genomic health | oncotype DX®

Genomic Health, Inc.
301 Penobscot Drive
Redwood City, CA 94063 USA
Tel (866) ONCOTYPE (866) 662-6897
www.oncotypeDX.com
Fax (866) 444-0640

Oncotype DX® Requisition Form

RXXXXXX

PATHOLOGY: Affix Specimen Barcode Here SXXXXXX

FORM INSTRUCTIONS: **SECTION I – V:** ORDERING MD 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

Oncotype DX Breast Cancer Assay

SELECT ONE:

☐ DCIS Score™ for Ductal Carcinoma In Situ Patient (no invasive cancer present)
☑ Recurrence Score® for Invasive Breast Cancer Patient

For invasive breast cancer patients, COMPLETE the following criteria fields:

ER STATUS: (Specimen assumed to be ER+ if no selection is made)
☑ Positive ☐ Negative ☐ Inconclusive by IHC ☐ Unknown

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

Oncotype DX Colon Cancer Assays

SELECT ONE of the following test types:

☐ Sequential Assays: MMR then Oncotype DX Colon Cancer if MMR is Proficient
☐ Oncotype DX Colon Cancer Assay
☐ MMR Assay for Recurrence Risk Assessment

SECTION III. PHYSICIAN INFORMATION

PRACTICE ACCOUNT:
ABC Clinic
123 Hospital Drive
Anytown, ST 00000
AXXXXXX

ORDERING PHYSICIAN NAME: (Name will appear on report) John Smith, M.D.
FAX: 555-555-2345
CONTACT NAME: Ann
CONTACT PHONE: 555-555-1234
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 II 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: X John Smith, M.D.
DATE (MM/DD/YYYY): 02/01/2012
PRINT NAME: John Smith, M.D.

EXCEPTION CRITERIA

SECTION IV. PATIENT INFORMATION

PATIENT NAME: Last, First, MI: Doe, Jane M.
DOB (MM/DD/YYYY): 01/01/1950
☑ Female ☐ Male
MEDICAL RECORD / PATIENT NUMBER: 821857
SSN:
ADDRESS: 333 Main Street
CITY: Anytown STATE: ST ZIP: 0000 COUNTRY:
PRIMARY PHONE: 555-555-3456
ALTERNATE PHONE: 555-555-4756
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 instruction for specimen processing in comments below)

BILLING INFORMATION

SUBMITTING DIAGNOSIS: Breast Cancer ICD-9 CODE: 174.9
BILLING TYPE: (COMPLETE the following & Attach Front/Back copy of insurance card)
☑ PRIVATE INSURANCE ☐ MEDICARE ☐ MEDICAID ☐ PATIENT ☐ BILL PATHOLOGY ACCOUNT Restricted to contracted accounts on file at Genomic Health
PRIMARY INSURANCE COMPANY NAME: Blue Cross of State
MEMBER ID: MBR222
PRIOR AUTHORIZATION #:
SECONDARY INSURANCE COMPANY NAME: Premium Health
MEMBER ID: MEM555
State reason for ordering Oncotype DX in support of treatment decision:

Provide information on why the test is needed to make your treatment decision...
STATEMENT OF MEDICAL NECESSITY

SECTION V. SERVICE OPTIONS

SPECIMEN RETRIEVAL — (SELECT ONE)

☑ 1. Genomic Health to request specimen from Pathology
LOCATION OF SPECIMEN: Bay Labs, Inc. PHONE: 555-555-5678 FAX: 555-555-1111
☐ 2. Ordering Physician to request specimen from Pathology

BENEFITS INVESTIGATION — (SELECT ONE)

☑ 1. Investigation not required
☐ 2. Investigate — Proceed with test and REPORT RESULTS
☐ 3. Investigate — Proceed with test and HOLD FINAL PROCESSING pending patient approval (May extend turn-around-time for report results)

PATHOLOGY to Complete

SECTION VI. PATHOLOGY INFORMATION — Submit within 24 hours —

ACCOUNT: Bay Labs, Inc.
123 Bay Drive
Anytown, ST 00000
AXXXXXX
SUBMITTING PATHOLOGIST NAME: (Name will appear on report) Bill Smith, M.D.
PHONE: 555-555-6789
FAX: 555-555-0123
BLOCK RETURN LOCATION: (If different from Pathology Account) PHONE: 555-555-6899 CONTACT NAME: Russell

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) SP-12-2222A 2)
DATE OF SURGERY (MM/DD/YYYY): 01/30/2012
DATE BLOCK PULLED FROM ARCHIVE: (Medicare Only)

Comments for Pathology
COMMENTS

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, an RS 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 ASSAYS

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

> **NOTE:** If "Sequential Assays" is selected, the Onco*type* DX Colon Cancer Assay will be run only if the specimen is MMR-P.

B. Enter the T4 and MMR-D status if known.

> **NOTE:** MMR-D = mismatch repair-deficient (specimens with a negative immunohistochemistry score for either MLH1 or MSH2).

C. 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 tests 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.

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, 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 no 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 colon cancer patient with adenocarcinoma or mucinous carcinoma.

SECTION IV. PATIENT INFORMATION / 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 and indicate the specimens to be processed in Section IV Pathology & Specimen Information. List the most representative specimen (i.e. the highest grade and largest cross sectional area of 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.

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. SERVICE OPTIONS

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.

BENEFITS INVESTIGATION

A. If option 2 or 3 is selected, GHI will contact your patient's insurance company to verify coverage and coverage amounts.

> **NOTE:** A Benefits Investigation will not be performed for the MMR Assay.

SECTION VI. PATHOLOGY & SPECIMEN INFORMATION

A. List the most representative specimen (i.e. the highest grade and largest cross sectional area of 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).
> - Before shipping, make a copy of the Requisition Form and retain it for your records.

FOR ADDITIONAL ASSISTANCE:

- **GO TO WWW.ONCOTYPEDX.COM** OR
- **CALL 866-ONCOTYPE (866-662-6897)**