validated the results of its bladder cancer diagnostic test in Chinese population

Fina Biotech has successfully validated the previously reported European study results of its bladder cancer diagnostic test in an independent Asian cohort. The prospective blinded study was carried out at the Fudan University Shanghai Cancer Center from 2014-2016 (n=520) to validate four non-invasive tests for BC diagnosis based on the gene expression patterns of urine.

A high accuracy has been found for the four gene classifiers in this independent Asian set. The classifiers composed of 5 and 10 genes achieved the best sensitivity (80.54% and 81.32%, respectively) maintaining a high specificity (91.67% and 85.61%, respectively). Sensitivity of 5-gene (GS_D5) and 10-gene (GS_D10) expression classifiers in recurrent BC cases (78 and 79%, respectively) is comparable to that of primary BC cases (82%).

The study proves that our non-invasive diagnostic BC tests can be reproduced in independent cohorts and in an external laboratory. All the four gene classifiers have shown equal or superior performance to the current gold standard in the present and previously reported validation studies. Consequently, they may be taken for consideration as molecular tests applicable to clinical practice in the management of BC.

This work was supported by bioMérieux, Fina Biotech and Biofina Diagnostics. For more information, please see <https://bit.ly/2Fz26Cx>

Fina Biotech (www.finabiotech.es) is a spin-off of Laboratorios Indas (www.indas.com), with a strong pipeline of biotechnology projects and a proven track record in product development. Fina Biotech has invested more than €12 million in 28 projects in the diagnostics and cell therapy fields, most of them in partnership with public and private institutions, laboratories and universities. A product developed by Fina Biotech, a diagnostic test for male infertility (Halosperm®) is already marketed. UROBEST®, a bladder cancer diagnostic test based on RT-qPCR technology has already been validated in European and Chinese clinical studies and has proven to have better sensitivity and specificity than other available diagnostic tests. Biofina Diagnostics has recently merged with Fina Biotech.

bioMérieux (www.biomerieux.com) is a leading international diagnostics group that specialises in the field of in vitro diagnostics for clinical and industrial applications. bioMérieux designs, develops, manufactures and markets systems (i.e. reagents, instruments and software) used both in clinical and industrial applications. bioMérieux is listed on the Premier Marché of Euronext, Paris (FR0010096479 – BIM).