

ARQUER DIAGNOSTIC'S INNOVATIVE URINE TEST INCLUDED IN EUROPEAN GUIDELINES FOR THE DETECTION OF RECURRENT BLADDER CANCER

ADXBLADDER: A non-invasive urine test is now a validated option for patients

Sunderland, United Kingdom, 16 March 2022 – For the first time a simple, innovative test which uses patented technology to detect the cancer biomarker MCM5 (Minichromosome Maintenance Complex Component 5) in urine, has been officially included in the European Association of Urology guidelines, as a recommendation for urologists in the follow up of low/intermediate risk non-muscle invasive bladder cancer (NMIBC).¹

Nadia Whittley, Chief Executive Officer of Arquer Diagnostics, said: *“This is a major milestone for patients as they now have a non-invasive alternative to cystoscopy in the monitoring of bladder cancer recurrence. We have worked together with a group of committed and incredibly talented urologists around the world to be able to produce rigorous clinical data which have provided the necessary background for the guidelines panel to be able to recommend our technology. We want to hope that this important step will provide urologists worldwide the reassurance that **ADXBLADDER** is safe and effective and that there is no reason for patients to undergo unnecessary invasive procedures when a non-invasive alternative is available”*

Arquer Diagnostics has conducted a comprehensive clinical study programme to ensure that urologists can be confident in the robustness of **ADXBLADDER** and the scientific rigour of the test. Data from recent clinical studies published in the Journal of Urology and European Urology Oncology, involving thousands of patients at centres around Europe, showed that **ADXBLADDER** can exclude the presence of high risk bladder cancer in both newly diagnosed patients, and those in follow up for bladder cancer recurrence monitoring, with a negative-predictive value (NPV) of 99%, without the need for invasive and unnecessary procedures.^{2,3,4}

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NOTES TO EDITORS:

Full background documents on **ADXBLADDER**, bladder cancer and Arquer Diagnostics are available on request along with details of case studies.

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For further information on Arquer Diagnostics please visit <https://arquerdx.com/>

About ADXBLADDER

- **ADXBLADDER** is a game-changing test - the first of its kind which uses patented technology to detect the biomarker protein MCM5 (Minichromosome Maintenance Complex Component 5) in urine which is present when cells grow uncontrollably.
- Normal, healthy cells 'switch off' and stop growing. These cells, such as those lining the bladder and which are in contact with the urine, do not contain MCM5. But the cells which continue to grow and cause cancer do contain MCM5.
- If **ADXBLADDER** cannot detect MCM5 in urine it is highly likely that cancer is not present. If urologists and oncologists do suspect cancer, they can then investigate further, using cystoscopy and tissue biopsy.
- After a urologist requests **ADXBLADDER**, a patient provides them with a urine sample which is then sent to the hospital laboratory. After undergoing a series of steps to isolate any MCM5 cells present, the sample is then put into the **ADXBLADDER** sample plate which fits in a standard ELISA (enzyme-linked immunosorbent assay) machine that is widely available in NHS hospital labs.
- A chemical enzyme then colour-codes any MCM5 present in the sample. If there is no colour change this accurately rules out bladder cancer. The test takes just 2.5 hours once in the lab.

About Bladder Cancer

- Bladder cancer is a disease in which the cells lining the urinary bladder lose their ability to regulate growth and start dividing uncontrollably. This abnormal growth results in a mass of cells that form a tumour.
- According to CRUK, bladder cancer affects more than 10,000 people a year in the UK and kills more than 5,400. Less than half of those diagnosed (46%) survive for 10 years or more.
- The majority of bladder cancer patients (around 76%) are diagnosed early at stage I or II when the disease is more treatable. However, between 24 to 28% are diagnosed at stage III or IV and between 17% and 20% already have metastases at diagnosis (stage IV).

About Arquer Diagnostics

Arquer Diagnostics is a UK-based company committed to manufacturing and marketing innovative, non-invasive cancer tests for diagnosis and monitoring, with its tests supported by highly regarded experts at leading international organisations.

REFERENCES

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