Genomic Health™ | Oncotype DX® Prostate Cancer Assay

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Oncotype DX® Prostate Requisition Form

Complete Form and FAX to: +1 650 569 2081

SECTION I. ONCOTYPE DX PROSTATE CANCER ASSAY

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): ☐ Very Low ☐ Low ☐ Intermediate

*NCCNv.3.2012

STUDY INFORMATION (If applicable)

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**

NAME ON CARD
CARD NO. EXPIRY DATE (Month / Year)

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

SECTION V. SPECIMEN INFORMATION (REQUIRED)

INCLUDE A PATHOLOGY REPORT WITH SPECIMEN SUBMISSION

No substitutions for this assay

SUBMITTING DIAGNOSIS: ☐ PROSTATE CANCER ☐ OTHER: _____

SPECIMEN / CASE NUMBER

DATE OF COLLECTION (Day / Month / Year)

SPECIMEN BARCODE
SXXXXXX

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

GHI008 Rev#20 DEC-2014

CONFIDENTIAL PATIENT INFORMATION

REQUISITION FORM INSTRUCTIONS

- Online ordering is available at 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 ≤ 6
- PSA < 10 ng/mL
- Clinical stage T1c
- Fewer than 3 positive biopsy cores, ≤ 50% involvement in any core
- PSA density < 0.15 ng/mL/g

NCCN Low Risk (Must meet **ALL** of the following criteria):
- Gleason Score ≤ 6
- PSA < 10 ng/mL
- Clinical stage T1-T2a

***Modified** NCCN Intermediate Risk (Must meet ONE of the following):
- Gleason Score ≤ 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 ≤ 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 Onco*type* DX Cancer Assay.

B. Payment may be made by providing public or private insurance insurance information, a valid credit card, a wire transfer or by enclosing an international money order.

1. Please provide the necessary information for the payment selection where needed.
2. Payment is required prior to reporting unless an institution/hospital contract is on file with GHI.
3. 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.
4. 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 Onco*type* 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 Onco*type* 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 Onco*type* DX assay and processing this order. (3) potential reimbursement or cost coverage by health insurance carriers for the Onco*type* 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.

Onco*type* 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 (≤ 6 months) prostate cancer patient meeting the NCCN Very Low risk, NCCN Low risk, or Modified NCCN Intermediate risk criteria specificed 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 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 Onco*type* 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 Onco*type* 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.

Onco*type* 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.

B. Please send either:
1. One fixed paraffin embedded tumor block.
2. Eight 5 µm 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 or call the number listed on the reverse side.

SHIPPING INSTRUCTIONS

A. Materials and equipment
1. Onco*type* DX Specimen Kit containing the patient specimen, pathology report and Onco*type* DX Requisition Form.

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

2. FedEx® International Airbill pre-printed with Genomic Health shipping information.
3. FedEx® Clinical Pak, Large (a plastic over wrap used to ship the specimen to Genomic Health).
4. Fedex® adhesive airbill pouch for the Fedex® Clinical Pak.

B. Place the Onco*type* 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 Onco*type* DX Specimen Collection and Transportation Kit to comply with these packaging regulations.

F. Complete the Fedex® International Airbill as follows:
1. 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.
2. 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 or call the number listed on the reverse side.
- Before shipping, make a copy of the Requisition Form and retain it for your records.

FOR ADDITIONAL ASSISTANCE VISIT ONCOTYPEDX.COM