

A comprehensive, genetic, laboratory developed test for identifying ALL stages of bladder cancer

**GALEAS™ / BLADDER**

DETECT | REPORT | MONITOR

# Bladder cancer causes >200K deaths globally each year

	UK	Europe	APAC	USA
Hematuria cases*	1,000,000	10,000,000	20,000,000	9,000,000
Cystoscopies*	110,000	2,030,000	2,080,000	900,000
Bladder Cancer cases	11,000	203,000	208,000	90,000

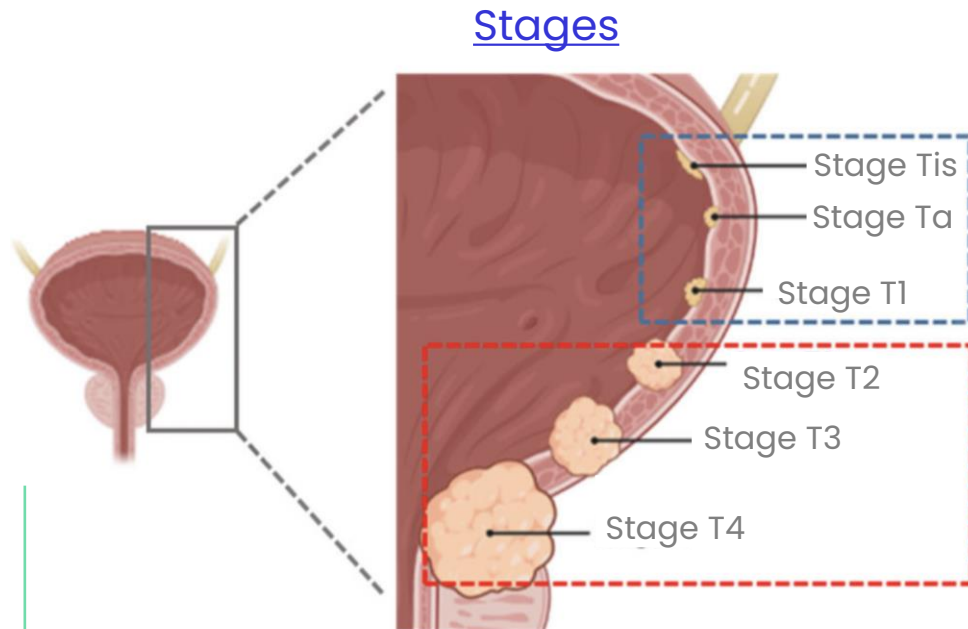
- 535,000** People living with bladder cancer in the USA (compared to 371,000 lung cancer)
- 70%** Of bladder cancer cases are lower grade **non-muscle invasive disease** (NMIBC) and require active surveillance for 5 year to life. 70% will recur within two years.
- 30%** Of cases are **muscle invasive disease** (MIBC) of which 50% progress/ die within 5 years.

BUT early detection can significantly impact survival

Early diagnosis results in >80% survival at 5 years compared to <10% late diagnosis.

# Stages of Bladder cancer

Two "types" of bladder cancer (BC)



Higher spreading probability worse prognosis

## Stages

## Grades

- G1: well differentiated
- G2: moderately differentiated
- G3: poorly differentiated

## NMIBC

- Tis: non-invasive
- Ta: non-invasive
- T1: tumor invades inner lining and connective tissue

## MIBC

- T2: tumor invades muscle
- T3: tumor invades perivesical fat and lymph nodes
- T4: tumor spreads to lymph nodes and other organs

## Non Muscle Invasive (NMIBC)

- Accounts for 75% of BC
- High recurrence rate (60%-70%)
- Low progression rate (20%-30%)
- High 5-year survival (96%)

**Treatment :** BCG/Mytomicin C

## Muscle Invasive (MIBC)

- Accounts for 25% of BC
- Low 5-year survival (45%)
- 50% progression post curative surgery

**Treatment :** Surgery, Radiotherapy, Chemotherapy (cisplatin), Immunotherapy

# Blood in the urine is best clinical indicator of bladder cancer

For a very long time, hematuria (or blood in the urine) has been known to be the most common symptom of bladder cancer:



## But hematuria can be due to many things, not just bladder cancer

### For example:

- ^ Bladder infection
- ^ Stones in the kidneys or bladder
- ^ Inflammation of the kidneys (nephritis)
- ^ Urinary tract injuries
- ^ Blood disorders (e.g. sickle cell disease, clotting disorders, anticoagulant and anti-platelet drugs)
- ^ Other causes, including less common infections (e.g. TB, schistosomiasis)

In fact **only 10%** of all patients presenting with hematuria will actually have bladder cancer .

## How do healthcare providers currently identify bladder cancer?

**Firstly**, a simple dipstick test is most commonly used to test for two types of hematuria:

- Visible (*macro haematuria*)
- Non-visible (*micro haematuria*)

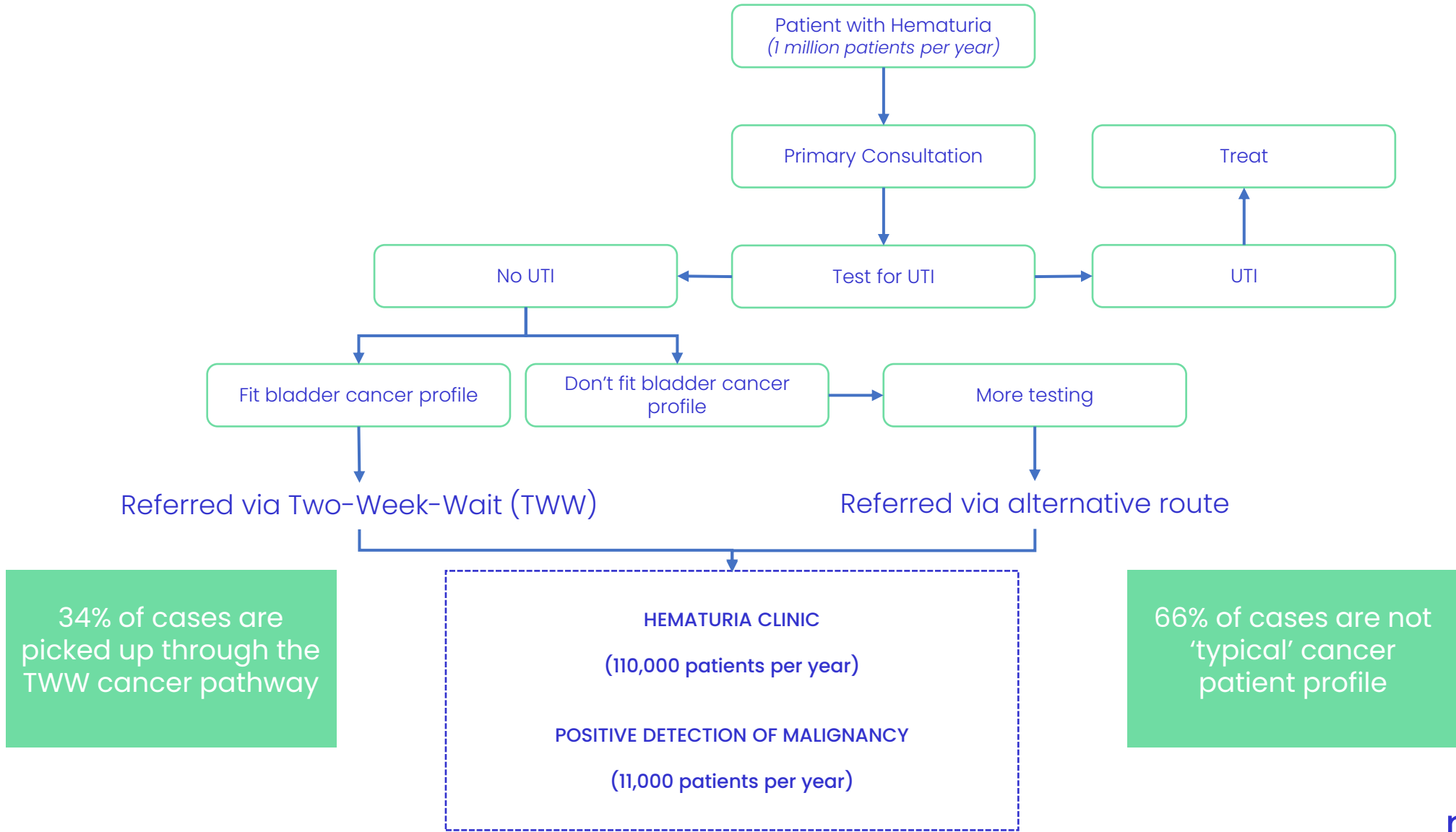
**Secondly**, patients are tested for a urinary tract infection (UTI).

**Thirdly**, patients who test negative for UTI are referred by doctors to a hematuria clinic to check to see if they have cancer.

The current standard of care to identify cancerous cells is a visual inspection in the bladder – an often painful, invasive, hospital-based procedure called a cystoscopy.



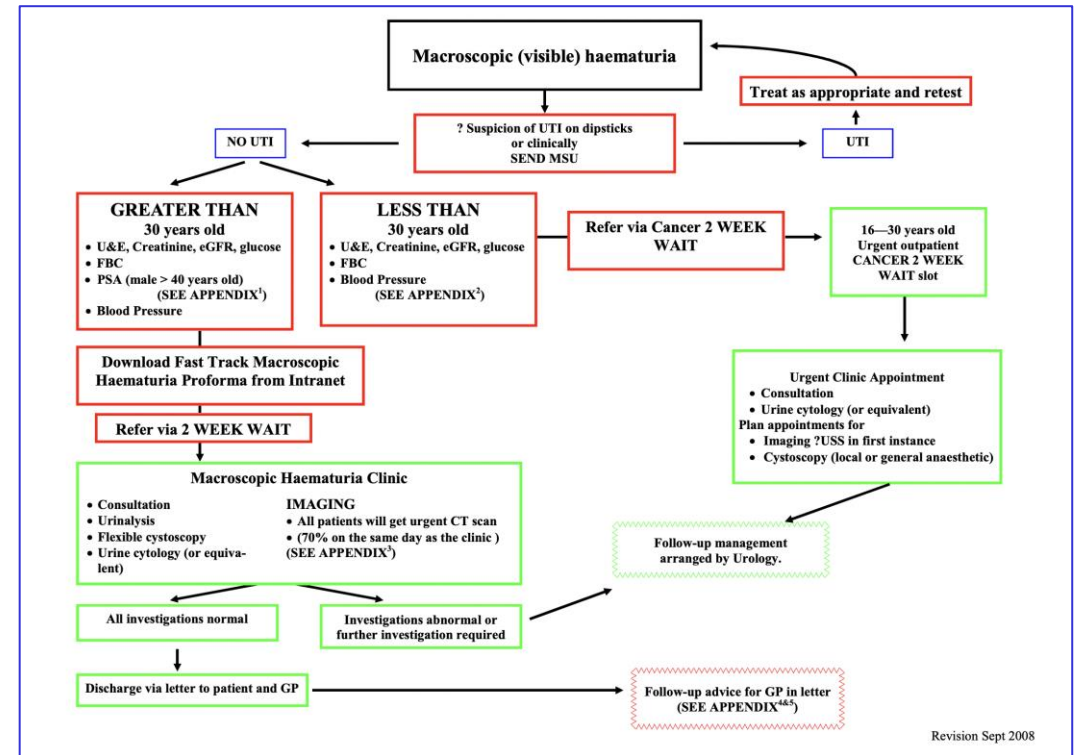
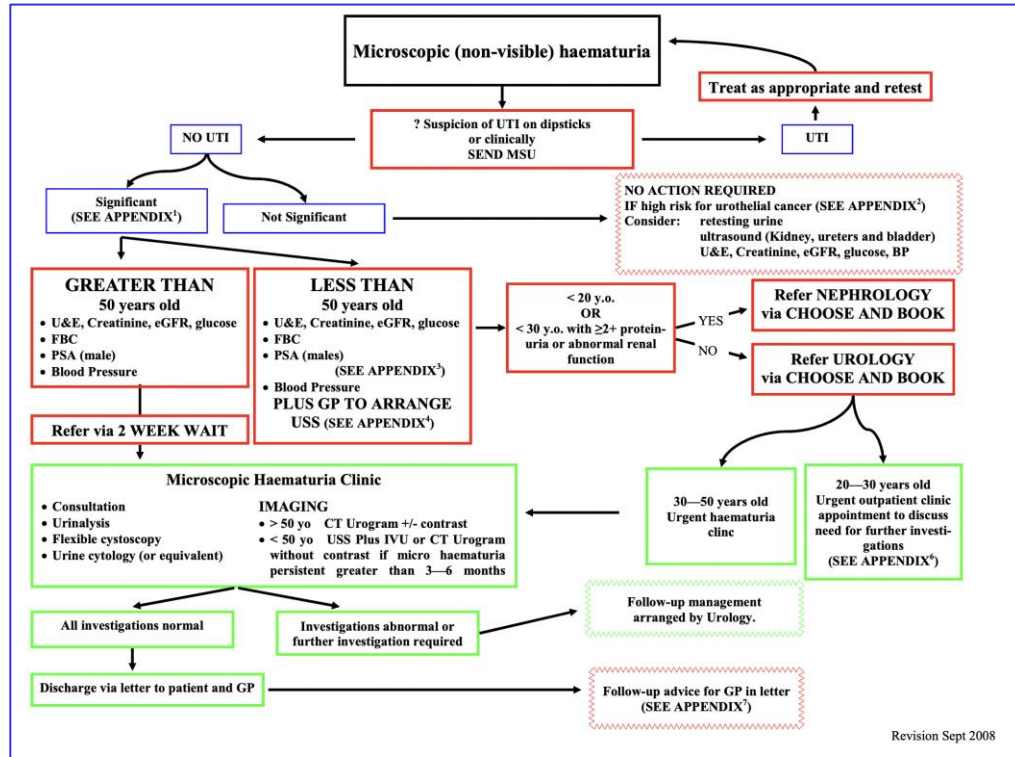
# Current UK NHS Hematuria Care Pathway\*



\*Simplified representation. For actual pathway see next slide.



# Current UK NHS Hematuria Care Pathway





## Why is the current standard of care failing patients?

I have had bladder cancer 4 times. The cystoscopy is so invasive, uncomfortable and embarrassing I actually dread it for weeks before.

NHS patient, commenting on a CR-UK blog post regarding the Nonacus Bladder cancer test

- ^ It is at best uncomfortable, at worst painful and invasive
- ^ It is inconvenient as it requires a hospital visit
- ^ It costs the healthcare provider time and money (£88M\* per year in the UK)
- ^ Is not without complications
- ^ Sensitivity and specificity is operator dependant.

AND

- ^ 90% of patients referred don't actually need it

*\* Cost of cystoscopy only (NHS Tariff £330), plus staff time and ancillary costs for £470. Does not represent the full pathway.*

**How can Doctors assess which patients referred with blood in their urine have bladder cancer and need surgery ...**

**...without sending thousands of patients for painful invasive cystoscopy tests?**

# Molecular Triage - Reducing the Burden



Patient with hematuria

Primary Consultation

Confirmed hematuria

110,000\*

Hematuria clinic

110,000\*



11,000\*

Confirmed by cystoscopy

Molecular TRIAGE

Urine Test

Detection of bladder cancer from DNA in a urine sample

110,000\*

Positive

Negative

11,000\*

99,000\*

Ca. 99,000 Avoided Cystoscopies per year (UK only)

\*= No. of patients based on UK figures

## Introducing GALEAS™ Bladder

### **A comprehensive, laboratory developed, genetic test for identifying all stages of bladder cancer from a urine sample**

- ^ Allows patients to provide a sample in the comfort of their own home. No hospital visits, no painful procedure.
- ^ Offers equivalent sensitivity and specificity to cystoscopy.
- ^ Reduces the number of unnecessary cystoscopies reducing costs and resource burden on clinics.
- ^ Leverages targeted next generation sequencing chemistry to accurately detect somatic mutations from 23 genes in over 96% of bladder cancer cases.

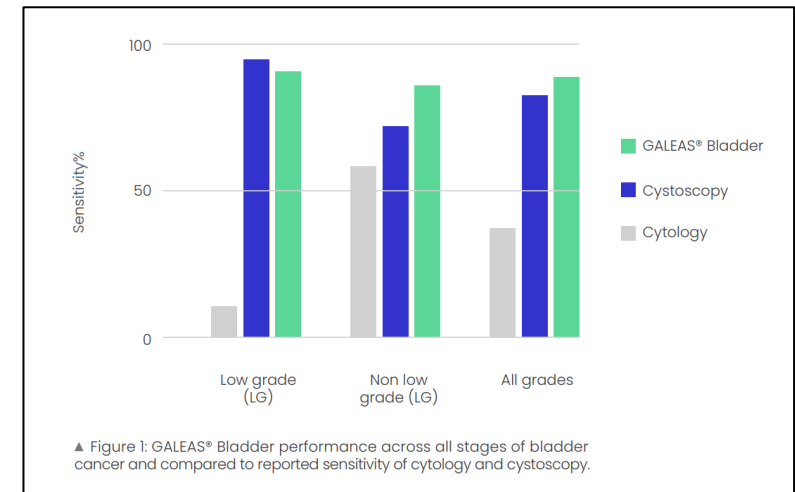
**GALEAS™ / BLADDER**

**DETECT | REPORT | MONITOR**

# GALEAS™ Bladder: Performance Data

- ^ Validated in ~770 urine samples from 3 UK clinical cohorts
  - ^ 382 positive bladder cancer cases
  - ^ 388 negative i.e. no cancer at the time of cystoscopy

	Sensitivity	Specificity	PPV	NPV
<b>pTa</b>	86%	86%	75%	93%
<b>T1</b>	95%	86%	66%	99%
<b>T2+</b>	89%	86%	60%	97%
<b>G1</b>	76%	86%	47%	96%
<b>G2</b>	92%	86%	67%	97%
<b>G3</b>	92%	86%	78%	95%
<b>NMIBC</b>	89%	86%	83%	92%
<b>MIBC</b>	89%	86%	60%	97%



- Equivalent sensitivity and specificity to cystoscopy across all grades and stages.
- Reducing cystoscopies by ~90%

## References

Svatek RS, Hollenbeck BK, Holmäng S, Lee R, Kim SP, Stenzl A, Lotan Y. The economics of bladder cancer: costs and considerations of caring for this disease. *Eur Urol.* 2014 Aug;66(2):253–62. doi: 10.1016/j.eururo.2014.01.006. Epub 2014 Jan 21. PMID: 24472711.

Zheng C, Lv Y, Zhong Q, Wang R, Jiang Q. Narrow band imaging diagnosis of bladder cancer: systematic review and meta-analysis. *BJU Int.* 2012 Dec;110(11 Pt B):E680–7. doi: 10.1111/j.1464-410X.2012.11500.x. Epub 2012 Sep 18. PMID: 22985502.

# GALEAS™ Bladder: from urine sample to test results

The test consists of four components



## Urine Collection Device

**Product Name:** Urine GALEAS™  
Urine Collection Device  
**Product code:** PRE\_GAL\_UCD

**Description:** Urine collection in preserver tubes for safe delivery to lab

### Steps:

1. Doctor/Clinician complete a test requisition form.
2. Doctor/Service lab provide patient with collection device.
3. Patient uses device and posts preserver tubes to service lab
4. Service lab scans tube into LIMS system and sends sample for gDNA extraction



## gDNA Extraction kit

**Product Name:** GALEAS™ Bead Xtract: Urine gDNA 96 sample  
**Product code:** PRE\_GAL\_BXG\_96

**Description:** Magnetic, bead-based automatable extraction of gDNA from urine cell pellet

### Steps:

1. Service lab spins urine sample and collects cell pellet
2. Service lab follows protocol to extract gDNA

*NB. DNA concentration and yield must be of suitable quality to progress to next step.*



## DNA Library Prep and Capture kit

**Product Name:** GALEAS™ Bladder Kit  
**Product Code:** NGS\_GAL\_BCP\_FR\_96\_(A,B,C,D format)

**Description:** Library preparation and hybridisation and capture kits for targeting SNVs associated with bladder cancer

### Steps:

1. Service lab prepares libraries using extracted gDNA
2. Service lab pools libraries and capture the targeted regions for sequencing
3. DNA library is sequenced using Illumina sequencers



## Patient Report

**Product Name:** GALEAS™ Bladder Analysis  
**Product code:** NGS\_GAL\_GBA

**Description:** Analysis software for generating report based on variant profile

### Steps:

1. Service lab analyses sequencing data through GALEAS bioinformatic pipeline
2. Positive or Negative patient report is generated (*either PDF or JSON format*)
3. Report submitted to Urologist
4. Urologist organises patient consultation.

# GALEAS™ Bladder Urine Collection Device

- ^ **An intuitive collection device**
  - ^ Flat packed ensures collection device is fit for purpose and not damaged when received by user
  - ^ Less storage and shipping space required reducing postage costs
  - ^ Easy assembly and intuitive use ensures good sample taking process and return rates
- ^ **50ml Falcon tube**
- ^ **Order with test**
  - ^ Dispatch to patient is responsibility of service/LDT laboratory
- ^ **LIMS tracking - Unique ID barcode on tube provides options:**
  1. Use unique tube ID barcode and associate with patient or
  2. Add specific patient ID barcode for sample tracking





## GALEAS™ Bladder: Urine Bead Xtract gDNA

**gDNA is extracted from urinary cell-pellets**

- ^ Simple, magnetic bead-based protocol
- ^ Optimised for >20ng of cell-pellet genomic DNA
- ^ Quick and easy workflow
- ^ Supports manual or automated preparation of 1-96 samples in a single batch



# GALEAS™ Bladder Kit

## Library Prep and Hybridization and Capture kits

- ^ GALEAS™ branded kits
  - specific GALEAS™ Bladder only control
- ^ 96 sample format only
- ^ Optimised for 20ng of cell-pellet genomic DNA
- ^ Quick and easy workflow – automation protocol available
- ^ Preparation of 1-96 samples in a single batch
- ^ Tracking SNPs and control regions included



# Comprehensive NGS panel

## Biomarkers were identified by Dr Rik Bryan and Dr Doug Ward at Birmingham University UK

- ^ NGS sequencing panel that targets promoter and exonic regions of 23 of the most relevant genes associated with bladder cancer.
- ^ Identified by a combination of publicly available data and deep exome sequencing
  - Exome studies were performed on Caucasian populations
- ^ The panel have been shown to accurately detect somatic mutations in over 96% of bladder cancers in over 770 clinical samples.
- 
- 
- ^ Compatible with all Illumina sequencers
- ^ 384 patient/sample indexes ensure that customer can use the GALEAS® Bladder Cancer panel on the smallest to the largest output sequencers.

AKT1	ERBB2	NRAS
BRAF	ERBB3	PIK3CA
C3orf70	ERRC2	RHOB
CDKN1A	FBXW7	RXRA
CDKN2A	FGFR3	SF3B1
CREBBP	HRAS	TERT (promoter)
CTNNB1	KDM6A	TP53
ELF3	KRAS	

# GALEAS™ Software – Cloud based, end to end solution for bioinformatics

- ^ Bulk upload of sequencing data (FASTQ files) via simple application; no minimum sample number
- ^ Automated 'sample to report' analysis pipeline, requiring no specialist training to interpret data
- ^ Simple report – 'Yes' or 'No' to likely presence of Bladder cancer
- ^ Detailed report of somatic variants identified
- ^ Report available as .pdf or .JSON and sent directly to service lab
- ^ Download batches of results
- ^ Reports on failed samples

GALEAS™/BLADDER  
DETECT | REPORT | MONITOR

## GALEAS Bladder

<b>Patient ID:</b> Patient281123-2-POS <b>Patient Name:</b> Anon Anon <b>Date of Birth:</b>	<b>Sample ID:</b> N0131 <b>Received:</b> 20/12/2022 <b>Processed:</b> 30/11/2023 <b>Report Date:</b> 04/12/2023 14:58 <b>Sample Type:</b> Urine Pellet	<b>Clinician:</b> Dr Bob Loblaw <b>Address:</b> Coombs Ford Stowmarket Ipswich IP145QR UK	<b>Customer:</b> Nonacus <b>Address:</b> Not provided
---	--	--	--

### Result Summary: **Positive**

A positive test result indicates that, at the time of GALEAS Bladder testing, cancer associated variants were detected and there is a high likelihood that cancer is present.  
Appropriate clinical follow up is required to confirm a clinical diagnosis.

### Variant Details

Gene	HOVSc	VAF
TERT	NA	2.5%

### Test Description

GALEAS Bladder data, generated on over 770 patient urine samples, has determined a test positive predictive value (PPV) of 87%, negative predictive value (NPV) of 96% and sensitivity of 89% for the detection of all stages of bladder cancer (ref 1,2,3).

The variants in this test have been validated as part of the GALEAS Bladder Triage Haematuria test only. They have not been validated as predictive markers for disease stratification or for the informing treatment decisions.

### Positive Explanation

GALEAS Bladder tests for somatic variants in selected regions from across 23 genes. The presence of somatic variants in these regions in urinary DNA has been shown to associate with the presence of bladder cancer. The detection of one or more of somatic variants indicates a high likelihood that cancer is present.

### Negative Explanation

GALEAS Bladder negative test result, at the time of testing, is determined by the lack of detection of cancer associated genomic variants in the urine sample, suggesting the presence of bladder cancer is unlikely. However, this does not completely exclude the presence of cancer now or in the future.

### QC Status

PASS

### QC Status Explanation

There was sufficient read depth across the regions to confidently determine a result.

### Test Limitations

The has not been validated as predictive biomarker for disease stratification or for informing treatment decisions.

### Methodology

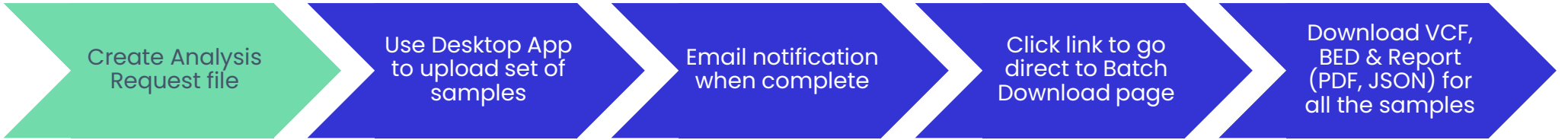
DNA was extracted from urine derived cell pellets and collected using the GALEAS Bladder Home Collection Kit. Extracted genomic DNA subsequently underwent target enrichment using the GALEAS Bladder Target Enrichment protocol with sequencing performed using Illumina sequencing by synthesis chemistry.

Data analysis was performed using the GALEAS Bladder analysis pipeline GALEAS Bladder version 23.12.1

### References

Nonacus Limited,  
Quinton Business Park, Unit 5,  
Ridgeway, Quinton,  
Birmingham B32 1AF,  
United Kingdom.  
Registered No: 3590278

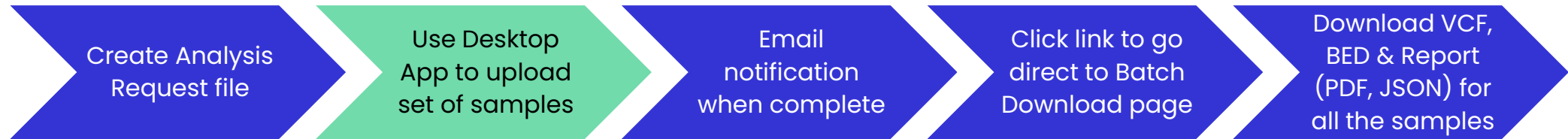
nonacus



AutoSave On | NP002.24 sample run2 • Last Modified: 31m ago | Search | Tim Gilb

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	AA	
	SampleID*	Sample Type*	PanelID*	PatientID*	Sample Date	Sample Description	DNA ng/ml	Elution vol	Plasma	Project	First Name	Surname	DOB	Cancer Diagnosis/Conditions	Patient Comment	ClinicianForename	ClinicianSurname	Clinician Address Line1	Clinician Address Line2	Clinician City	Clinician Country Name	Clinician Postcode	Received Date					
1																												
2	BP006	Urine Pellet	969	Test BP006	01/12/2022	Test BP006				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
3	BP044	Urine Pellet	969	Test BP044	01/12/2022	Test BP044				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
4	BP049	Urine Pellet	969	Test BP049	01/12/2022	Test BP049				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
5	BP122	Urine Pellet	969	Test BP122	01/12/2022	Test BP122				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
6	BP169	Urine Pellet	969	Test BP169	01/12/2022	Test BP169				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
7	BP199	Urine Pellet	969	Test BP199	01/12/2022	Test BP199				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
8	N0067	Urine Pellet	969	Test N0067	01/12/2022	Test N0067				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
9	N0417	Urine Pellet	969	Test N0417	01/12/2022	Test N0417				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
10	N0423	Urine Pellet	969	Test N0423	01/12/2022	Test N0423				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
11	N0477	Urine Pellet	969	Test N0477	01/12/2022	Test N0477				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
12	N870	Urine Pellet	969	Test N870	01/12/2022	Test N870				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
13	N890	Urine Pellet	969	Test N890	01/12/2022	Test N890				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
14	N892	Urine Pellet	969	Test N892	01/12/2022	Test N892				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
15	P017081	Urine Pellet	969	Test P017081	01/12/2022	Test P017081				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
16	s0052	Urine Pellet	969	Test s0052	01/12/2022	Test s0052				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
17	s0130	Urine Pellet	969	Test s0130	01/12/2022	Test s0130				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
18	s0329	Urine Pellet	969	Test s0329	01/12/2022	Test s0329				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
19	s0377	Urine Pellet	969	Test s0377	01/12/2022	Test s0377				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
20	s0430	Urine Pellet	969	Test s0430	01/12/2022	Test s0430				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
21	s0562	Urine Pellet	969	Test s0562	01/12/2022	Test s0562				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
22	s0581	Urine Pellet	969	Test s0581	01/12/2022	Test s0581				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
23	s0601	Urine Pellet	969	Test s0601	01/12/2022	Test s0601				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
24	S0835	Urine Pellet	969	Test S0835	01/12/2022	Test S0835				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
25	s0873	Urine Pellet	969	Test S0873	01/12/2022	Test S0873				NP0002	Anon			Bladder Cancer		Dr Bob	Loblaw	Coombs Ford	Stowmarket	Ipswich	UK	IP145QR	07/12/2022					
26																												
27																												
28																												
29																												
30																												
31																												
32																												
33																												
34																												
35																												
36																												
37																												
38																												
39																												

Sheet1 | Ready | Accessibility: Good to go | 70%



Nonacus Batch Uploader

nonACUS

Tim Gilbert

Single Sample Files Upload | **Batch Upload**

Analysis Request File \*

add file NPD002\_8\_RandD\_sample\_run\_v11.xlsx

Sample Files Folder \*

add file 24 files

Upload

Download ARF Template File

Copyright © 2023 Nonacus. All Rights Reserved. v.1.0.11.0

Download 3rd Party Attribution Document

Name	Date modified	Type	Size
1BP006.1.fastq	09/12/2022 16:50	gz	199,598 KB
1BP006.2.fastq	09/12/2022 15:40	gz	34,224 KB
1BP006.3.fastq	09/12/2022 16:59	gz	207,573 KB
1BP044.1.fastq	09/12/2022 16:35	gz	263,277 KB
1BP044.2.fastq	09/12/2022 15:44	gz	44,973 KB
1BP044.3.fastq	09/12/2022 16:59	gz	268,868 KB
1BP049.1.fastq	09/12/2022 17:00	gz	214,171 KB
1BP049.2.fastq	09/12/2022 15:41	gz	37,594 KB
1BP049.3.fastq	09/12/2022 16:19	gz	220,491 KB
1BP122.1.fastq	09/12/2022 17:03	gz	284,768 KB
1BP122.2.fastq	09/12/2022 15:43	gz	49,347 KB
1BP122.3.fastq	09/12/2022 15:41	gz	294,897 KB
1BP169.1.fastq	09/12/2022 16:28	gz	213,496 KB
1BP169.2.fastq	09/12/2022 15:52	gz	38,442 KB
1BP169.3.fastq	09/12/2022 16:45	gz	219,476 KB
BP199.1.fastq	09/12/2022 16:59	gz	249,248 KB
BP199.2.fastq	09/12/2022 16:11	gz	42,952 KB
BP199.3.fastq	09/12/2022 16:53	gz	257,657 KB
N0067.1.fastq	09/12/2022 15:55	gz	149,792 KB
N0067.2.fastq	09/12/2022 16:07	gz	25,919 KB
N0067.3.fastq	09/12/2022 16:22	gz	154,353 KB
N0417.1.fastq	09/12/2022 16:42	gz	261,281 KB
N0417.2.fastq	09/12/2022 16:10	gz	46,038 KB
N0417.3.fastq	09/12/2022 15:42	gz	273,913 KB
N0423.1.fastq	09/12/2022 16:35	gz	274,364 KB
N0423.2.fastq	09/12/2022 16:09	gz	49,238 KB
N0423.3.fastq	09/12/2022 17:01	gz	286,552 KB
N0477.1.fastq	09/12/2022 16:49	gz	237,851 KB
N0477.2.fastq	09/12/2022 16:06	gz	41,291 KB
N0477.3.fastq	09/12/2022 16:48	gz	246,372 KB
N870.1.fastq	09/12/2022 16:59	gz	249,863 KB
N870.2.fastq	09/12/2022 16:12	gz	44,514 KB
N870.3.fastq	09/12/2022 17:00	gz	263,453 KB
N890.1.fastq	09/12/2022 17:00	gz	310,874 KB
N890.2.fastq	09/12/2022 16:10	gz	54,951 KB
N890.3.fastq	09/12/2022 15:45	gz	325,251 KB
N892.1.fastq	09/12/2022 15:49	gz	247,056 KB
N892.2.fastq	09/12/2022 16:08	gz	44,055 KB
N892.3.fastq	09/12/2022 16:23	gz	260,630 KB

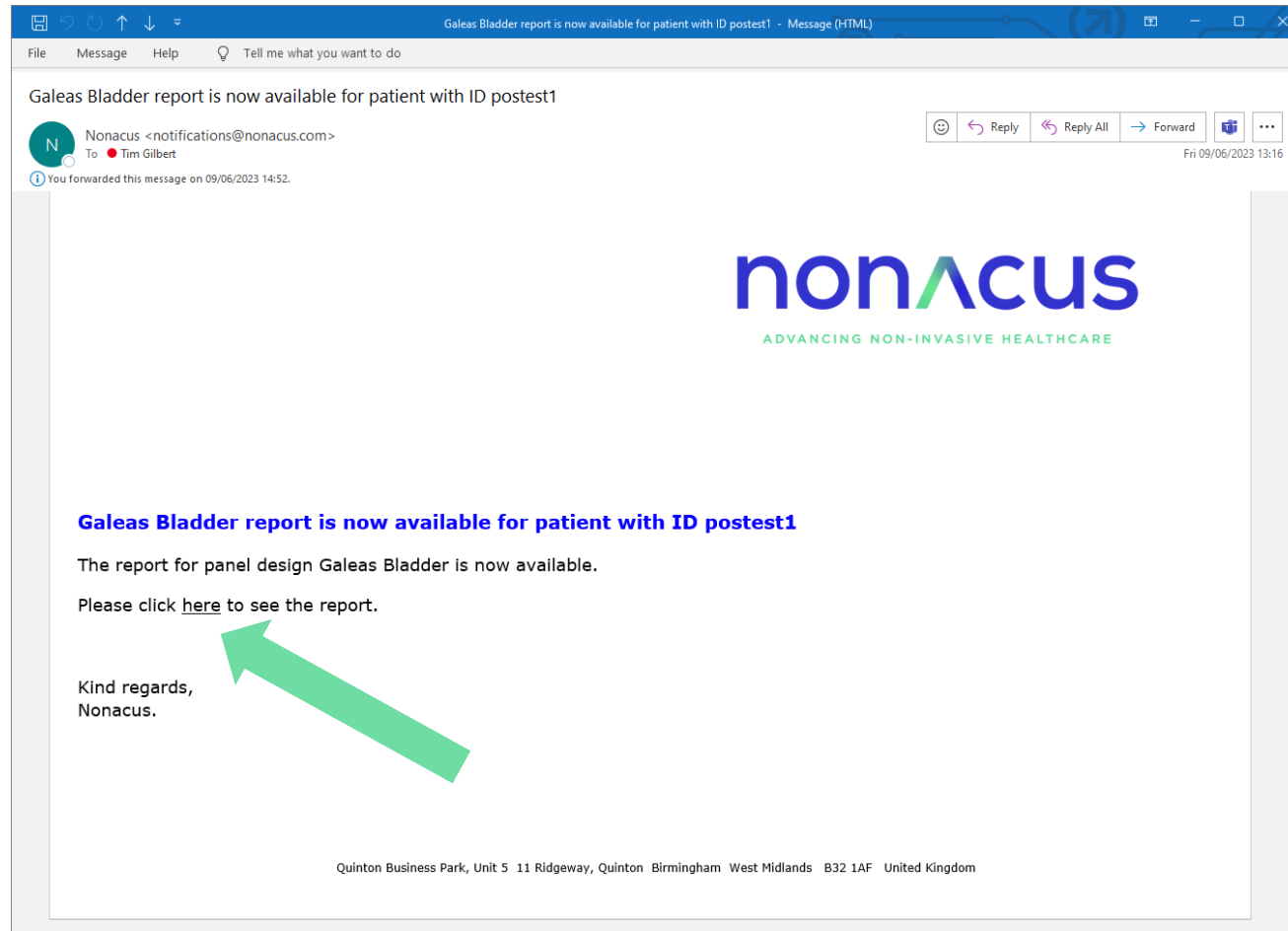
Create Analysis Request file

Use Desktop App to upload set of samples

Email notification when complete

Click link to go direct to Batch Download page

Download VCF, BED & Report (PDF, JSON) for all the samples





Create Analysis Request file

Use Desktop App to upload set of samples

Email notification when complete

Click link to go direct to Batch Download page

Download VCF, BED & Report (PDF, JSON) for all the samples

nonacus

Panel Design Groups Projects **Batch Management** Filter Sets Resources

Batches

Date from: 07/05/2023 Date to: 07/06/2023

Upload File Name	Number of Samples	Date	Name	Batch Status	Sample Status	QC Summary	Action
NPG002_8_RandD_sample_run_v11	2	07/06/2023 09:00:19	Tim Gilbert	completed	0 failed samples		download

5 items per page

Copyright © 2023 Nonacus. All Rights Reserved. [www.nonacus.com](http://www.nonacus.com)

GALEAS/BLADDER  
DETECT | REPORT | MONITOR

**GALEAS Bladder**

Patient ID: NPG002 1123-2-POS  
Patient Name: Aron Aron  
Date of Birth: [Redacted]

Sample ID: N0131  
Received: 20/12/2023  
Processed: 30/11/2023  
Report Date: 04/12/2023 14:58  
Sample Type: Urine Pellet

Clinician: Dr Bob Lobb  
Address: Coombs Ford  
Stowmarket  
Suffolk  
IP14 5QR  
UK

Customer: Nonacus  
Address: Not provided

**Result Summary: Positive**

A positive test result indicates that, at the time of GALEAS Bladder testing, cancer associated variants were detected and there is a high likelihood that cancer is present.

Appropriate clinical follow up is required to confirm a clinical diagnosis.

**Variant Details**

Gene	HDV5	VAF
TERT	NA	2.5%

**Test Description**

GALEAS Bladder data, generated on over 770 patient urine samples, has determined a test positive predictive value (PPV) of 87%, negative predictive value (NPV) of 96% and sensitivity of 89% for the detection of all stages of bladder cancer (st 1,2,3).

The variants in this test have been validated as part of the GALEAS Bladder Triage Haematuria test only. They have not been validated as predictive markers for disease stratification or for informing treatment decisions.

**Positive Explanation**

GALEAS Bladder tests for somatic variants in selected regions from across 23 genes. The presence of somatic variants in these regions in urinary DNA has been shown to associate with the presence of bladder cancer. The detection of one or more of somatic variants indicates a high likelihood that cancer is present.

**Negative Explanation**

GALEAS Bladder negative test result, at the time of testing, is determined by the lack of detection of cancer associated genomic variants in the urine sample, suggesting the presence of bladder cancer is unlikely. However, this does not completely exclude the presence of cancer now or in the future.

**QC Status**

PASS

**QC Status Explanation**

There was sufficient read depth across the regions to confidently determine a result.

**Test Limitations**

The test has not been validated as predictive biomarker for disease stratification or for informing treatment decisions.

**Methodology**

DNA was extracted from urine derived cell pellets and collected using the GALEAS Bladder Home Collection Kit. Extracted genomic DNA subsequently underwent target enrichment using the GALEAS Bladder Target Enrichment protocol with a sequencing performed using Illumina sequencing by synthesis chemistry.

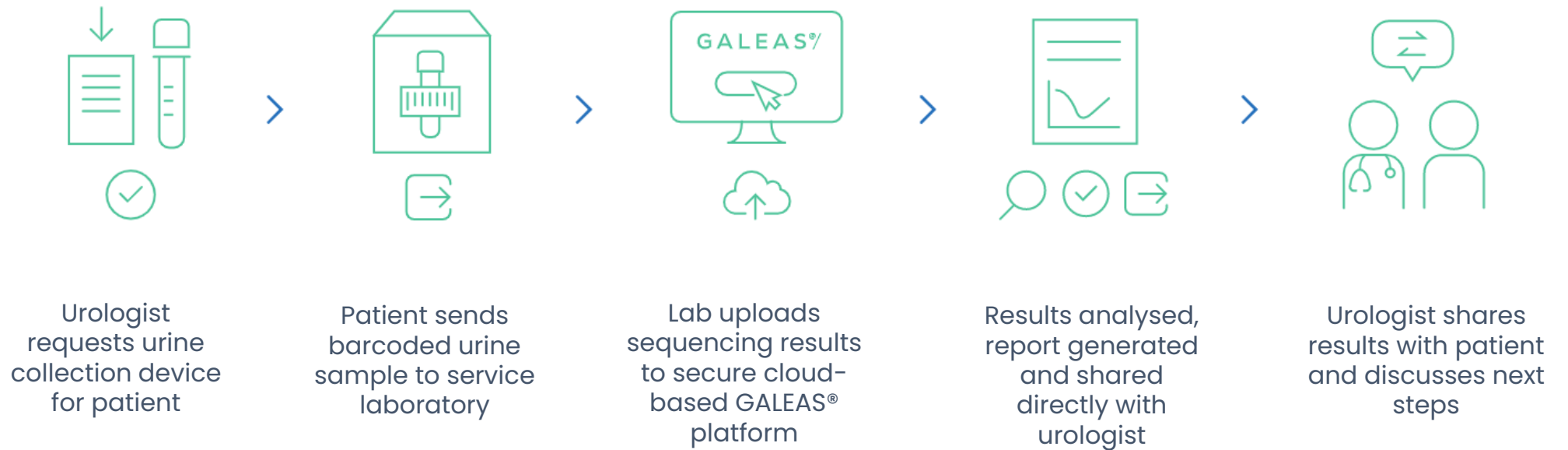
Data analysis was performed using the GALEAS Bladder analysis pipeline GALEAS Bladder version 23.12.1

**References**

Nonacus Limited,  
Cannon Business Park, Unit 5,  
Ridgeway, Queensbury,  
Barnsley, S70 1AF,  
United Kingdom.  
Registered No: 08502729

nonacus

# Workflow



## Support/Controls

### **LDT validation kit**

- ^ Range of positive and negative 'non-cancer' DNA controls
- ^ Full workflow validation coming later

### **Probe for control regions**

- ^ Targeting variants with high VAF
- ^ Included in panel design

### **24 tracking SNPs included in panel design**

# Advantages of GALEAS™ Bladder

## NOW

- ^ NGS assay with high **analytical sensitivity equivalent** to cystoscopy across all stages of bladder cancer (Other genomics tests are able to detect low grade Bladder cancer but not high grade).
- ^ Unlike other genomics tests, NGS panels with a wider range of markers overcome tumour heterogeneity so you are **less likely to miss a cancer**.
- ^ Automated and scalable workflow which can be **run in any NGS capable laboratory**
- ^ **Sample to answer solution** including bioinformatics and reporting
- ^ Part of a **suite of products** for oncology and liquid biopsy

**And in the FUTURE, the broad range of mutations detected by GALEAS™ Bladder will allow:**

## Future advantages of GALEAS™ Bladder

### **Disease stratification**

- ^ We are building the clinical evidence to demonstrate that GALEAS™ Bladder can stratify low- and high-grade bladder cancer which will be key in improving patient outcomes

### **Companion diagnostics**

- ^ Many Pharma companies are using genetic signatures to target therapies E.g. FGFR3 inhibitors

### **Whole care pathway**

- ^ Bladder cancer has one of the highest recurrence rates of any cancer. GALEAS™ Bladder has the potential to be used as an alternative to cystoscopies in monitoring patients for recurrence without changing workflows (see next slide)

# NMIBC Surveillance

GALEAS™ Bladder could be used to reduce the number of cystoscopies in the surveillance pathway by 46%

Discharge from treatment to surveillance



## Current NMIBC surveillance pathway



Cystoscopy



Low Risk	3 Procedures	over 5 years
Intermediate Risk	7 Procedures	over 5 years
High Risk	14 Procedures	over 5 years

Discharge from treatment to surveillance



## SOC Supported with GALEAS Bladder

Molecular Surveillance with  
**GALEAS**™/BLADDER



Cystoscopy



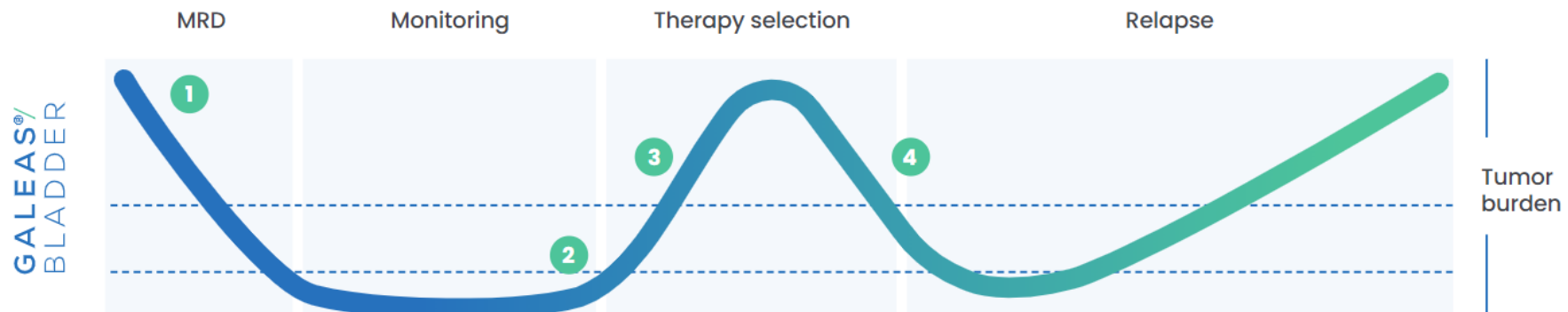
Alternating between cystoscopy and molecular testing (post 3 months) will reduce the number of cystoscopies by

**46%**

# Circulating tumor DNA (ctDNA) guided monitoring for **MIBC**

The unique design of GALEAS® Bladder allows the test to be used as a blood-based test, post surgical resection to detect circulating tumor DNA and monitor treatment response and resistance in MIBC.

- 1 De-escalation of adjuvant therapy post surgical resection in ctDNA negative patients<sup>(3,4)</sup>.
- 2 Earlier identification of disease recurrence or progression.
- 3 Selection of patients for immunotherapy<sup>(5)</sup>.
- 4 Monitoring of treatment response or resistance.



1. Ward et al. Eur Urol Oncol, 2023, Highly Sensitive and Specific Detection of Bladder Cancer via Targeted Ultra-deep Sequencing of Urinary DNA.
2. Ward et al. BJU Int, 2019, Targeted deep sequencing of urothelial bladder cancers and associated urinary DNA: a 23-gene panel with utility for non-invasive diagnosis and risk stratification.
3. Tie et al. NEJM, 2022, Circulating Tumour DNA Analysis Guiding Adjuvant Therapy in Stage II Colon Cancer.
4. Van Drop et al. Nat Med, 2023, High- or low- dose preoperative ipilimumab plus nivoluman in stage III urothelial cancer: the phase 1B NABUCCO trial.
5. Powles et al. Nature, 2021, ctDNA guiding adjuvant immunotherapy in urothelial carcinoma.





# GALEAS™ / BLADDER

DETECT | REPORT | MONITOR