



# 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**

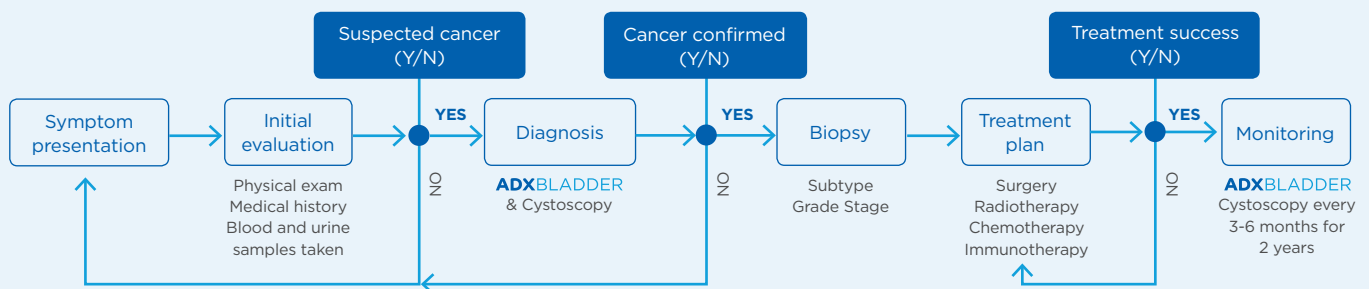
 **Rapid**

**Easy-to-use  
ELISA Test**

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

**Results in  
2.5 hours**

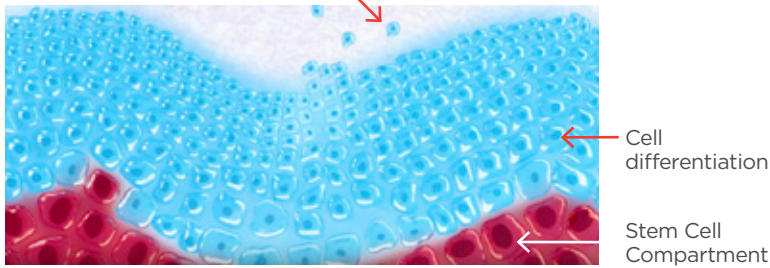
## Where does **ADXBLADDER** fit on the patient pathway?



**ADXBLADDER** testing is based on the principles of MCM5 protein expression. MCM proteins have been linked with accurate cancer detection across all populations for over 20 years.

**Normal Epithelium**

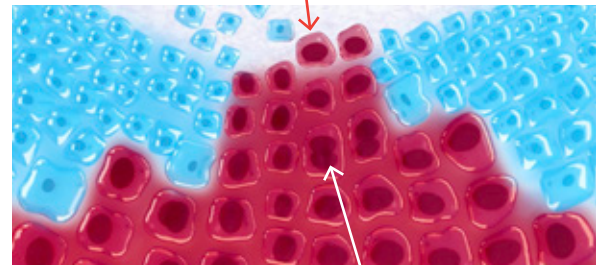
MCM5 negative cells shed into the urine



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

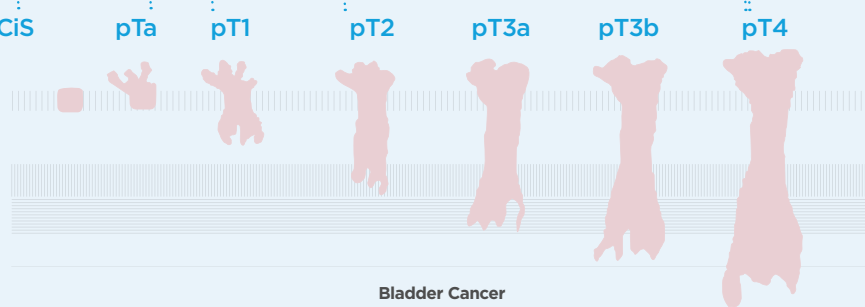
**Study Sites**

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

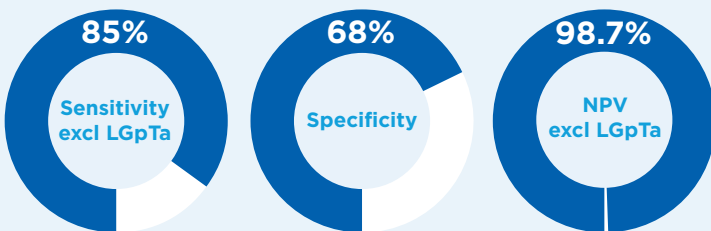
**SENSITIVITIES**

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

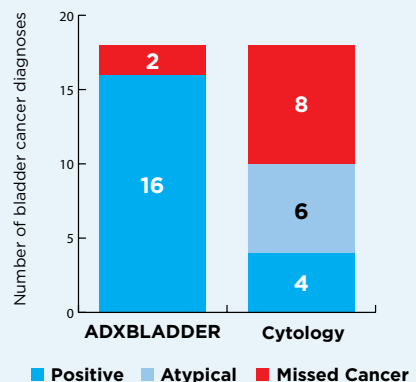
- Bladder Lumen
- Urothelium
- Lamina Propria
- Inner Muscle
- Outer Muscle
- Peri-vesical Fat
- Other organs



**ADXBLADDER Performance excl LGpTa**



**ADXBLADDER vs Cytology**



# Bladder Cancer Follow Up

## Study Population

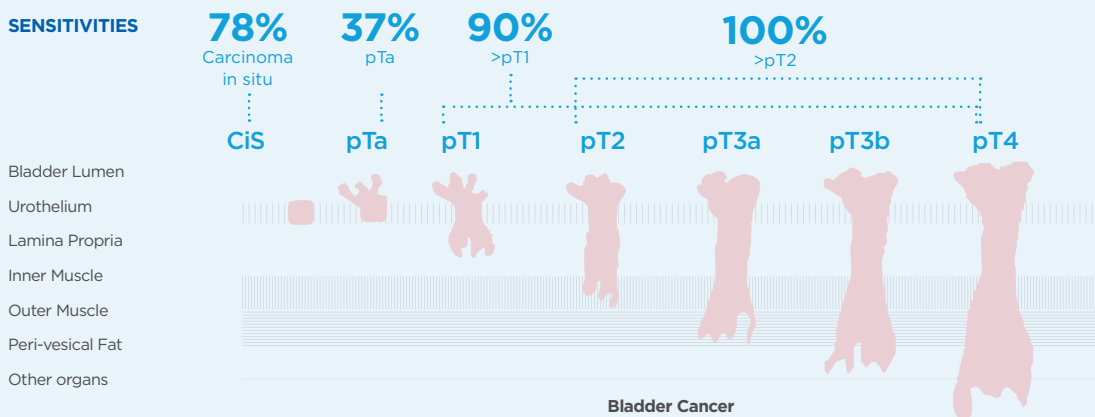
# 1192

Patients  
undergoing  
follow-up  
cystoscopy

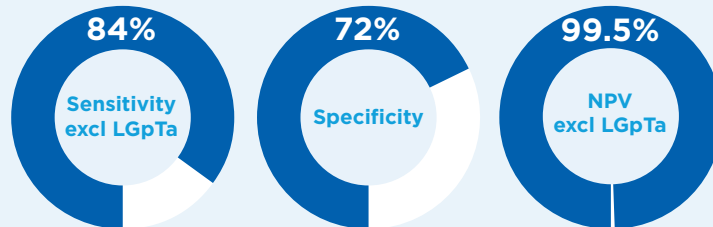
## Study Sites

- 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

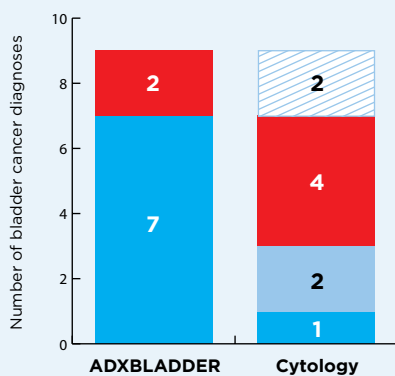
## SENSITIVITIES



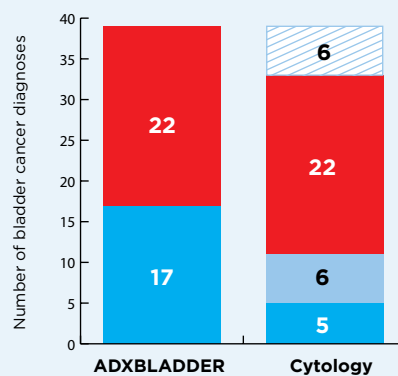
## ADXBLADDER Performance excl LGpTa



## ADXBLADDER vs Cytology excl LGpTa tumours



## ADXBLADDER vs Cytology for all tumours



■ Positive ■ Atypical ■ Missed Cancer ▨ Non-Diagnostic

■ 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 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>

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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