



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**

 **Reliable**

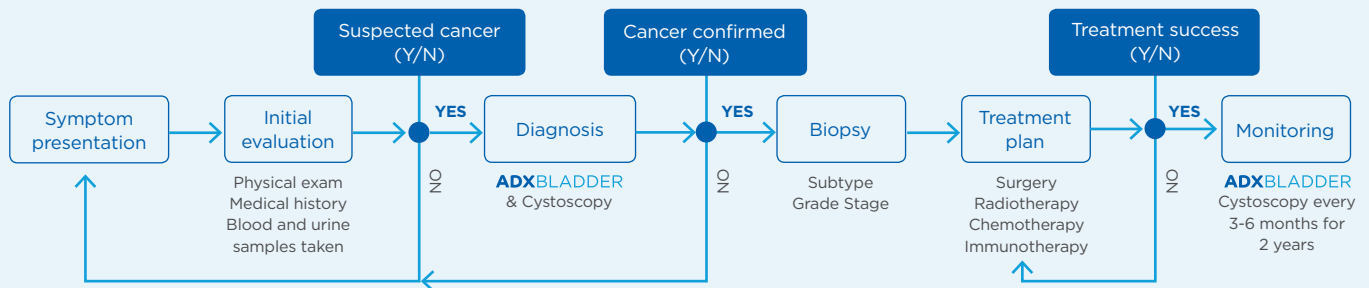
 **Rapid**

**Easy-to-use
ELISA Test**

**Breakthrough
N.P.V. & High
Sensitivity**

**Results in
2.5 hours**

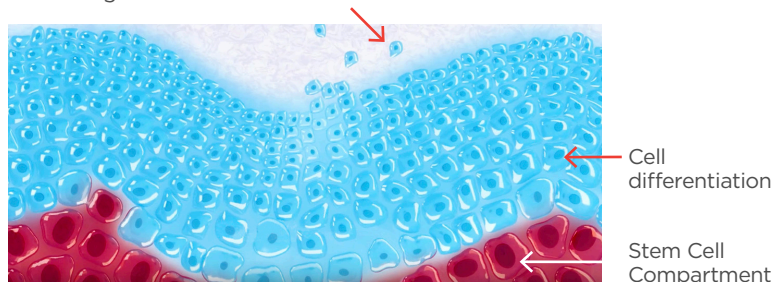
Where does **ADXBLADDER** fit on the patient pathway?



The **ADXBLADDER** 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

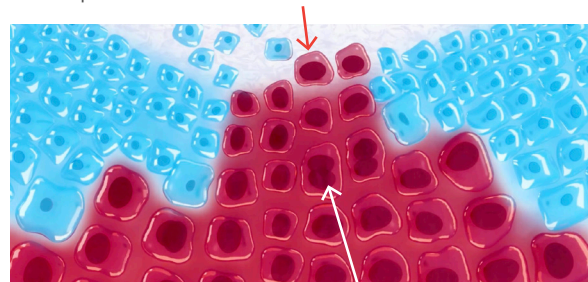
MCM5 negative cells shed into the urine



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



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

Bladder Cancer Diagnosis

Study Population

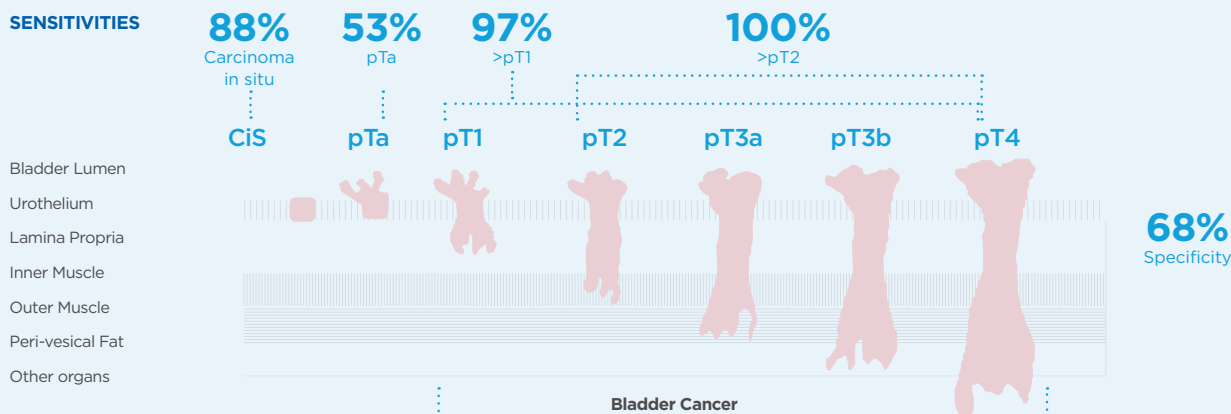
856

patients with visible and non-visible haematuria

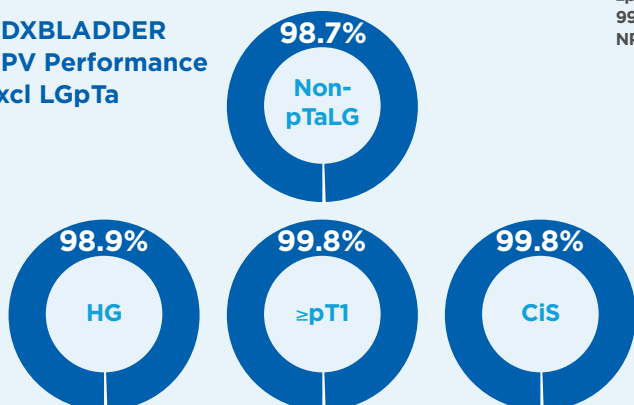
Study Sites

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

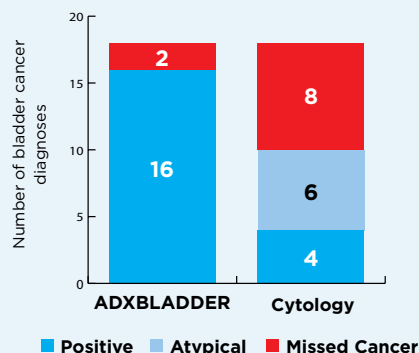
SENSITIVITIES



ADXBLADDER NPV Performance excl LGpTa



ADXBLADDER vs Cytology



Bladder Cancer Follow Up

Study Population

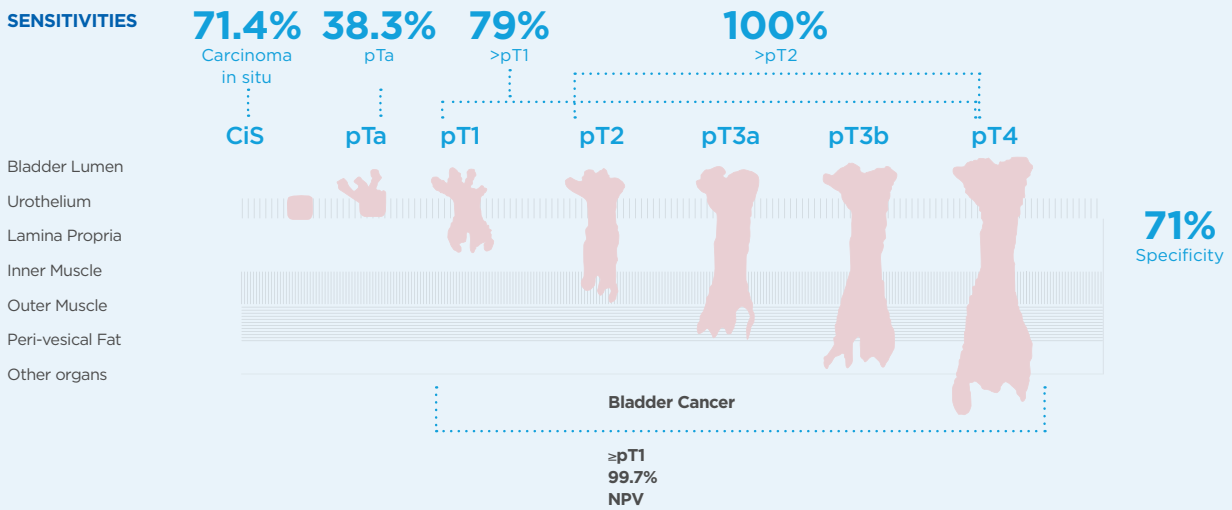
1718

Patients recruited for follow-up cystoscopy

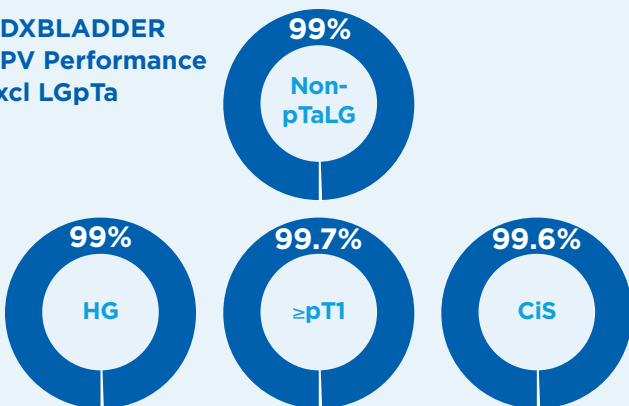
Study Sites

- Sunderland Royal Hospital, UK
- Ospedale Molinette, Turin, IT
- Università' Policlinico Milano, IT
- Hôpital Pitié-Salpêtrière, 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

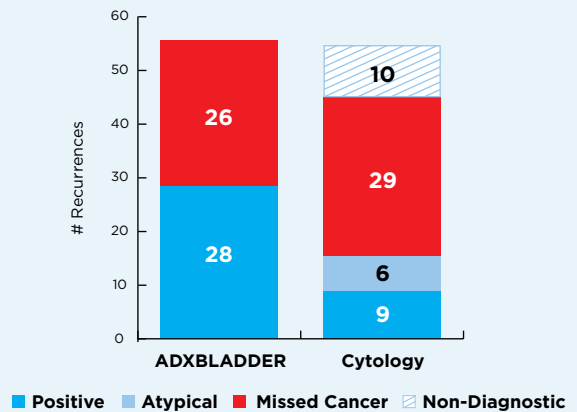
SENSITIVITIES



ADXBLADDER NPV Performance excl LGpTa



ADXBLADDER vs Cytology for all tumours





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 microwells 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).



MD 695770



ISO 13485

LOCAL DISTRIBUTOR



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