DECIPHER BLADDER TURBT

GenomeDx Biosciences
CLIA License # 05D2055897

Bladder Test Requisition

CLIENT/PHYSICIAN INFORMATION

Gray highlighted areas are required fields

A

PATIENT INFORMATION

B

Patient Name (Last, First) _____ DOB ____/____/____ (Month / Day / Year) ☐ Male ☐ Female

Address _____ City _____ State ____ ZIP _____ Primary Phone ____-____-____ Alternative Phone ____-____-____

MRN/Patient ID # _____ Email _____

Ethnicity: ☐ White (non-Hispanic) ☐ White (Hispanic) ☐ Black/African ☐ Asian ☐ Unknown ☐ Other _____

BILLING INFORMATION

Please provide a copy of both sides of the insurance cards and/or a copy of the patient demographics sheet - Gray highlighted areas are required fields

C

Billing Type: ☐ Private Insurance ☐ Medicare ☐ Patient ☐ Other _____ **Select ICD-10 Code:** _____ Date of Discharge ____/____/____

☐ **BILL TO INSURANCE** ☐ **Medical Necessity Established** ☐ C67.9 Malignant neoplasm of bladder, unspecified ☐ Other _____

Primary Insurance _____ Name of Insured _____ Relationship to Patient _____ Subscriber ID # _____ Group # _____

Secondary Insurance _____ Name of Insured _____ Relationship to Patient _____ Subscriber ID # _____ Group # _____

PATHOLOGY/SPECIMEN INFORMATION

Please attach pathology report (required for testing)

Gray highlighted areas are required fields

D

Laboratory _____

Telephone ____-____-____ Fax ____-____-____

Please return block(s) to: Address _____

City _____ State ____ ZIP _____

Telephone ____-____-____ Fax ____-____-____

Submitting Pathologist _____

Primary Histology Type:
☑ Urothelial/Transitional Cell Carcinoma
Select if present:
☐ Squamous Differentiation ☐ Glandular Differentiation
☐ Micropapillary ☐ Other

Lymph-Vascular Invasion:
☐ Not Identified ☐ Present ☐ Indeterminate ☐ Not Reported

Tumor Type: *(Check all that apply)* ☐ Muscle Invasive Carcinoma ☐ Non-Muscle Invasive Carcinoma ☐ Carcinoma In-Situ

Tumor Grade: ☐ Low Grade ☐ High Grade

Specimen Type: ☑ TURBT *(TURBT used for radical cystectomy decision)* Date of TURBT ____/____/____ (Month / Day / Year) Specimen ID # _____ Number of Blocks _____ Slides _____ Other _____

AUTHORIZATION

E

I confirm that this test is medically necessary and results will be used for treatment decisions and medical management for the patient. I hereby authorize testing and an informed consent has been obtained. I confirm that I have on file the patient's assignment of benefits authorizing benefits to be paid to ancillary service providers such as GenomeDx Biosciences. I authorize GenomeDx to release information provided by me to process the claim for this service. As part of the Decipher testing, additional genomic information will be collected and provided upon patient request as **research use only (RUO) data**. Please read the reverse side under Decipher GRID® for details.

Print Name _____ Date ____/____/____ (Month / Day / Year) **SIGNATURE** _____

Additional Physicians Requiring Results - Name _____ Telephone ____-____-____ Fax ____-____-____

DECIPHER TESTING

Gray highlighted areas are required fields

F

DECIPHER BLADDER TURBT

Clinical History: *Check all that apply*

Prior Diagnosis of Non-Muscle Invasive Bladder Cancer (NMIBC): ☐ Yes ☐ No Evidence of Distant Metastasis: ☐ Yes ☐ No

Prior Intravesical Therapy: ☐ Yes ☐ No If Yes: ☐ BCG ☐ Chemotherapy ☐ Other _____

Pre-Decipher Treatment Recommendations:

☐ Immediate radical cystectomy (RC)
☐ Neoadjuvant chemotherapy followed by RC, specify regimen _____
☐ Chemoradiotherapy, specify regimen _____
☐ Other _____

Lab use only

PLEASE FAX TO: 855-324-2768 OR EMAIL TO: orders@genomedx.com

GENOMEDX

10355 Science Center Dr., Suite 240
San Diego, CA 92121
888-792-1601
customersupport@genomedx.com

Decipher® Requisition Form Instructions

A. **Client/Physician Information** – Verify contact information. Provide correct information if missing or incorrect.

B. **Patient Information** – Enter patient name and date of birth as they are required to perform the test. Patient address information is necessary for billing purposes. If you are providing patient information with a copy of a face sheet, you must still enter patient name and date of birth.

C. **Billing Information** – Please indicate the billing type. If patient has Medicare, please enter the date of discharge. The ICD-10 diagnosis codes must be defined for the most detailed level of specificity available. Please refer to your ICD-10 manual for a complete listing.

C67.0	Malignant neoplasm of trigone of bladder	C67.1	Malignant neoplasm of dome of bladder	C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder	C67.4	Malignant neoplasm of posterior wall of bladder	C67.5	Malignant neoplasm of bladder neck including internal urethral orifice
C67.6	Malignant neoplasm of ureteric orifice				
C67.7	Malignant neoplasm of urachus	C67.8	Malignant neoplasm of overlapping sites of bladder	C67.9	Malignant neoplasm of bladder, unspecified.

Select the party responsible for payment of the Decipher test. GenomeDx will submit claims to all private insurance, Medicare and other government plans for insured patients.

D. **Pathology/Specimen Information** – Enter pathologist name, specimen information, and pathology laboratory contact information. The requested information is required in order to run the Decipher test. Ensure a copy of the TURBT pathology report or surgical pathology report is provided along with the requisition form.

E. **Authorization** – Please sign, date and fax or email the test requisition form to GenomeDx Biosciences Laboratory to the fax number provided.

ATTENTION: Signing or submitting this form constitutes a certification of the following:

a. With respect to tests reimbursed by Medicare, Medicaid or other third party payers, the Decipher test is medically necessary and the results will be used in addition to other clinical information in the management of the patient's condition.
b. If the ordering physician is not the treating physician, the ordering physician confirms that the treating physician has deemed the Decipher test medically necessary and the results will be used in addition to other clinical information in the management of the patient's condition.

F. **Decipher Testing** – Please provide the requested clinical history: Prior Diagnosis of Non-Muscle Invasive Bladder Cancer (NMIBC), Evidence of Distant Metastasis, Prior Intravesical Therapy and Pre-Decipher Treatment Recommendations: Immediate Radical Cystectomy (RC), Neoadjuvant Chemotherapy followed by RC (specify regimen), Chemoradiotherapy (specify regimen) and Other (specify).

Indications for Decipher

- Specimen Type: TURBT (Trans-Urethral Resection of Bladder Tumor)
- Tumor Type: Muscle Invasive Carcinoma
- Primary Histology Type: Urothelial/Transitional Cell Carcinoma
- No evidence of distant metastasis
- No prior neoadjuvant chemotherapy

DECIPHER BY GENOME DX

Decipher® Description

Decipher Genomic Subtyping Classifier (GSC), a microarray gene expression assay, is used to classify formalin-fixed paraffin-embedded (FFPE) bladder tumor samples into one of four molecular subtypes (Luminal, Luminal Infiltrated, Basal, Basal Claudin-Low) based on functional molecular pathways. The GSC has been developed and validated in 305 neoadjuvant chemotherapy and 476 radical cystectomy alone patients from 10 leading cancer centers in North America and Europe. GSC measures RNA expression levels of 149 genes used to calculate multinomial probabilities of the tumor sample belonging to each of the four molecular subtypes. The higher the score, the more certain the sample will belong to assigned subtype. The patient tumor samples are classified as belonging to the subtype with the highest probability. The Decipher GSC molecular subtypes are based on a consensus classification derived from The Cancer Genome Atlas project and other previously published schema. The GSC has AUCs ranging from 0.85 to 0.97 for classifying a tumor sample into one of the four molecular subtypes in two independent validation cohorts (n=558). Results from Decipher Bladder are intended for use by the physician and patient as an adjunct to conventional clinical variables and models currently used for determining prognosis of patients diagnosed with muscle invasive bladder cancer using FFPE TURBT specimens.

DECIPHER GRID BY GENOME DX

Decipher GRID® - RUO DATA

The Decipher technology platform collects up to 1.4 million data points for each patient when the Decipher test is performed. Patients can access their genomic data at any time by requesting it from their ordering physician or contacting GenomeDx directly. The genomic data will be securely stored in the Decipher GRID database, and will be de-identified prior to research use. For more information, visit DecipherGRID.com

Contact Information

Phone: Customer Support Toll-Free: 1-888-792-1601 • US Toll-Free Fax: 1-855-324-2768 • **Web:** GenomeDx.com/DecipherTest.com
Address: GenomeDx Biosciences Laboratory, 10355 Science Center Drive, Suite 240, San Diego, CA 92121

The GenomeDx Biosciences Laboratory is licensed for high complexity testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).