Oncotype DX® Requisition Form • oncotypeIQ.com

Genomic Health® | oncotypeDX®

Territory	Phone	Fax
Europe, Middle East, Africa	+41-22-715-2900	+41-44-583-787
Canada, Asia Pacific, Latin America	+1-866-662-6897	+1-650-569-2081

For supported local numbers please see back of form or visit www.oncotypeiq.com

Study Information/Code. _____

SECTION I. TEST & CLINICAL INFORMATION

Invasive Breast Cancer

❑ **Oncotype DX Breast Recurrence Score™** for Invasive Breast Cancer Patient

ER STATUS:
- ❑ Positive
- ❑ Negative
- ❑ Inconclusive by IHC
- ❑ Unknown

NODE STATUS:
- ❑ Negative
- ❑ Micromets pNmi (0.2-2.0mm)
- ❑ Positive 1-3
- ❑ Positive 4-9

Ductal Carcinoma in Situ

❑ **Oncotype DX Breast DCIS Score™**

Tumor Size (cm): _____ . _____

Patient Age at Diagnosis:
- ❑ Less than 50 years of age
- ❑ Greater than or equal to 50 years of age

Provide accurate tumor size based on excisional biopsy pathology report. Missing or inaccurate tumor size will impact the risk estimates on the report, and you may be contacted.

Colon Cancer

Important: *Stage (AJCC 6th ed.) and Assay selection informs the results on the report.*

Stage II Patient
(T3 or T4) AND Node Negative
❑ Oncotype DX Colon Recurrence Score™ (for known MMR Proficient tumors)

Stage III A/B Patient
Any T AND 1-3 Positive Nodes
❑ Oncotype DX Colon Recurrence Score™

SECTION II. ORDERING PHYSICIAN

_____ Ordering Physician First Name, Last Name

_____ Phone _____ Fax

_____ Email

_____ Institution

_____ Street Address

_____ City _____ Province

_____ Post Code _____ Country

_____ Office Contact Name & Email

Additional Physician (Optional)

_____ Additional Physician First Name, Last Name

_____ Phone _____ Fax

_____ Email

_____ Institution

_____ Street Address

_____ City _____ Province

_____ Post Code _____ Country

_____ Office Contact Name & Email

Pathology (Optional)

_____ Pathologist First Name, Last Name

_____ Phone _____ Fax

_____ Email

_____ Institution

_____ Street Address

_____ City _____ Province

_____ Post Code _____ Country

_____ Office Contact Name & Email

SECTION III. PATIENT INFORMATION

_____ Patient First Name, Last Name/Patient ID

_____ ❑ Female ❑ Male

DOB (Day/Month/Year)

_____ Medical Record # / Patient # (If applicable)

_____ Street Address, City

_____ _____ _____ Province Postal Code Country

_____ _____ Phone E-Mail

SECTION IV. BILLING AND DIAGNOSIS

Please select ONE billing or payment option and complete the form (See reverse for details.)

_____ _____ Submitting Diagnosis ICD-10 Code

Select one billing option:
1) ❑ **Insurance**
2) ❑ **Institution/Hospital** (Restricted to contracts on file with GHI.)
3) ❑ **Patient**

Please complete below for bill insurance or institution option & attach copy of insurance card.

_____ Insurance or Institution

_____ _____ Patient Insurance Number Insurance Authorization Number

SECTION V. SPECIMEN INFORMATION (Required) — No substitutions for this assay

Specimen Retrieval

❑ 1) Genomic Health to request specimen on my behalf

_____ _____ _____ Location of Specimen Phone Fax

❑ 2) Ordering Physician to request specimen

Multiple Primaries

Is more than one primary tumor being submitted for testing? ❑ Yes ❑ No
Specimens will be processed sequentially as listed below.

Specimen ID/Case Number (Only one specimen is typically required)	Specimen Barcode	Date of Surgery (Day/Month/Year)
1) _____	SXXXXXX	1) _____
2) _____	SXXXXXX	2) _____

SECTION VI. PHYSICIANSIGNATURE & SPECIMEN STATUS

_____ Physician Signature (Required)

_____ Date (Day/Month/Year)

Your signature confirms 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.

Block Return Location: (Leave blank if submitting slides)

_____ _____ _____ Contact Name Phone Address

Specimen Comments/Exception Criteria (See reverse for definition)

GHI288-EU, Rev #1

REQUISITION FORM INSTRUCTIONS

1. Complete all sections of the Requisition Form. Missing information may result in delays in test results.
2. Include the form with the specimen collection kit.
3. Onco*type* DX® results will be delivered to the ordering physician and additional recipients according to the preferences on file at Genomic Health, Inc. (GHI). Online delivery of the report is available as well. For assistance in setting up an Online Portal Account for online ordering or to change your report delivery preference, please contact Customer Service at the number listed on this form. *See additional notes below for further instructions.*

SECTION I. TEST & CLINICAL INFORMATION

1. Select the requested test and enter clinical information where required.
    a. Invasive Breast Cancer patients
        i. Enter the ER Status and Nodal Status of the patient. Please ensure this information is accurate, as it informs the report results.
            1. A specimen submitted for the Oncotype DX® Breast Recurrence Score™ must be estrogen receptor positive (ER+) by either the IHC method used by a referring laboratory or the quantitative RT-PCR method used by GHI. If GHI determines that the submitted specimen is not ER+ by either method, a result will not be reported and the patient / payer will not be billed. The specimen is assumed to be ER+ if no selection is made.
            2. The node status is required to determine the extent of the clinical experience information to be included in the report for your patient. If the node status is not provided, a report with clinical experience for both node negative and node positive specimens will be sent. Additionally, the node status may be required for payor coverage determinations. If the node status is not specified, GHI may use the pathology report, if provided, to determine the node status for reimbursement purposes.
        ii. Result reports will include ER, PR, and HER2 scores.
    b. Ductal Carcinoma In Situ patients
        i. Result reports will include ER and PR scores.
        ii. Provide accurate tumor size and patient age at diagnosis. Missing or inaccurate tumor size or patient age at diagnosis will impact the risk estimates on the report, and you may be contacted.
        iii. The tumor size should be based on the excisional biopsy pathology report. If no residual DCIS was found on the excisional biopsy, use the tumor size determined on the core biopsy pathology report. If the tumor size is not reported, please write "Not Available."
    c. Colon Cancer patients
        i. The use of the test in stage II MMR-Deficient or in Stage III C patients has limited clinical applicability.
2. In some cases, Genomic Health may use additional assessment methods, including confirmatory testing for HER2 status, to verify that the specimen meets the criteria for the Onco*type* DX test.

SECTION II. ORDERING PHYSICIAN

1. 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 patient.
2. The Office Contact for each physician may be contacted for any missing data follow-up or as needed to process the order.
3. **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.

SECTION III. PATIENT INFORMATION

Complete all lines. Some lines require more than one piece of information.
The Medical Record # / Patient # may not apply for all orders.

SECTION IV. BILLING AND DIAGNOSIS

1. Provide the submitting diagnosis of the patient. If the submitting diagnosis does not fit the assay criteria you may be contacted.
2. Indicate the method of payment for the Oncotype DX Cancer Assay.
3. Provide public or private insurance information.
4. If patient is selected, a Genomic Health representative will contact the patient to obtain payment.

SECTION V. SPECIMEN INFORMATION (REQUIRED)

1. If indicated, GHI will request the retrieval of the appropriate specimen for the ordered assay on your behalf. The laboratory or hospital will be instructed to send the specimen directly to Genomic Health Inc.'s laboratory located at 301 Penobscot Drive, Redwood City, CA 94063 U.S.A.
2. If more than one primary tumor is being submitted for the patient, indicate this on the requisition form. The specimens will be processed sequentially as listed.
3. If multiple blocks from the same primary tumor are being submitted and the first specimen is not sufficient to complete the assay, GHI will test the specimens in the order listed.
4. While the GHI laboratory can accept tumor blocks and unstained slides, unstained slides are preferred.
5. Include a copy of the pathology report with the Specimen Kit box. The pathology report may be used for reimbursement and/or administrative purposes.

SECTION VI. PHYSICIAN SIGNATURE & SPECIMEN STATUS

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

NOTE: *Stamped signatures are NOT acceptable.*

3. 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 or her 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 in the breast assay or colon assay section below unless otherwise indicated in the Exception Criteria field; (5) the correct stage/assay has been selected for the colon cancer assays.

   If GHI determines that the specimen does not fit the criteria stated in the applicable assay criteria section below, 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.

   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.

   In some cases additional assessment methods, including confirmatory testing of HER2 status, may be used to verify that the specimen meets the criteria for the Onco*type* DX assay.

ONCOTYPE DX BREAST CANCER ASSAY CRITERIA

1. **Invasive Breast Cancer patients**
   If the Requisition Form attestation has been signed, no exception criteria have been entered, and the completed specimen criteria fields do not indicate otherwise, you attest that the specimen is from a newly diagnosed female patient with Stage I, II, or III (T3, N1) ER positive breast cancer.
2. **Ductal Carcinoma In Situ patients.**
   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 female patient with DCIS (Stage 0: Tis, N0, M0). Patients with multi-focal disease are not appropriate for the assay.

ONCOTYPE DX COLON CANCER ASSAY CRITERIA

1. 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 Stage II or Stage III A/B colon cancer patient with adenocarcinoma or mucinous carcinoma. The use of the test in Stage II MMR-Deficient or in Stage III C patients has limited clinical applicability.

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 www.oncotypeiq.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 this form to discuss any special requirements.

1. For specimen criteria and specimen preparation instructions, visit www.oncotypeiq.com, or call the number listed on this form.
2. Please send either:
   a. One fixed paraffin embedded tumor block. Formalin is the preferred fixative. Tissues processed in other fixatives should not be submitted.
   b. Fifteen 5µm serial unstained slides, labeled to indicate the order in which they were cut.
3. All specimens must be labeled with S-Barcode labels from the Specimen Collection and Transportation Kit for the patient.
4. Affix a coinciding S-Barcode next to the Specimen / Case Number on the Requisition Form.
5. If you have any questions, please contact Customer Service.

NOTE: The Onco*type* DX 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.

SHIPPING INSTRUCTIONS

1. Before shipping, make a copy of the Oncotype DX Requisition Form and retain it for your records.
2. Place the Oncotype DX Requisition Form, specimen, copy of pathology report and relevant documents inside the Oncotype DX Specimen Kit.
3. Load Oncotype DX Specimen Kit in the FedEx® Large Clinical Pak.
4. Place the completed FedEx International Air Waybill and 3 copies of the commercial invoice in the clear document pouch located on the FedEx Clinical Pak.
5. Use only street addresses (no P.O. boxes) when completing the waybill.
6. Seal the Clinical Pak by removing the plastic adhesive protector from the white strip and secure.
7. All FedEx shipping charges are covered by Genomic Health.
8. Contact Customer Service to order additional kits:
   Europe, Middle East, Africa: EuropeanSupport@genomichealth.com
   Canada, Asia Pacific, Latin America: International@genomichealth.com.

NOTE:

- To order additional kits, contact Customer Service at the number listed on this form.
- Before shipping, make a copy of the Requisition Form and retain if for your records.

Country	Phone	Fax
CA	+866-662-6897	+650-569-2081
UK	+44-20-3031-8087	+44-20-7067-9405
IRE	+353-1-697-1568	+353-1-506-0331
CH	+41-84-844-4468	+41-44-583-0787
NL	+31-20-701-8039	+31-20-796-5286
FR	+33-1-77-68-89-18	+33-1-70-99-31-25
DE	+49-6989-914253	+49-8938-038058
IT	+39-06-899-70196	+39-06-45210-8188
AT	+43-1-267-5076	+43-1253-021211

FOR ADDITIONAL ASSISTANCE VISIT: **WWW.ONCOTYPEIQ.COM**