Decipher
BLADDER GENOMIC CLASSIFIER

SAMPLE REPORT

PATIENT REPORT

PATIENT	SPECIMEN INFORMATION	ORDERING PHYSICIAN
Name: **Sample Patient**	Order Date: **--/--/----**	Name: **Sample Physician, MD**
Date of Birth: **--/--/----**	Specimen ID: **----------**	Clinic: **Sample Clinic**
Medical Record **#: ----------**	Specimen Received Date: **--/--/----**	Address: **123 Birch Avenue, Suite A, Anytown, CA 54321**
Sex**: _**	Accession ID: **MC-123456**	

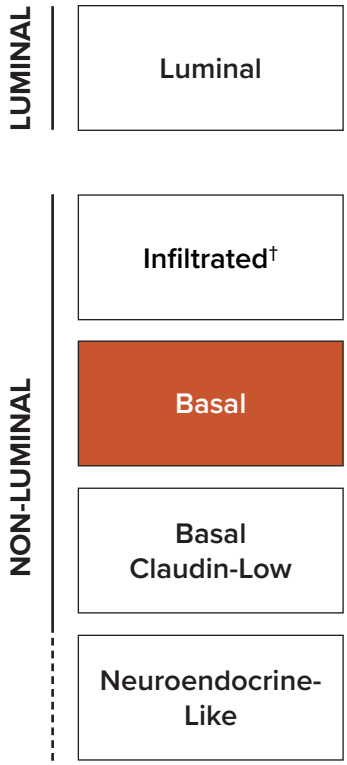
CLINICAL AND PATHOLOGY DETAILS

For reference only, not used in calculation of genomic subtype

Date of Procedure: **01/02/2021**
Specimen Type: **TURBT**

Tumor Type: **Non-Muscle Invasive Bladder Carcinoma**
Tumor Stage: **cT1**

DECIPHER GENOMIC RESULTS



BLADDER CANCER SUBTYPE: BASAL

INTERPRETATION

Non-luminal subtypes of bladder cancer are associated with a less favorable prognosis.[1,2] In comparison with luminal subtype disease:

Risk of Upstaging	Basal subtype bladder cancer is more likely to be non-organ-confined (node-positive and/or pT3 or greater) at radical cystectomy.[1]

Approved By:

E-SIGNED BY NAME, CREDENTIAL ON DATE AT TIME

CLIA ID# 05D2055897
CAP # 8859006
Lab Director: [Lab Director Name, MD]

† Luminal Infiltrated

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SUBTYPE PROBABILITIES

Subtype	Probability
Luminal	5%
Infiltrated†	3%
Basal	87%
Basal Claudin-Low	5%
Neuroendocrine-Like	0%

Luminal. These tumors more frequently have a papillary morphology[2,4-6] with urothelial differentiation and express markers associated with luminal cells (e.g., *FGFR3, GATA3, KRT20*). Luminal tumors may have higher FGFR3 activity and/or *NECTIN4* gene expression.[4,7,8]

Infiltrated†. These tumors tend to show higher levels of stromal and / or immune cell infiltration.[2]

Basal. These tumors are generally poorly differentiated, with higher expression of basal cell markers (i.e., *KRT5/6, KRT14*).[2,4-6]

Basal Claudin-Low. These tumors are an aggressive variant of the basal subtype that shows lower expression of claudin genes.[2,9] These tumors are enriched with immune cells, but their anti-tumor function is actively suppressed. In a retrospective analysis of a Phase 2 clinical trial (NCT02736266), basal claudin-low tumors were found to derive greater benefit from neoadjuvant pembrolizumab as compared to other subtypes.[10,11]

Neuroendocrine-Like. These tumors have a histological appearance consistent with conventional urothelial carcinoma, but have similar gene expression profiles as small cell / neuroendocrine carcinoma (e.g., high *SYP*, *ENO2*).[4-6,12]

† Luminal Infiltrated

FINDINGS FROM CLINICAL STUDIES RELEVANT TO THIS PATIENT

In a clinical study of 206 patients with node-negative, non-metastatic cT1 and cT2 bladder cancer who received radical cystectomy alone, pathological upstaging occurred in 23% of cT1 and 57% of cT2 patients.[1]

- Patients with luminal subtype tumors had lower rates of upstaging to non-organ confined disease (node-positive or pT3 or greater) than those with non-luminal subtype disease.
  - 34% of patients with luminal subtype disease were upstaged at radical cystectomy.
  - 51% of patients with non-luminal subtype disease were upstaged at radical cystectomy.

TEST DESCRIPTION

Hematoxylin and Eosin (H&E) slides are microscopically reviewed by a pathologist to identify the optimal area of tumor that satisfies specimen requirements. The selected region of the tumor is microdissected from surrounding non-neoplastic tissue and submitted for testing. Decipher Bladder Genomic Subtyping Classifier (GSC) uses an oligonucleotide microarray to measure 219 genes to determine the probability of a patient tumor sample belonging to each of five molecular subtypes (Luminal, Luminal Infiltrated, Basal, Basal Claudin-Low, and Neuroendocrine-Like) based on functional molecular pathways. The tumor samples are classified as belonging to the subtype with the highest calculated probability.[1-3,12]

INTENDED USE

Decipher Bladder GSC is intended for use in patients with American Joint Committee on Cancer (AJCC) Stage I to IIIA bladder cancer who are candidates for definitive local therapy such as chemotherapy, radical cystectomy, or chemoradiation, and have not yet received pelvic radiation or chemotherapy for treatment of bladder cancer. Results are intended for use as an adjunct to conventional clinical variables and nomograms currently used in determining treatment for these patients.

REFERENCES

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