Genomic Health® | Oncotype DX®

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Oncotype DX® Requisition Form

PATHOLOGY:
Affix Specimen Barcode Here SXXXXXX

FORM INSTRUCTIONS: SECTION I – V: ORDERING PHYSICIAN TO COMPLETE **SECTION VI:** PATHOLOGY TO COMPLETE

ORDERING PHYSICIAN to Complete

SECTION I. SUBMISSION STATUS

☐ FIRST SUBMISSION ☐ RESUBMISSION — Associated Requisition _____ STUDY NAME / CODE: _____

SECTION II. ASSAY & SPECIMEN CRITERIA (SELECT ONE)

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)**
- ☐ MMR Assay for Recurrence Risk Assessment

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

- ☐ Oncotype DX Colon Cancer *and* MMR Assays
- ☐ Oncotype DX Colon Cancer Assay
- ☐ MMR Assay for Recurrence Risk Assessment

SECTION III. PHYSICIAN INFORMATION

PRACTICE ACCOUNT:

ORDERING PHYSICIAN NAME: (Name will appear on report) FAX:

CONTACT NAME: CONTACT PHONE:

ADDITIONAL PHYSICIAN / RECIPIENT NAME: (Name will appear on report)

PHONE: FAX:

PHYSICIAN SIGNATURE & EXCEPTION CRITERIA

Your signature constitutes a Certification of Medical Necessity and a certification that you have obtained the patient's consent for Genomic Health Inc.'s release of the test results to the patient's third party payer when necessary as part of the reimbursement process. Read Section III on the reverse side for full details. By signing this form you are stating that *either* **1)** the patient meets the criteria stated in Section III on the reverse side of this form OR **2)** if the patient does not meet these criteria, that you have entered the reason(s) in the Exception Criteria space provided.

ORDERING PHYSICIAN SIGNATURE: DATE (MM/DD/YYYY):

X _____ _____

PRINT NAME: _____

SECTION IV. PATIENT INFORMATION

PATIENT NAME: Last, First, MI

DOB (MM/DD/YYYY): ☐ Female ☐ Male

MEDICAL RECORD / PATIENT NUMBER: SSN:

ADDRESS:

CITY: STATE: ZIP: COUNTRY:

PRIMARY PHONE: ALTERNATE PHONE:

HOSPITAL STATUS: (Medicare Only) ☐ Hospital Inpatient (> 24 hour stay) ☐ Hospital Outpatient ☐ Non-hospital Patient
└ Inpatient Discharge Date _____

MULTIPLE PRIMARIES: (See back of form for details) ☐ No ☐ Yes (If YES, include instructions for specimen processing in comments below)

BENEFITS INVESTIGATION / BILLING INFORMATION

Genomic Health will investigate insurance benefits and contact the patient should their potential financial responsibility exceed $100. See reverse side for details.

SUBMITTING DIAGNOSIS: _____ ICD-9 CODE: _____

BILLING TYPE: COMPLETE the following & attach a copy of patient's insurance card (front / back).

☐ PRIVATE INSURANCE ☐ MEDICARE ☐ MEDICAID ☐ PATIENT ☐ BILL PATHOLOGY ACCOUNT Restricted to contracted accounts on file at Genomic Health

PRIMARY INSURANCE COMPANY NAME: MEMBER ID:

PRIOR AUTHORIZATION #:

SECONDARY INSURANCE COMPANY NAME: MEMBER ID:

SECTION V. SPECIMEN RETRIEVAL

☐ 1. Genomic Health to request specimen from Pathology

Location of Specimen: Phone: Fax: Contact Name:

☐ 2. Ordering Physician to request specimen from Pathology

PATHOLOGY to Complete

SECTION VI. PATHOLOGY INFORMATION — Submit within 24 hours —

ACCOUNT:

SUBMITTING PATHOLOGIST NAME: (Name will appear on report)

PHONE: FAX:

BLOCK RETURN LOCATION: (If different from Pathology Account) PHONE: CONTACT NAME:

SPECIMEN INFORMATION (REQUIRED)

SPECIMEN ID(s): Only one specimen is typically required
The Oncotype DX assay will be completed on the specimens in the order listed below:

1) _____ 2) _____

DATE OF SURGERY (MM/DD/YYYY): **DATE BLOCK PULLED FROM ARCHIVE:** (Medicare Only)

_____ _____

No substitutions for this assay

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REQUISITION FORM INSTRUCTIONS

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

B. After signing, fax the completed Requisition Form to 866-444-0640 or, if submitting a specimen, include the form with the specimen collection kit.

C. Online ordering is available at www.online.genomichealth.com. For assistance in setting up an Online Portal Account for online ordering, please contact Customer Service at customerservice@genomichealth.com or 866-ONCOTYPE (866-662-6897).

D. Assay results will be delivered to the ordering physician and additional recipients according to the physicians' preferences on file at Genomic Health, Inc. (GHI). To establish or change report delivery preferences, please contact Customer Service at customerservice@genomichealth.com or by calling 866-ONCOTYPE (866-662-6897).

SECTION I. SUBMISSION STATUS

A. Select the submission type.

B. If this requisition is a resubmission, include the associated 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 III for assay criteria.

ONCOTYPE DX COLON CANCER ASSAY

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 III for assay criteria.

SECTION III. PHYSICIAN INFORMATION / SIGNATURE & ASSAY CRITERIA

PHYSICIAN INFORMATION

A. ADDITIONAL PHYSICIAN / RECIPIENT INFORMATION (OPTIONAL). If another physician is responsible for the care of this patient and has requested a copy of the report, enter the applicable information in the spaces provided under this section.

SIGNATURE

A. 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) with respect to tests reimbursed by Medicare, Medicaid or other third party payers, the test is medically necessary and the results will be used in the management of the patient; (2) If the ordering physician is not the treating physician (or his/her authorized representative), the ordering physician confirms that the treating physician has ordered the assay for this purpose; (3) the treating physician has obtained the patient's consent for GHI to send the patient's test results to the patient's third party payer in connection with an appeal of a reimbursement denial or other reimbursement matter, if GHI has made prior attempts to obtain reimbursement without the release of such test results; (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 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.

SECTION IV. PATIENT INFORMATION / BENEFITS INVESTIGATION / BILLING INFORMATION

PATIENT INFORMATION

A. **Hospitalization Status** is required if the patient's insurance is MEDICARE. If inpatient status is selected, enter the date of discharge from the hospital.

B. **Multiple Primaries:** For patients with multiple primary tumors, select YES. Indicate the specimen(s) to be processed in Section VI, Pathology & Specimen Information. List the most representative specimen (i.e. the highest grade and largest tumor) on line one. The specimen on line one will be processed first.

> **NOTE:** If multiple tests are processed, there will be a charge for each test. Contact Customer Service to discuss insurance coverage information.

BENEFITS INVESTIGATION / BILLING INFORMATION

Benefits Investigation

A. Genomic Health will investigate insurance benefits and may contact the patient should their potential financial responsibility exceed $100.

B. A Benefits Investigation will not be performed for the MMR Assay.

> **NOTE:** Insurance reimbursement is affected by many factors. Genomic Health makes no representation or guarantee that full or partial insurance reimbursement or any other payment will be available. While Genomic Health tries to provide correct information, we make no representations or warranties, expressed or implied, as to the accuracy of the information. These support services have no independent value to providers and are included within the cost of the Onco*type* DX testing services.

Billing Information

A. Indicate the party responsible for payment.

B. If **Private Insurance / Medicare / Medicaid** is selected:
1. Include a copy of the front and back of both the primary and secondary insurance cards.
2. All **Medicare** patients will have an eligibility check and may be contacted during the process.

C. If **Patient** is selected, a representative will contact the ordering physician's office to collect payment information.

D. Before selecting **Bill Pathology Account**, verify with GHI that you have a contracted account on file.

E. Complete the Primary and Secondary Insurance Information fields.

F. GHI will use the statement of medical necessity you provide to expedite insurance appeals.

SECTION V. SPECIMEN RETRIEVAL

A. If indicated, GHI will request the retrieval of the appropriate specimen for the ordered assay on your behalf.

> **NOTE**: If the specimen retrieval section is not completed and the specimen is not submitted with the Requisition Form, GHI will request the specimen on your behalf. GHI will contact your office to determine the location of the patient's specimen.

SECTION VI. PATHOLOGY & SPECIMEN INFORMATION

A. List the most representative specimen (i.e. the highest grade and largest tumor) on line one.

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

C. Include a copy of the pathology report with the Specimen Kit submission box. The pathology report may be used for reimbursement and/or administrative purposes.

> **NOTE:** If more than one tumor is being submitted for the patient, each tumor must be labeled with a unique Specimen Barcode (S-Barcode). GHI is not responsible for selecting the order in which specimens will be run. GHI will use the specimens in the order listed to complete the test.

SPECIMEN INSTRUCTIONS

A. For specimen criteria and specimen preparation instructions, visit www.oncotypeDX.com or call 866-ONCOTYPE (866-662-6897).

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 to the top right corner of the Requisition Form.

E. If you have any questions, please contact Customer Service at 866-ONCOTYPE (866-662-6897).

> **NOTE:** Assay 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.

DOMESTIC SHIPPING INSTRUCTIONS

A. Materials and equipment
1. Onco*type* DX Specimen Kit containing the patient specimen, pathology report and Onco*type* DX Requisition Form.
2. FedEx® Clinical Pak, Large plastic over wrap used to ship the specimen to Genomic Health.
3. FedEx® US Airbill pre-printed with Genomic Health shipping information.
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® US Airbill.

D. Seal the Clinical Pak by removing the plastic adhesive protector from the white strip and secure.

E. Place the package in the designated FedEx® pickup location at your site.

F. If your site does not have standard FedEx® pickup, call 800-GO FEDEX (800-463-3339) to arrange for pick up.

> **NOTE:**
> - To order additional kits, e-mail Customer Service at customerservice@genomichealth.com or call 866-ONCOTYPE (866-662-6897).