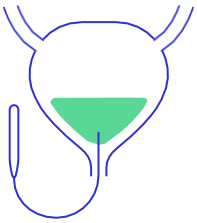
GALEAS™ Bladder
膀胱がんスクリーニング

nonacus
ADVANCING NON-INVASIVE HEALTHCARE

GALEAS/BLADDER
DETECT | REPORT | MONITOR

GALEAS Bladderは、英国バーミンガム大学の研究者とnonacusが共同で開発した膀胱がんスクリーニング検査です。すべての膀胱がんに見られる主要な体細胞変異をターゲットとした次世代シーケンシング（NGS）技術で解析します。Nonacusが開発した超高感度のNGS技術を基に、GALEAS Bladderは尿中に含まれる腫瘍由来gDNAを高感度かつ正確に検出します。



膀胱鏡検査 (1,2)

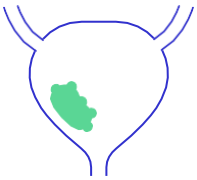
感度 84%
特異度 86%
NPV 96%

1. Chao-Zhe Zhu, et al., J Cancer. 2019, A review on the accuracy of bladder cancer detection methods.
2. Quentin Alimi, et al., Neurourol Urodyn. 2018. Reliability of urinary cytology and cystoscopy for the screening and diagnosis of bladder cancer in patients with neurogenic bladder: A systematic review.

性能データ

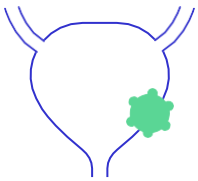
GALEAS Bladderは、3つの臨床コホートから得られた770の尿サンプルにおいて、膀胱がんのすべてのステージとグレードにわたり高い検出感度と特異性を示しました。

	Sensitivity	Specificity	NPV
pTa	86%	86%	93%
T1	95%	86%	99%
T2+	89%	86%	97%
G1	76%	86%	96%
G2	92%	86%	97%
G3	92%	86%	95
NMIBC	89%	86%	92%
MIBC	89%	86%	97%



GALEAS Bladder NMIBC

感度 89%
特異度 86%
NPV 92%



GALEAS Bladder MIBC

感度 89%
特異度 86%
NPV 97%

23 遺伝子 の体細胞変異を検出

770 症例 の臨床コホートの尿サンプルを用いて検証(3,4)

		Grade			Stage		
	Total	1	2	3	pTa	T1	T2+
Cancer	382	62	119	201	187	106	89
Non Cancer	388						

3. Ward et al ; Eur Urol Oncol, 2023, Highly Sensitive and Specific Detection of Bladder Cancer via Targeted Ultra-deep Sequencing of Urinary DNA
4. 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

GALEAS™ Bladderの介入機会
血尿トリアージ

毎年、数十万人の血尿患者が、がんの有無を確認するために膀胱鏡検査を行う医療機関に紹介されています。しかし、これらの紹介のうち、膀胱がんと診断されるのはわずか約10%です。つまり、何十万人もの患者が不必要でありながら痛みを伴う、侵襲的な処置を受け、膨大な医療コストが生じています。
GALEAS™ Bladderは、血尿患者に対する非侵襲的な分子トリアージを提供し、迅速かつ正確に膀胱がんを検出し、診断の効率化を図ります。この検査は700を超える患者の尿サンプルで検証され、膀胱がんのすべてのステージとグレードにおいて高い性能を示しました[1, 2]。

10% の血尿患者のみが膀胱がんと診断

90% の膀胱鏡検査の実施を回避できるため医療機関の負担を軽減

結果報告書

- 陽性もしくは陰性の判定結果
- 検出された体細胞変異の詳細

GALEAS BLADDER
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GALEAS Bladder

Patient ID:
Patient Name:
Date of Birth:
Sample ID:
Received:
Processed:
Report Date:
Sample Type: Urine Pellet
Clinician:
Address:
Customer:
Address:

Result Summary: **Positive - Variants detected**

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	HGVSc	VAF
HRAS	c.35G>T	99.9%
TERT	NA	77.0%

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 [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 of more of somatic variants indicates a high likelihood that cancer is present.

Negative Explanation

A GALEAS Bladder negative test result, at the time of testing, is determined by the lack of detection of cancer associated somatic 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 sequencing performed using Illumina sequencing by synthesis chemistry.

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

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Nonacusは、GALEAS Bladderの開発および性能評価を行っています。
GALEAS Bladderは、 Laboratory Developed Test （LDT）であり、現時点ではCEマークを取得していません。

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代理店記入欄