

Complete Form and FAX to: +1 650 569 2081

**SECTION I. ONCOTYPE DX PROSTATE CANCER ASSAY** **STUDY INFORMATION** (If applicable)

**REQUIRED:** Test results will be customized based on risk assessment indicated below. See reverse for NCCN clinical risk criteria.

Patient's NCCN Clinical Risk Assessment\* (Select ONE):

\*NCCN v.3.2012

☐ Very Low ☐ Low ☐ Intermediate

Study Name / Code:

**SECTION II. ORDERING PHYSICIAN**

LAST NAME \_\_\_\_\_  
FIRST NAME \_\_\_\_\_  
PHONE \_\_\_\_\_ FAX \_\_\_\_\_  
E-MAIL \_\_\_\_\_  
INSTITUTION NAME \_\_\_\_\_  
STREET ADDRESS \_\_\_\_\_  
CITY \_\_\_\_\_ PROVINCE \_\_\_\_\_  
POST CODE \_\_\_\_\_ COUNTRY \_\_\_\_\_  
OFFICE CONTACT NAME & E-MAIL \_\_\_\_\_

**ADDITIONAL PHYSICIAN** (Optional)

LAST NAME \_\_\_\_\_  
FIRST NAME \_\_\_\_\_  
PHONE \_\_\_\_\_ FAX \_\_\_\_\_  
E-MAIL \_\_\_\_\_  
INSTITUTION NAME \_\_\_\_\_  
STREET ADDRESS \_\_\_\_\_  
CITY \_\_\_\_\_ PROVINCE \_\_\_\_\_  
POST CODE \_\_\_\_\_ COUNTRY \_\_\_\_\_  
OFFICE CONTACT NAME & E-MAIL \_\_\_\_\_

**PATHOLOGY** (Optional)

LAST NAME \_\_\_\_\_  
FIRST NAME \_\_\_\_\_  
PHONE \_\_\_\_\_ FAX \_\_\_\_\_  
E-MAIL \_\_\_\_\_  
INSTITUTION NAME \_\_\_\_\_  
STREET ADDRESS \_\_\_\_\_  
CITY \_\_\_\_\_ PROVINCE \_\_\_\_\_  
POST CODE \_\_\_\_\_ COUNTRY \_\_\_\_\_  
OFFICE CONTACT NAME & E-MAIL \_\_\_\_\_

**SECTION III. PATIENT**

LAST NAME \_\_\_\_\_  
FIRST NAME \_\_\_\_\_  
DATE OF BIRTH (Day / Month / Year) \_\_\_\_\_  
☐ Male ☐ Female  
MEDICAL NUMBER \_\_\_\_\_  
STREET ADDRESS \_\_\_\_\_  
CITY \_\_\_\_\_  
PROVINCE \_\_\_\_\_  
COUNTRY \_\_\_\_\_ POST CODE \_\_\_\_\_  
E-MAIL \_\_\_\_\_  
PHONE \_\_\_\_\_

**SECTION IV. BILLING** – Please select ONE billing or payment option and complete the information. (See reverse for details.)

1) ☐ INSTITUTION / HOSPITAL (Restricted to contracts on file with GHI.)

2) ☐ INSURANCE (Please attach a copy of insurance card.)

ICD-10 CODE ☐ C61 ☐ Other: \_\_\_\_\_

INSURANCE NAME \_\_\_\_\_

CITY / PROVINCE \_\_\_\_\_ POST CODE \_\_\_\_\_

PATIENT INSURANCE NO. \_\_\_\_\_

PHONE \_\_\_\_\_

STREET ADDRESS \_\_\_\_\_

PRIOR AUTHORIZATION NO. \_\_\_\_\_

3) ☐ CREDIT CARD

OR ☐ WIRE: Please refer to the reverse side of this form for bank account information.

NAME ON CARD \_\_\_\_\_

CARD NO. \_\_\_\_\_ EXPIRY DATE (Month / Year) \_\_\_\_\_

**SECTION V. SPECIMEN INFORMATION (REQUIRED)**

INCLUDE A PATHOLOGY REPORT WITH SPECIMEN SUBMISSION

SUBMITTING DIAGNOSIS: ☐ PROSTATE CANCER

SPECIMEN / CASE NUMBER \_\_\_\_\_

DATE OF COLLECTION (Day / Month / Year) \_\_\_\_\_

**SPECIMEN BARCODE**

☐ OTHER: \_\_\_\_\_



**SECTION VI. PHYSICIAN SIGNATURE & SPECIMEN STATUS**

PHYSICIAN SIGNATURE (Required)

DATE (Day / Month / Year)

X

NAME

Your signature attests that you have read and accept the terms stated on the reverse side. Specifically by signing this form you are stating that *either 1)* the patient meets the criteria stated on the reverse side of this form *OR 2)* if the patient does not meet these criteria, that you have selected the exceptions as they apply or indicated them in the Exception Criteria space below. GHI may contact you should your patient not meet these criteria. **3)** The proper NCCN Clinical Risk Assessment has been selected above.

EXCEPTION CRITERIA (See reverse for definition.)

BLOCK RETURN LOCATION (Leave blank if submitting slides.)	STREET ADDRESS	CONTACT NAME	PHONE
COMMENTS			

CONFIDENTIAL PATIENT INFORMATION

## REQUISITION FORM INSTRUCTIONS

- Online ordering is available at [online.genomichealth.com](http://online.genomichealth.com). For assistance in setting up a Portal Account for online ordering, please contact Customer Service.
- Assay results will be delivered to the Ordering Physician and additional recipients via the secure online portal and/or by fax based on the physicians' report delivery preferences on file at Genomic Health, Inc. (GHI). To establish or change report delivery preferences, please contact Customer Service.
- The result report is based upon GHI's analysis of the submitted specimen and information provided on the Requisition Form. Additional materials or information that may have been submitted with the specimen are not considered in analyzing the specimen or preparing the report.

### ASSAY

- A. Select the appropriate NCCN® Risk Assessment (NCCN v.3.2012).

NCCN clinical risk assessment is required to determine the extent of the clinical experience information to be included in the report for the patient. If the NCCN clinical risk assessment is not provided, a report with clinical experience for all three risk categories (Very Low Risk, Low Risk & Modified Intermediate Risk) will be sent.

NCCN Very Low Risk (Must meet **ALL** of the following criteria):

- Gleason Score  $\leq 6$
- PSA  $< 10$  ng/mL
- Clinical stage T1c
- Fewer than 3 positive biopsy cores,  $\leq 50\%$  involvement in any core
- PSA density  $< 0.15$  ng/mL/g

NCCN Low Risk (Must meet **ALL** of the following criteria):

- Gleason Score  $\leq 6$
- PSA  $< 10$  ng/mL
- Clinical stage T1-T2a

\***Modified** NCCN Intermediate Risk (Must meet **ONE** of the following):

- Gleason Score  $\leq 6$ , AND  
Clinical stage T2b-T2c, OR  
PSA 10-20 ng/mL
- Gleason Score 3+4, AND all of the following:  
Fewer than 4 positive biopsy cores  
Clinical stage T1-T2c  
PSA  $\leq 20$  ng/mL

### ORDERING PHYSICIAN

- A. Complete all lines. Some lines require more than one piece of information. The Ordering Physician should be the physician treating the patient or ordering on behalf of the physician.
- B. The Office Contact for each physician will be contacted for any missing data follow-up or as needed to process the order.
- C. **Additional Physician / Pathology:**  
If another physician is responsible for the care of this patient and has requested a copy of the report, enter the information in the applicable spaces provided under this section.

### PATIENT INFORMATION

Complete all lines. Some lines require more than one piece of information. The Medical Number may not apply for all orders.

### BILLING INFORMATION

- A. Indicate the method of payment for the *Oncotype DX* Cancer Assay.
- B. Payment may be made by providing public or private insurance information, a valid credit card, a wire transfer or by enclosing an international money order.
- Please provide the necessary information for the payment selection where needed.
  - Payment is required prior to reporting unless an institution/hospital contract is on file with GHI.
  - For **credit cards**, the patient should be advised to contact the issuing credit card company to pre-authorize the international charge in order to prevent declined credit card transaction.
  - For **wire transfers**:  
Please remit to: Credit: Bank of America, 530 Lytton Avenue, Palo Alto, CA 94301  
Swift Code: BOFAUS3N For Credit of: Genomic Health, Inc  
Routing/ABA #: 121000358 Account #: 14999 23547  
By order of: "Sending Company Name" or "Patient Name"

### SPECIMEN INFORMATION

- A. Select the appropriate diagnosis.
- B. While GHI laboratory can accept tumor blocks and unstained slides, unstained slides are preferred.
- C. Specimen / Case Number is the specimen identifier given by a hospital storing the tissue and is unique to the patient.
- D. Specimen Barcode labels provided with the *Oncotype DX* Specimen Kit should be placed in this section.
- E. Include a copy of the pathology report with the Specimen Kit box. The pathology report may be used for reimbursement and / or administrative purposes.

### PHYSICIAN SIGNATURE & ATTESTATION

- A. If required by local law, it is the responsibility of the Ordering Physician to obtain consent from the patient to send his private health information to Genomic Health in the United States.
- B. SIGNATURE: Sign and date the Requisition Form and print your name. The signature must be of an Ordering Physician (treating physician or pathologist) or his/her representative.

**NOTE:** Stamped signatures are NOT acceptable.

- B. ATTESTATION: The signature constitutes a certification of the following: (1) the treating physician remains free in his or her medical decisions on how to use the results of the *Oncotype DX* assay for the further management of the concerned patient; (2) the treating physician has obtained in writing the concerned patient's data privacy consent to transmit his personal health data recorded on this Requisition Form to GHI for the purpose of performing the *Oncotype DX* assay and processing this order. (3) potential reimbursement or cost coverage by health insurance carriers

for the *Oncotype DX* assay is generally subject to the regulations applicable in the patient's country of residence; if no reimbursement or cost coverage is available, the patient may be the ultimate payer; (4) the patient meets the criteria defined below unless otherwise indicated in the Exception Criteria field on the reverse side.

GHI will run the assay and report a result unless it determines that the specimen does not have adequate cancer tissue or it determines that the Requisition Form provides insufficient information to perform and report a result.

### Oncotype DX Prostate Cancer Specimen Criteria

- A. If the Requisition Form attestation has been signed and no exception criteria have been entered, you attest that the specimen is from a newly diagnosed and biopsied ( $\leq 6$  months) prostate cancer patient meeting the NCCN Very Low risk, NCCN Low risk, or Modified NCCN Intermediate risk criteria specified in the Assay Section on this page.

If GHI determines that the specimen does not fit the criteria stated above, the patient's test report will indicate, where appropriate, that the clinical interpretation of the assay result is unknown or adjusted. In all cases, it is the treating physician's responsibility to determine whether and how the assay result should be used in determining a treatment plan for that patient.

- B. In some cases additional assessment methods may be used to verify that the specimen meets the criteria for the *Oncotype DX* assay.

### SUBMIT REQUISITION FORM TO GENOMIC HEALTH

- A. Fax the completed, signed Requisition Form to the fax number indicated on the reverse side.

## SPECIMEN INSTRUCTIONS

### SPECIMEN PREPARATION INSTRUCTIONS

GHI is able to accept specimens from most countries outside of the US for the *Oncotype DX* Cancer Assay.

A Customs Declaration is also required for the specimen to be accepted into the United States. A sample Customs Declaration can be found at [oncotypedx.com](http://oncotypedx.com).

*Oncotype DX* Specimen Kits comply with international packaging regulations for diagnostic specimens (IATA 650 Packaging Instruction). Contact Customer Service at the number listed on the reverse side in advance to discuss any special requirements.

- A. For specimen criteria and specimen preparation instructions, visit [oncotypedx.com](http://oncotypedx.com).
- B. Please send either:
- One fixed paraffin embedded tumor block.
  - Eight 5  $\mu$ m serial unstained slides.

**IMPORTANT:** Hand number the serially sectioned slides to indicate the order in which they were cut. Unnumbered slides will be rejected.

- C. Neutral buffered formalin is the preferred fixative. Alternative fixatives are not recommended.
- D. All specimens must be labeled with S-Barcode labels from the Specimen Collection and Transportation Kit for the patient.
- E. Affix a coinciding S-Barcode in the designated area on the Requisition Form.

**NOTE:** Discard any remaining S-Barcode labels and do not use for future submissions.

- F. If you have any questions, please contact customer service at [international@genomichealth.com](mailto:international@genomichealth.com) or call the number listed on the reverse side.

## SHIPPING INSTRUCTIONS

- A. Materials and equipment
- Oncotype DX* Specimen Kit containing the patient specimen, pathology report and *Oncotype DX* Requisition Form.

**NOTE:** All materials listed are included in the *Oncotype DX* Specimen Collection and Transportation Kit. To order additional kits, please email [international@genomichealth.com](mailto:international@genomichealth.com) or call the number listed on the reverse side. Kits cannot be sent to P.O. boxes.

- FedEx® International Airbill pre-printed with Genomic Health shipping information.
  - FedEx® Clinical Pak, Large (a plastic over wrap used to ship the specimen to Genomic Health).
  - FedEx® adhesive airbill pouch for the FedEx® Clinical Pak.
- B. Place the *Oncotype DX* Specimen Kit into the FedEx® Clinical Pak.
- C. Complete the FedEx® International Airbill.
- D. Seal the Clinical Pak by removing the plastic adhesive protector from the white strip and secure.
- E. Check the box on the Clinical Pak indicating that the packaging is in compliance with IATA 650 / CE packaging regulations. GHI has designed the *Oncotype DX* Specimen Collection and Transportation Kit to comply with these packaging regulations.
- F. Complete the FedEx® International Airbill as follows:
- Section 6. Special Handling: Under the question, "Does this contain dangerous goods?" please check "No". The fixed paraffin-embedded (FPE) specimen is noninfectious; thus, it is not classified as a dangerous good.
  - Place the Airbill in the outer sleeve along with 3 copies of the customer declaration and/or commercial invoice.
- G. Contact Genomic Health Customer Service should you need assistance with shipping via FedEx®

**NOTE:**

- To order additional kits, email Customer Service at [international@genomichealth.com](mailto:international@genomichealth.com) or call the number listed on the reverse side.
- Before shipping, make a copy of the Requisition Form and retain it for your records.

NCCN is a registered trademark of the National Comprehensive Cancer Network, which does not endorse any product or therapy.

## FOR ADDITIONAL ASSISTANCE VISIT ONCOTYPEDX.COM