ARQUER
DIAGNOSTICS

ADXBLADDER
MCM5 ELISA KIT

A non-invasive urine test for the diagnosis and follow-up of bladder cancer

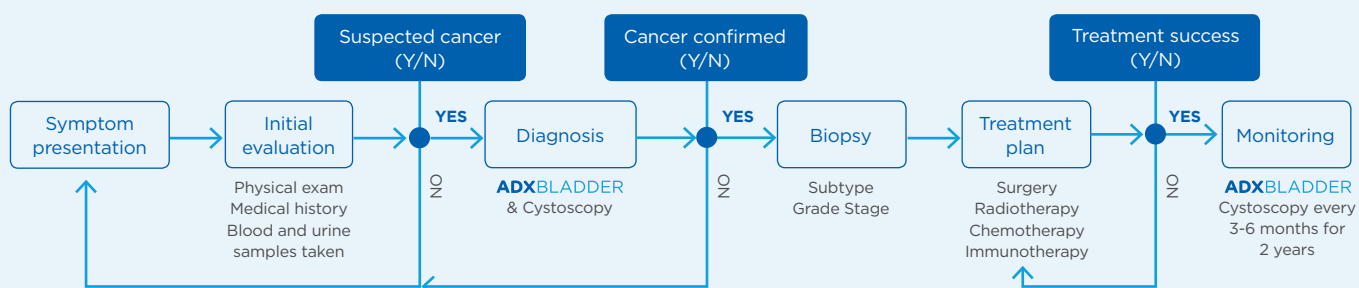Results you can have confidence in.

✓ Simple

Easy-to-use ELISA Test

✓ Reliable

Breakthrough N.P.V. & High Sensitivity

✓ Rapid

Results in 2.5 hours

Where does **ADX**BLADDER fit on the patient pathway?

Suspected cancer (Y/N)

Cancer confirmed (Y/N)

Treatment success (Y/N)

Symptom presentation → Initial evaluation → **YES** → Diagnosis → **YES** → Biopsy → Treatment plan → **YES** → Monitoring

NO — NO — NO

Physical exam
Medical history
Blood and urine
samples taken

ADXBLADDER
& Cystoscopy

Subtype
Grade Stage

Surgery
Radiotherapy
Chemotherapy
Immunotherapy

ADXBLADDER
Cystoscopy every
3-6 months for
2 years

INSPIRING CONFIDENCE

arquerdx.com

The **ADX**BLADDER test is based on the principle of detecting the protein produced by expression of the *MCM5* gene (MCM5). Proteins expressed by *MCM* genes have been linked with accurate cancer detection across all populations for over 20 years.

Normal Epithelium
MCM5 negative cells shed into the urine

Cell differentiation

Stem Cell Compartment

MCM5 is not expressed in fully differentiated cells minimising the potential for false positive results from blood cells or bacterial and inflammatory cells due to urinary tract infections.

Malignancy / Dysplasia
MCM5 positive cells shed into the urine

Arrested differentiation
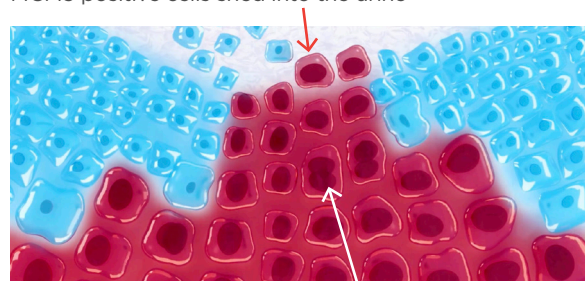
When a bladder tumour is present MCM5 positive cells are shed into the urine where they can be sensitively detected by **ADX**BLADDER.

Bladder Cancer Diagnosis
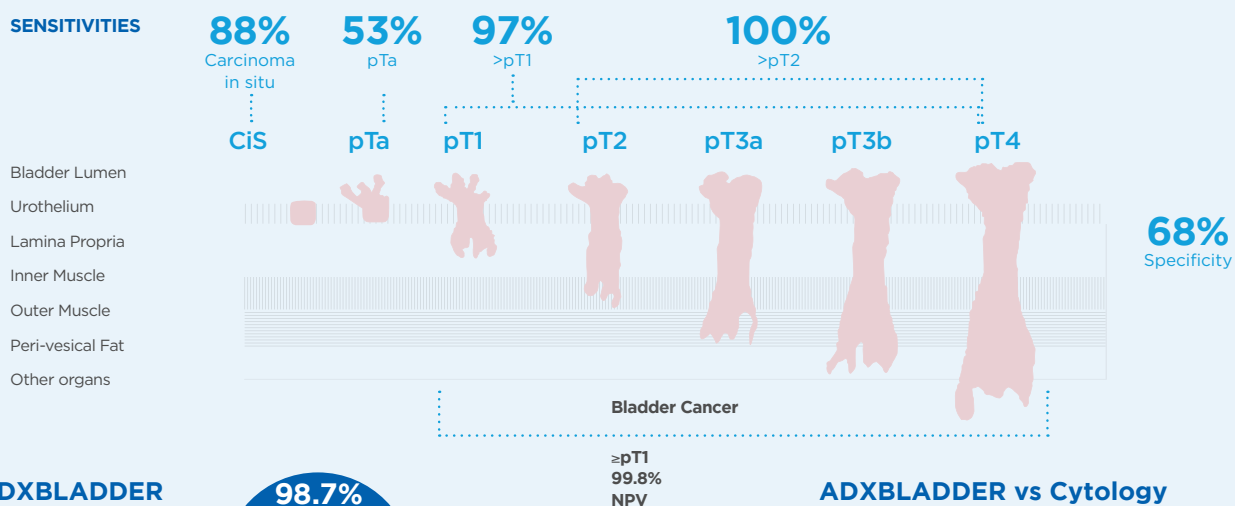
Study Population
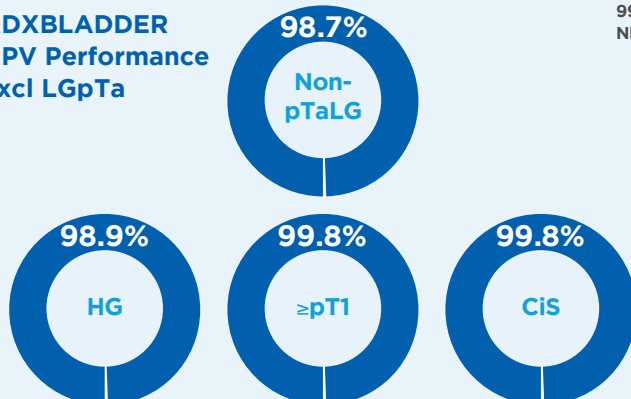### 856
patients with visible and non-visible haematuria

Study Sites
- Sunderland Royal Hospital
- Charing Cross Hospital
- Cumberland Infirmary
- West Cumberland Hospital
- Ninewells Hospital
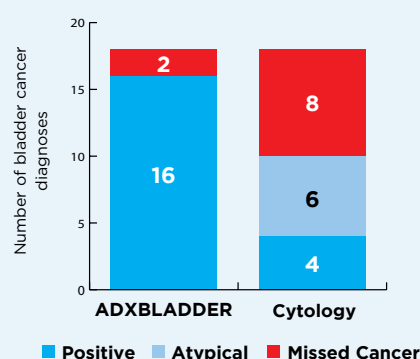- Southampton General Hospital
- The James Cook University Hospital

SENSITIVITIES

88%	53%	97%	100%
Carcinoma in situ	pTa	>pT1	>pT2

CiS pTa pT1 pT2 pT3a pT3b pT4

Bladder Lumen
Urothelium
Lamina Propria
Inner Muscle
Outer Muscle
Peri-vesical Fat
Other organs

68% Specificity

Bladder Cancer

≥pT1 99.8% NPV

ADXBLADDER NPV Performance excl LGpTa

98.7% Non-pTaLG

98.9% HG

99.8% ≥pT1

99.8% CiS

ADXBLADDER vs Cytology

Number of bladder cancer diagnoses

ADXBLADDER: Positive 16, Missed Cancer 2
Cytology: Positive 4, Atypical 6, Missed Cancer 8

■ Positive ■ Atypical ■ Missed Cancer

Bladder Cancer Follow Up
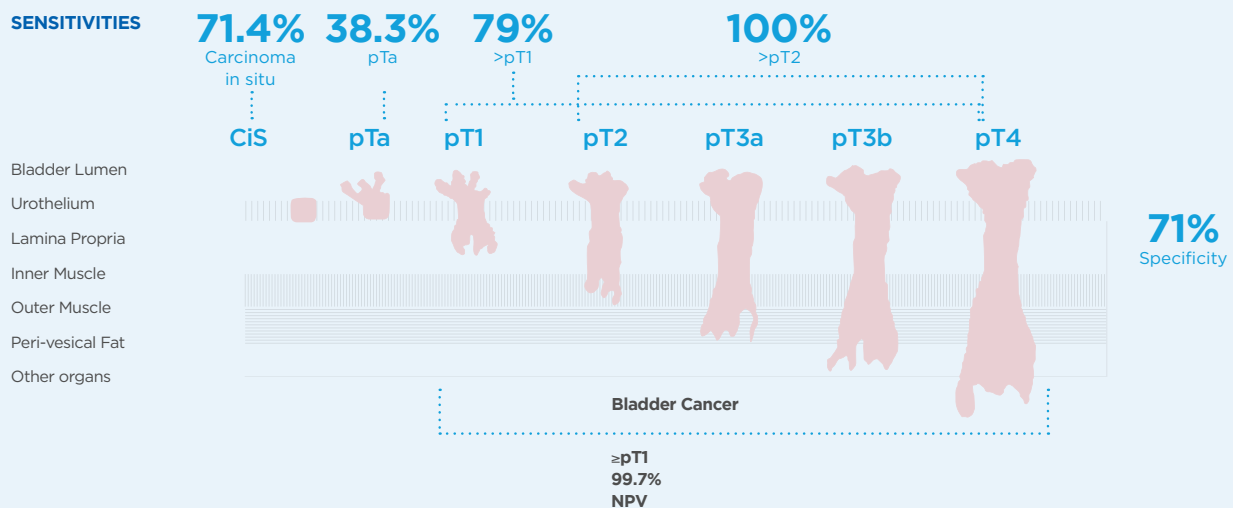
Study Population

1718

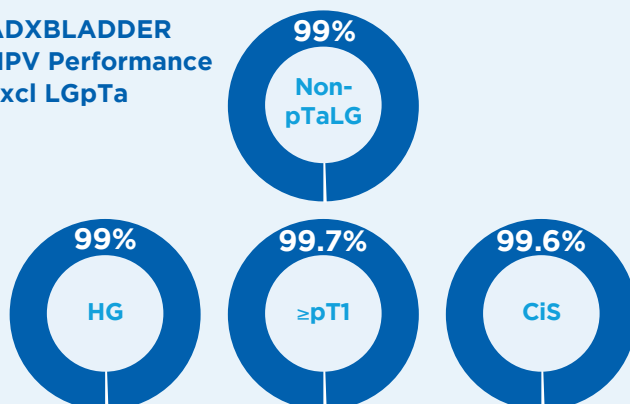**Patients recruited for follow-up cystoscopy**

Study Sites

- **Sunderland Royal Hospital, UK**
- **Ospedale Molinette, Turin, IT**
- **Universita' Policlinico Milano, IT**
- **Hôpital Pitié-Salpétrière, Paris, FR**
- **Southampton General Hospital, UK**
- **Fundacio Puigvert, Barcelona, ES**

- **Cumberland Infirmary, UK**
- **West Cumberland Hospital, UK**
- **University Hospital of North Tees, UK**
- **Radboud University Medical Centre, NL**
- **King's Mill Hospital, UK**
- **Pinderfields Hospital, UK**
- **York Hospital, UK**
- **James Cook University Hospital, UK**

- **Hôpital Edouard Herriot, Lyon, FR**
- **Freeman Hospital, UK**
- **Scunthorpe General Hospital, UK**
- **Princess Alexandra Hospital, UK**
- **Ninewells Hospital, UK**
- **Charing Cross Hospital, UK**
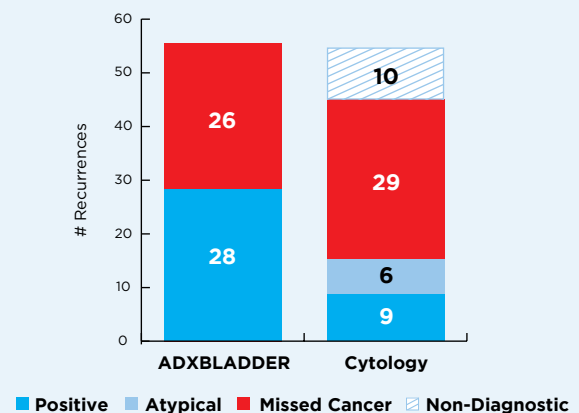- **Barnsley Hospital, UK**

SENSITIVITIES

71.4% Carcinoma in situ	**38.3%** pTa	**79%** >pT1		**100%** >pT2		
CiS	pTa	pT1	pT2	pT3a	pT3b	pT4

Bladder Lumen
Urothelium
Lamina Propria
Inner Muscle
Outer Muscle
Peri-vesical Fat
Other organs

71% Specificity

Bladder Cancer

≥pT1
99.7%
NPV

ADXBLADDER NPV Performance excl LGpTa

- **99%** Non-pTaLG
- **99%** HG
- **99.7%** ≥pT1
- **99.6%** CiS

ADXBLADDER vs Cytology for all tumours

ADXBLADDER	Cytology
Missed Cancer: 26	Non-Diagnostic: 10
Positive: 28	Missed Cancer: 29
	Atypical: 6
	Positive: 9

Recurrences (y-axis)

■ Positive   ■ Atypical   ■ Missed Cancer   ▨ Non-Diagnostic

ADXBLADDER

All the reagents required to prepare and run samples for analysis by manual or automated ELISA

- One x 96 microwell plate of 12, 8 microwell strips coated with mouse monoclonal anti-MCM5 antibody
- Wash solution, 20x concentrate
- Anti-MCM5 antibody-HRP conjugate
- TMB substrate reagent
- Stop solution
- Lysis buffer/ Negative Control
- Positive Control

Expiry 24 months

Product Code MC5001B

ADXCONTROL-B

2mL ready-to-use recombinant MCM5 protein

ADXCONTROL-B is an external control reagent to be used with the Arquer Diagnostics ADXBLADDER (MC5001B) test kit only. It is intended to verify the test is performing correctly and provide a means for day-to-day or batch-to-batch reproducibility of ADXBLADDER.

Product Code CN5001B

ADXLYSIS

1 x 25mL Lysis buffer / Negative Control

ADXLYSIS is intended to be used in the processing of urine samples which will be tested using the Arquer Diagnostics ADXBLADDER (MC5001B) test kit.

For sites who process samples remotely from where they are tested

Product Code LYS0001

ADXWASH

1x 25mL 20x concentrate wash solution

ADXWASH is to be used for washing the microwellls in the Arquer Diagnostics ADXBLADDER (MC5001B) test kit.

For sites who use automation with large dead volumes or priming volumes

Product Code WA0001

References:

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

Roupret M, 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 J Urol. 2020;101097JU0000000000001084. doi:10.1097/JU.0000000000001084

Palou J, et al. PD03-05: Diagnostic performance of MCM5 in the diagnosis of recurrence bladder cancer Results from a large prospective, blinded, multicentric, European study. J of Urology 203:e73-e74 DOI: 10.1097/JU.0000000000000823.05

Bladder cancer: ESMO Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology 00: 1–9, 2018

Williams GH, Stoeber K. Cell cycle markers in clinical oncology. Curr Opin Chem Bio 19, 672-679 (2007).

Stoeber K et al. Diagnosis of genito-urinary tract cancer by detection of minichromosome maintenance 5 protein in urine sediments. JNCI94 (14) 1071 (2002).

CE

BIOKOM
d i a g n o s t y k a

MD 695770

bsi.

UKAS MANAGEMENT SYSTEMS
0003

ISO 13485