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HIGHLY-ACCURATE URINE TEST WHICH CAN RULE OUT BLADDER CANCER TO HELP CLEAR COVID-19 BACKLOG

Simple and painless urine test being offered for free to NHS

Sunderland, United Kingdom, Thursday 23 July 2020 –A SIMPLE, highly accurate and painless urine test which can rule out bladder cancer in just a few hours is today being offered free to the NHS to help doctors clear the backlog of people waiting for diagnosis or monitoring as a result of COVID-19 hospital closures.

Recent figures from Cancer Research UK (CRUK)¹ revealed that more than two million people in the UK were left waiting for screening, tests and treatments for all cancers in the first 10 weeks of lockdown alone and an estimated 290,000 people also missed out on an urgent suspected cancer referral for further tests in those 10 weeks, a time period during which 20,300 cancers would normally be caught.

The UK-based company behind the **ADXBLADDER** test, Arquer Diagnostics, is making thousands of its tests available free of charge to NHS hospitals across the UK until the end of September to help patients with suspected bladder cancer be quickly assessed. Rigorous clinical trials have shown that **ADXBLADDER** is able to rule out cancer 99%^{2,3} of the time, without any other standard diagnostic testing. The usual tests include cystoscopy, which sees a tube with a camera inserted into the bladder, and cytology, a test that looks at cells under a microscope. **ADXBladder** can be used at the diagnosis referral stage to rule out the presence of cancer and at follow-ups to monitor whether cancer has returned.

Bladder cancer affects more than 10,000 people a year in the UK⁴ according to CRUK and kills more than 5,400. Less than half of those diagnosed (46%) survive for 10 years or more⁴. It is thought around 18,000* people already referred to a hospital urologist for suspected bladder cancer have not been tested because the usual diagnostic tools of cystoscopy and ultrasound as well as face -to-face consultations were all cancelled or postponed as part of the NHS-wide pandemic response. Experts are now warning that urology departments could take at least a year to get through the backlog if they only use cystoscopies which could lead to those who may have the disease missing out on urgent treatment, with potentially fatal consequences.

Mr Stuart McCracken, Clinical Lecturer and Honorary Consultant Urologist, Newcastle University and Sunderland Royal Infirmary, said: *“The impact COVID-19 has had on cancer services has been devastating and we must act quickly to ensure that any patient who has missed out on an appointment is seen as soon as possible. We know those most at risk of many cancers, including bladder, are also those most vulnerable to catching, and dying from, COVID-19. A test such as **ADXBLADDER** is quick, simple and highly accurate which means we can use it swiftly to work out those more likely to need follow-up tests and those who can wait until the COVID-19 risk is lower.”*

NHS guidelines from the National Institute for Health and Care Excellence (NICE)⁵ state that everyone with any suspected cancer should have their first referral appointment within two weeks



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but experts fear this target has slipped by at least 75%¹ during lockdown. NICE also recommends that all patients with blood in their urine should be offered a cystoscopy, followed up by other tests such as an ultrasound if necessary. However, cystoscopy can miss up to 30% of bladder tumours^{6,7} and is an uncomfortable, invasive and sometimes painful procedure, plus it has to be conducted within a hospital setting thereby exposing patients to an increased risk of contracting COVID-19.

ADXBLADDER is a game-changing test which can detect a hallmark cancer biomarker protein called MCM5 (Minichromosome Maintenance Complex Component 5) in the urine. If **ADXBLADDER** cannot detect MCM5 in the urine it is highly likely that cancer is not present. If it is present, urologists can then investigate further, using cystoscopy and tissue biopsy. A urologist asks a patient to provide a urine sample which is then tested using **ADXBLADDER** in a standard ELISA (enzyme-linked immunosorbent assay) machine that is widely available in NHS hospital labs. The test takes just two and a half hours once in the lab and urologists will typically get the results back in a few days. It also has the potential to save the NHS money, as this test relies on a very cost-effective technology.

Mr Tim Dudderidge, a Consultant Urological Surgeon at University Hospital Southampton who specialises in uro-oncology, said: "**ADXBLADDER** is different to previous cancer urine tests as it's a new way of looking for cancer. The reason an MCM5 test is so powerful is that it gives us a message about uncontrolled cellular growth, which is the hallmark signature of cancer. If cancer is present, so is MCM5. Having a test like this is a great advance, allowing us to rule out cancer with very high accuracy, and also helping improve how we monitor bladder cancer in patients for any recurrence."

Nadia Whittle, Chief Executive Officer of Arquer Diagnostics, said: "We have all heard about the devastating impact that COVID-19 has had on cancer services across the UK. Our **ADXBLADDER** test is quick, painless and can rule out bladder cancer with 99% accuracy because it works by detecting a cancer protein which would be shed into the urine if a tumour was present.

"At a time when urology services are desperately trying to work through a backlog of thousands of patients who are waiting to find out if they have bladder cancer or if their disease has returned, we are offering as many tests as the NHS needs free of charge to quickly determine which patients are clear of the disease and which need further tests.

"Every single person waiting for a diagnosis deserves not to have to wait any longer for peace of mind that they are cancer-free or to be able to begin vital treatment if required. Urologists should get in touch with Arquer Diagnostics as soon as possible and we can then make the tests available to their hospitals and clinics."

Anita Brown, 49, from Hampshire had to wait over a year to be diagnosed with bladder cancer, by which time her tumour had already grown through the bladder lining and begun to affect her lymph nodes, liver and had spread to her bones meaning her disease was terminal. The mother-of-one had a long history of regular urinary tract infections (UTIs) and, after discovering blood in her urine, was eventually diagnosed with bladder cancer in 2016. Anita, who used to work as a carer but now writes her own blog, has had chemotherapy, radiotherapy and her bladder removed and now lives



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with a stoma bag to collect her urine. She is adamant that quick, early diagnosis is vital to ensure no one goes through what she has.

She said: "If I had been offered a simple urine test early on, the doctor would have seen quickly that I was likely to have a tumour. Instead, I faced months of delays which meant by the time I was finally diagnosed, I was really unwell and the resulting treatment has been incredibly traumatic. Living with cancer is hard but it's also becoming more common. I want everyone to have the opportunity to live well and early diagnosis is key to that, so I welcome this new test wholeheartedly."

*110,000 cystoscopies a year = 9,000 per month. Three months of lockdown with only 30% capacity = around 18,000 missed

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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.

For further press information please contact Sarah Wolf at The Difference Collective 07747 733216 sarah.wolf@thedifferencecollective.com or email the whole team arquer.comms@thedifferencecollective.com

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 the 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 the 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 and urologists will typically get the results back in a few days.

About Bladder Cancer



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- 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 UK⁴ and kills more than 5,400⁴. Less than half of those diagnosed (46%) survive for 10 years or more⁴.
- The majority of bladder cancer patients (around 76%) are diagnosed early at stage I or II when the disease is more treatable⁴. However, between 24 to 28% are diagnosed at stage III or IV and between 17% and 20% already have metastases at diagnosis (stage IV)⁴

About Arquer

- Arquer Diagnostics is a UK-based company committed to manufacturing and marketing innovative, non-invasive cancer tests for diagnosis and monitoring.
- Arquer's approach and tests are supported by highly-regarded experts at leading international organisations: University Hospital Southampton and Sunderland Royal Hospital in the UK; Pitié Salpêtrière University Hospital and Hôpital Edouard Herriot, Lyon in France; University Hospital Fundació Puigvert in Spain; Radboud University Medical Centre, Nijmegen in The Netherlands; as well as Ospedale Molinette, Turin, and Università Policlinico Milano, in Italy.

Biographies of Mr Stuart McCracken and Mr Tim Dudderidge – interviews available on request

Mr Stuart McCracken is a consultant urologist. He studied at Nottingham University Medical School and after basic surgical training, he undertook a period of research focusing on targetable molecular pathways in advanced prostate cancer leading to the award of a Doctor of Philosophy (PhD). His urology training was undertaken in the North East where Stuart is now a Senior Lecturer and Honorary Consultant Urological Surgeon, dividing his time between Newcastle University and Sunderland Royal Hospital. He sits on the Executive Board of the Academic Section of the British Association of Urological Surgeons.

Mr Tim Dudderidge is a highly trained consultant urologist based in Southampton, who specialises in urological cancer diagnostics. Mr Dudderidge qualified from the University of Bristol and trained in London at King's College Hospital, University College Hospital, Imperial Healthcare and the Royal Marsden Hospital. He embarked on a Royal College of Surgeons Uro-Oncology Fellowship at Imperial in 2009 and subsequently was the UK's First Robotic Surgery Fellow at the Royal Marsden. His training has also included a two-year research period as Lecturer in Molecular Uro-Pathology, for which he was awarded two masters degrees. He also holds an MD (Doctor of Medicine) from the University of Bristol for his work on "Minichromosome Maintenance Proteins (MCMs) in Urological cancer Management".

REFERENCES

¹ <https://scienceblog.cancerresearchuk.org/2020/06/22/getting-cancer-services-back-on-track-during-the-covid-19-pandemic>

² Dudderidge T, et al. A Novel, non-invasive Test Enabling Bladder Cancer Detection in Urine Sediment of Patients Presenting with Haematuria—A Prospective Multicentre Performance Evaluation of ADXBLADDER. *Eur Urol Oncol* (2019), <https://doi.org/10.1016/j.euo.2019.06.006>.
<https://www.sciencedirect.com/science/article/pii/S2588931119300811?via%3Dihub>

³ Roupret M, Gontero P, McCracken SRC, et al. Diagnostic Accuracy of MCM5 for the Detection of Recurrence in Non Muscle Invasive Bladder Cancer Follow up: A Blinded, Prospective Cohort, Multicentric European Study



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[published online ahead of print, 2020 Apr 21]. J Urol. 2020;101097JU000000000001084.
doi:10.1097/JU.0000000000001084 <https://pubmed.ncbi.nlm.nih.gov/32314931/>

⁴ <https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/bladder-cancer>

⁵ <https://www.nice.org.uk/guidance/ng2>

⁶ Daniltchenko D. Long-term benefit of 5-aminolevulinic acid fluorescence assisted transurethral resection of superficial bladder cancer: 5-year results of a prospective randomized study. J Urol. 2005;174:2129–33.

⁷ Denzinger S. Clinically relevant reduction in risk of recurrence of superficial bladder cancer using 5-aminolevulinic acid-induced fluorescence diagnosis: 8-year results of prospective randomized study. Urology. 2007;69:675–9.