

GALEAS Bladder

Patient ID: CellLineA_C1
Patient Name:
Date of Birth:

Sample ID: CellLineA_C1_S3
Received: 23/12/2023
Processed: 24/12/2023
Report Date: 24/12/2023 01:18
Sample Type: Urine Pellet

Clinician:
Address: Not provided

Customer: IGL
Address:
Quinton

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	20.7%
TERT	NA	17.2%

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 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

A 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 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

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Registered No: 9590278

GALEAS™/BLADDER

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1. Ward DG, Baxter L, Ott S, et al. Highly Sensitive and Specific Detection of Bladder Cancer via Targeted Ultra-deep Sequencing of Urinary DNA. *Eur Urol Oncol.* 2023;6(1):67-75. doi:10.1016/j.euo.2022.03.005
2. Ward DG, Gordon NS, Boucher RH, et al. Targeted deep sequencing of urothelial bladder cancers and associated urinary DNA: a 23-gene panel with utility for non-invasive diagnosis and risk stratification. *BJU Int.* 2019;124(3):532-544. doi:10.1111/bju.14808
3. Feber A, et al. GALEAS Bladder - A non-invasive biomarker for the detection of bladder cancer. White paper 2023

Genes Covered

Selected regions of the following genes are covered; C3orf70, ERCC2, RHOB, CDKN1A, FBXW7, RXRA, ATK1, ERBB2, NRAS, BRAF, ERBB2, PIK3CA, CDKN2A, FGFR3, SF3B1, CREBBP, HRAS, TERT (promoter), CTNNB1, KDM6A, TP53, ELF3, KRAS