Urine-based genetic test that indicates probability of up to 100% of high-grade bladder cancer

Launched at the Global Congress on Bladder Cancer - BLADDR 2019 - in Paris, October 2019

After 10 years in development with a team of European researchers, ArrayGenomics is now offering a patented oligonucleotide microarray assay that provides the most clinically relevant profile of a patient's bladder carcinoma (B-TCC) available on the market today.[1.] The **BCA-1 Test** analyses DNA from a single urine sample and has been shown to be a highly sensitive clinical tool with one study highlighting the ability to identify 100% of high risk patients harbouring a high grade disease (with 95% overall sensitivity to predict positive cystoscopy).[1]

B-TCC has long been recognised as an optimal carcinoma for the investigation of DNA alterations in urine due to its 50-80% recurrence rate. The non-invasive BCA-1 Test is therefore an important development in the use of genomic profiling and has potential clinical applications for surveillance and grading of bladder cancer as an adjunct to cystoscopy.

The **BCA-1 Test** analyses 27 markers which have been selected to cover all known genomic zones implicated in bladder cancer. This is five times more than any other commercially available test and the combination of these markers ensures a level of sensitivity that matches or exceeds cystoscopy.[2] ArrayGenomics has now obtained a worldwide patent for these 27 genomic markers.

High sensitivity and NPV of the BCA-1 Test

Studies to assess the performance of the **BCA-1 Test** based on cytogenetic abnormalities to diagnose, stage and grade B-TCC from urine showed an excellent prognostic and predictive performance.[2.] It could discriminate low-grade from high-grade tumours with an overall sensitivity of 95%, specificity of 86% and a negative predictive value (NPV) 98.6%.[1,2]

Further studies have shown that the BCA-1 Test is able to identify patients harbouring a high grade disease. From analysis of 164 urine samples, researchers were able to differentiate B-TCC from non-malignant conditions with an accuracy of 100% for patients without history of bladder cancer. For follow-up of B-TCC, 100% of high grade tumours were diagnosed and the sensitivity to predict positive cystoscopy was 95%. [1]

Said Professor Olivier Cussenot, Head of Surgery Oncology & Urology, Hospital Tenon (Paris, France), *"My experience of BCA-1 Test across more than 700 patients is its ability to detect all high grade cancers and in many cases before they could be identified during cystoscopy."*

An adjunct to current diagnostic methods

ArrayGenomics is now offering the **BCA-1 Test** to clinicians and patients on-line and believe it can be a valuable adjunct to current diagnostic pathways, including cystoscopy. There are several advantages:

The BCA-1 Test has the potential to avoid unnecessary cystoscopy

In one BCA-1 trial, **it was found that half of the cystoscopies would have been** unnecessary had a **BCA-1 Test** been used in the first instance. Of 95 patients with a negative cystoscopy, 49 (51%) were found to be negative. If BCA-1 had been used **first,** these patients would not have been identified **as needing a** cystoscopy, thereby saving costs and improving patient care.[3]

The BCA-1 Test can improve patient quality of life

The **BCA-1 Test** requires a patient-supplied urine sample, so it is non-invasive and simple to administer. For patients living with bladder cancer it provides additional information about their exposure to bladder cancer at any given point in time.

It may also offer opportunities for targeted or alternative interventions that offer improved outcomes over the longer term.

Said, Steven Jones, VP Marketing from ArrayGenomics, *"Our vision is to work with health providers to enhance care pathways for bladder cancer. The **BCA-1 Test** can provide fast, pain-free, accurate diagnosis and prognosis at a given point in time, helping patients and doctors to make decisions about an individual's cancer journey."*

The BCA-1 Test has the potential to reduce healthcare costs

If the **BCA-1 Test** was used on **a** regular basis, savings could be made by health providers. There is a significant cost associated with investigating haematuria, largely due to the cost of the cystoscopy. It has been estimated in the UK that the cost of investigating patients who are subsequently found to be negative contributes to one third of the total cost of managing patients with non muscle-invasive bladder cancer (estimated to be £100 million in 2008)[4]. The prospect of an alternative, non-invasive test that relies on biomarkers in urine has been long awaited by urologists – and patients.

Worldwide patents have been achieved on the basis of the 27 markers that underpin the **BCA-1 Test** and ArrayGenomics is now making the test available **on-line**. **The BCA-1 Test** will be available for patients to purchase via an on-line portal – www.bca-1.com.

The company is keen to work with the urologist community to develop applications for their technology and is welcoming enquiries from clinicians who want to explore the advantages of the **BCA-1 Test** for their patients or who are interested to join our expert review panel.

Contact

Media: Lyn Cruickshank (WallaceHealth) <lyn@wallacehealth.co.uk>

Notes:

Bladder cancer is the 10th most common cancer in the UK. There are on average over 10,000 new cases every year, with most cases diagnosed in those over 60. Bladder cancer survival in the UK has increased over the last 40 years – half of those diagnosed will survive for ten years or more after diagnosis, compared with just a third 40 years ago.[5]

Non muscle-invasive B-TCC has the highest recurrence rate of any carcinoma. In addition, B-TCC is the most expensive carcinoma per patient between diagnosis and death, because of its 50-80% recurrence rate. Progression from a high grade non muscle-invasive cancer to a muscle-invasive cancer occurs in 10-20% of cases.[1]

References

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