Send the ‘Application for the Oncotype DX Test’ form with this ‘Oncotype DX Requisition Form’ and the patient’s ‘Pathology Report’ by email to: customerservice@stbiopharma.com or fax to: 1800 798 829.
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. Oncotype 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 for online ordering or to change your delivery preferences, please contact Customer Services at international@genomichealth.com or by calling Tel +1-650-569-2080 for Customer Service.

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, report results will include ER and PR scores. For Invasive Breast Cancer patients, report results 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 Oncotype 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 Axilis” is selected, the Oncotype DX Colon Cancer Assay will be run only if the specimen is Mammotrack-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 IV. PATIENT

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 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 V. PAYMENT

Complete the “Application for the Oncotype DX Test” form, which can be downloaded from the Specialised Therapeutics Australia website: www.specialisedtherapeutics.com.au

Specialised Therapeutics Australia accept the following methods of payment:

- Bank cheques
- Australia Post money order
- Electronic Funds Transfer (EFT)
- Credit Card – only Visa and MasterCard are accepted and a 1.25% surcharge is applied

NOTE: The process of collecting the tissue, shipping to Genomic Health and Oncotype DX testing will commence following receipt of payment.

SECTION VI. SPECIMEN INFORMATION (REQUIRED)

A. If the first specimen submitted is not sufficient to complete the assay, GHI will test the specimen in the order listed provided that all specimens received are from the same primary tumor (checklist indicated as No).

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

C. Specimen / Case Number is the specimen identifier given by hospital storing the tissue and is unique to the patient. Specimen Barcode labels provided with the Oncotype DX Specimen Kit should be placed in this section.

D. Include a copy of the pathology report with the Specimen Kit box. The pathology report may be used to determine treatment or administrative purposes.

NOTE: If more than one tumor is being submitted for the patient, each tumor must be labeled with a unique identifying Specimen Barcode (S Barcode) and check YES for multiple primaries. Completes one Requisition Form per cancer type for each patient. There will be a charge for each test.

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 submit / her personal 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. ATTENTION: 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 or her 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 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 assay.

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 undetermined. 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 Oncotype 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 T1a, No, 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 and coverage is available, the patient may be the ultimate payer.

The following criteria are required to be met with arowing sample to be included in the Oncotype DX assay.

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 I or II A/B colon cancer patient with adenocarcinoma or mucinous carcinoma. The use of the test in stage II MMN-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 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 the Oncotype DX website.

Oncotype DX Specimen Kits comply with international packaging regulations for diagnostic specimens (ATA 650 Packaging Instruction). Contact Customer Service at Tel +1-650-569-2080 in advance to discuss any special requirements.

A. For specimen criteria and specimen preparation instructions, visit www.oncotypeDX.com, or call Tel +1-650-569-2080.

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 Sum serial unstained slides, labeled to indicate the order in which they were cut.
3. All specimens must be labeled with 5-Barcode labels from the Specimen Collection and Transportation Kit for the patient.
4. AXIA a cancelling 5-S Barcode next to the Specimen / Case Number on the Requisition Form.
5. If there is any question, please contact Customer Services at international@genomichealth.com or Tel +1-650-569-2080.

SHIPPING INSTRUCTIONS

A. Materials and equipment

1. 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 or call Tel +1-650-569-2080 for Customer Service with questions. 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.


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:

1. Section B. Special Handling: Under the question, “Does this contain dangerous goods?”, please check “No”. The fixed paraffin-embedded (FFP) 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, e-mail Customer Service at international@genomichealth.com or call +1 650-569-2080.
- Before shipping, make a copy of the Requisition Form and return it for your records.