Genomic Health® | oncotype DX®

Customer Service Contact Information

	Phone	Fax
UK	020 3031 8087	020 7067 9405
IRE	(01) 697 1568	(01) 506 0331
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NL	+31 020 701 8039	+31 20 796 5286
EUR	+41 22 715 2900	+41 44 583 0787

Oncotype DX® Requisition Form

SECTION I. SUBMISSION STATUS

☐ FIRST SUBMISSION ☐ RESUBMISSION — Original Requisition No. _____ STUDY NAME / CODE _____

SECTION II. ASSAY & SPECIMEN CRITERIA

Oncotype DX Breast Cancer Assay

Ductal Carcinoma In Situ

☐ DCIS Score™ for Ductal Carcinoma In Situ Patient (no invasive cancer present)

– OR –

Invasive Breast Cancer

☐ Recurrence Score® for Invasive Breast Cancer Patient

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

**NODE STATUS:*
- ☐ Negative
- ☐ Micromets pN1mi (0.2-2.0mm)
- ☐ Positive 1-3
- ☐ Positive 4+

Oncotype DX Colon Cancer Assay

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

Stage II Patient
(T3 or T4) AND Node Negative

- ☐ Sequential Assays: MMR then Oncotype DX Colon Cancer *if* MMR Proficient
- ☐ Oncotype DX Colon Cancer Assay (for known MMR Proficient tumors)

Stage III A/B Patient
Any T AND 1-3 Positive Nodes

- ☐ Oncotype DX Colon Cancer *and* MMR Assays
- ☐ Oncotype DX Colon Cancer Assay

SECTION III. ORDERING PHYSICIAN

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

ADDITIONAL PHYSICIAN (Optional)

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

PATHOLOGY (Optional)

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

SECTION IV. PATIENT

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

SECTION V. BILLING – Please select **ONE** billing or payment option and complete the information. (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
STREET ADDRESS CITY/PROVINCE POST CODE
COUNTRY PHONE

SECTION VI. SPECIMEN INFORMATION (REQUIRED)

SPECIMEN RETRIEVAL

☐ Genomic Health to request specimen on my behalf.

LOCATION OF SPECIMEN
PHONE FAX

☐ Ordering Physician to request specimen.

MULTIPLE PRIMARIES Is more than one primary tumor being submitted for testing? Specimens will be processed as listed below. ☐ YES ☐ NO

SPECIMEN / CASE NUMBER Only one specimen is typically required

SPECIMEN BARCODE

DATE OF SURGERY (Day / Month / Year)

1. _____ SXXXXXX _____
2. _____ SXXXXXX _____

No substitutions for this assay

SECTION VII. PHYSICIAN SIGNATURE & SPECIMEN STATUS

PHYSICIAN SIGNATURE (Required) DATE (Day / Month / Year)

X

NAME

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.

EXCEPTION CRITERIA (See reverse for definition.)

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

Genomic Health, Inc. | 301 Penobscot Drive | Redwood City | CA | 94063-4700 | U.S.A. | www.oncotypeDX.com/contact

REQUISITION FORM INSTRUCTIONS

A. Complete all sections of the Requisition Form. Missing information may result in delays in test results.

B. Include the form with the specimen collection kit.

C. 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 the front side of this form.

See additional notes below for further instructions.

SECTION I. SUBMISSION STATUS

A. Select the submission type.

B. If this requisition is a resubmission, include the original requisition number.

SECTION II. ASSAY & SPECIMEN CRITERIA

ONCOTYPE DX BREAST CANCER ASSAY

A. Select ONE assay from the available options to be ordered.

> **NOTE:** For Ductal Carcinoma In Situ patients, result reports will include ER and PR scores. For Invasive Breast Cancer patients, result reports will include ER, PR, and HER2 scores.

B. For Invasive Breast Cancer patients, enter the ER and Node Status.
ER Status: A specimen submitted for Onco*type* DX Breast Cancer Assay testing 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.

***Node Status:** Enter the node status for the patient in the designated area. 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.

C. See Section VII for assay criteria.

ONCOTYPE DX COLON CANCER ASSAYS

A. Select ONE assay from the available options to be ordered.

> **NOTE:** For Stage II patients, if "Sequential Assays" is selected, the Onco*type* DX Colon Cancer Assay will be run only if the specimen is Mismatch Repair Proficient (MMR-P). MMR-P specimens have a positive immunohistochemistry score for both MLH1 and MSH2.

B. See Section VII for assay criteria.

SECTION III. 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 that 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.

SECTION IV. PATIENT

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

SECTION V. BILLING

A. Indicate the method of payment for the Onco*type* DX Cancer Assay.

B. Provide public or private insurance information.

C. If patient is selected, a Genomic Health representative will contact the patient to obtain payment.

SECTION VI. SPECIMEN INFORMATION (REQUIRED)

A. 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.

B. If more than one primary tumor is being submitted for the patient, indicate this on the requisition form. A Customer Service representative will contact you to discuss processing order. There will be a charge for each test run.

C. 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.

D. While the GHI laboratory can accept tumor blocks and unstained slides, unstained slides are preferred.

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.

SECTION VII. PHYSICIAN SIGNATURE & SPECIMEN STATUS

A. 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.

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.*

C. ATTESTATION: The signature constitutes a certification of the following: (1) the treating physcian 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

A. 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).

B. 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.

ONCOTYPE DX COLON CANCER ASSAY 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 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 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.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 front side of this form to discuss any special requirements.

A. For specimen criteria and specimen preparation instructions, visit www.oncotypeDX.com, or call the number listed on the front of this form.

B. Please send either:
1. One fixed paraffin embedded tumor block (neutral buffered formalin is the preferred fixative. Alternative fixatives are not recommended.)
2. Fifteen 5µm serial unstained slides, labeled to indicate the order in which they were cut.

C. All specimens must be labeled with S-Barcode labels from the Specimen Collection and Transportation Kit for the patient.

D. Affix a coinciding S-Barcode next to the Specimen / Case Number on the Requisition Form.

E. 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

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, contact customer serivce at the number listed on the front side of this form. 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® Airbill.

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 Customer Service should you need assistance with shipping via FedEx®.

> **NOTE:**
> - To order additional kits, contact Customer Service at the number listed on the front side of this form.
> - Before shipping, make a copy of the Requisition Form and retain it for your records.

FOR ADDITIONAL ASSISTANCE VISIT:
WWW.ONCOTYPEDX.COM