

PATHOLOGY: Time Sensitive — Please Expedite

Fax (866) 444-0640



PATHOLOGY:
Affix Specimen Barcode Here SXXXXXX

I. ASSAY / SUBMISSION TYPE

ASSAY: **BREAST** **COLON** SUBMISSION: **FIRST** **RESUBMISSION** — Associated Requisition _____

II. ORDERING PHYSICIAN INFORMATION

PRACTICE ACCOUNT
ABC Clinic XXXXXXXX

ORDERING PHYSICIAN NAME
John Smith, M.D.

CONTACT NAME
Shannon

PHONE FAX
555-111-2222 *555-222-5555*

III. ADDITIONAL PHYSICIAN (Name will appear on report.)

ADDITIONAL PHYSICIAN / RECIPIENT NAME (Optional)

ADDRESS

CITY STATE ZIP COUNTRY

PHONE FAX

IV. PATIENT INFORMATION

PATIENT NAME: Last, First MI
Doe Jane S

DOB (MM/DD/YYYY) Female Male
02/16/1965

MEDICAL RECORD / PATIENT NUMBER SSN
921857 *000-00-0000*

ADDRESS 1
333 Main Street

ADDRESS 2
Apt. 5

CITY STATE ZIP COUNTRY
Anytown ST 00000 USA

HOME PHONE WORK PHONE
555-332-1111

CELL PHONE
555-999-2222

V. BILLING INFORMATION

SUBMITTING DIAGNOSIS *breast cancer* ICD-9 CODE *174.9*

PRIVATE INSURANCE (Attach Front/Back copy of insurance card.)

Primary *Blue Cross of State*

MEMBER ID *555-1111*

Secondary *PremiumPointe Health*

MEMBER ID *555-0000*

Prior Authorization # _____

MEDICARE
(Complete additional information below.)
All Medicare patients will have an eligibility check and may be contacted during the process.

Hospital Inpatient (> 24 hour stay)
Discharge Date _____

Hospital Outpatient

Non-hospital Patient

MEDICAID
(Attach Front/Back copy of insurance card.)

PATIENT SELF-PAY Check (US), certified funds, money order, or credit card
Name on Credit Card _____

Credit Card # _____

Expiration Date (MM/YY) _____

BILL PATHOLOGY ACCOUNT Restricted to contracted accounts on file at Genomic Health

VI. BENEFITS INVESTIGATION — SERVICE OPTIONS (SELECT ONE)

1. No Investigation Required. 2. **YES Investigate** — Proceed with test and **REPORT RESULTS**. 3. **YES Investigate** — Proceed with test and **HOLD FINAL PROCESSING** pending patient approval. (May extend turn-around-time for report results.)

STATEMENT OF MEDICAL NECESSITY (Please state why the patient needs this test and any past experiences using Oncotype DX to support treatment decisions.)
Comments on why the test is needed to make your treatment decision...

VII. SPECIMEN RETRIEVAL — SERVICE OPTIONS (SELECT ONE)

1. I want Genomic Health to request the specimen. (COMPLETE the information below.) 2. I will arrange having the specimen sent. (FAX this form to Pathology.)

LOCATION OF SPECIMEN PHONE FAX CONTACT NAME
BayLabs, Inc. *555-222-1212* *555-222-1222*

VIII. PHYSICIAN SIGNATURE & SPECIMEN STATUS — REQUIRED

ORDERING PHYSICIAN SIGNATURE DATE (MM/DD/YYYY)
X John Smith MD. *02/01/2011*

PRINT NAME
John Smith, M.D.

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. Please read Section VIII 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 VIII 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. A Genomic Health representative may contact you should your patient not meet these criteria.

Please select specimen status for the Oncotype DX cancer assay selected above:

BREAST ASSAY: **Node Negative** **Node Positive (1-3 Nodes)**
 Micromets (pN1mi: 0.2–2.0mm) **Node Positive (4+ Nodes)**

COLON ASSAY: T4: Yes No Unknown
MSI-H or MMR-D: Yes No Unknown

EXCEPTION CRITERIA

IX. PATHOLOGY INFORMATION

ACCOUNT
BayLabs, Inc. XXXXXXXX

SUBMITTING PATHOLOGIST NAME
Bill Smith, M.D.

PHONE FAX
555-222-1212 *555-222-1222*

SPECIMEN IDs: The Oncotype DX assay will be completed on the specimens in the order listed below. Only one specimen is typically required. MULTIPLE PRIMARIES: Yes No

1) *SP-07-1111A* 3) _____

2) _____ 4) _____

DATE OF SURGERY (MM/DD/YYYY) DATE BLOCK PULLED FROM ARCHIVE (Required for Medicare.)
01/30/2011

BLOCK RETURN LOCATION (if different than the Pathology Account listed above.) PHONE CONTACT NAME
555-222-1213 *Jessie*

ORDERING PHYSICIAN to Complete

PATHOLOGY to Complete

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. 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).
- C. *Oncotype DX*® results will be delivered to the ordering physician and additional recipients according to the ordering 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. ASSAY / SUBMISSION TYPE

- A. Please select the assay and submission type.
- B. If this requisition is a resubmission, include the associated requisition number.

SECTION II. ORDERING PHYSICIAN INFORMATION

- A. To ensure prompt processing review each line as some lines require more than one piece of information.

SECTION III. ADDITIONAL PHYSICIAN / RECIPIENT INFORMATION (OPTIONAL)

- A. 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.

NOTE: Reports cannot be sent to P.O. boxes.

SECTION IV. PATIENT INFORMATION

- A. To ensure prompt processing review each line as some lines require more than one piece of information.

SECTION V. BILLING INFORMATION

- A. Indicate the party responsible for payment of the *Oncotype DX* Cancer Assay.
- B. If **Private Insurance / Medicare / Medicaid**:
 1. Include a copy of the front and back of both the primary and secondary insurance cards.
 2. Note which insurance is primary and secondary for the patient.
- C. If **Medicare**, indicate the patient's hospitalization status at the time of surgery.
 1. If **In-patient** was selected for Medicare, enter the date of discharge from the hospital.
 2. All Medicare patients will have an eligibility check and may be contacted during the process.
- D. If **Patient Self-pay**, provide credit card information or enclose payment. Payment is required prior to processing.
- E. Before submitting the patient's specimen, verify with GHI when selecting "**Bill Pathology Account**" if you are NOT currently a contracted account.

SECTION VI. BENEFITS INVESTIGATION

- A. If YES is checked, GHI will contact your patient's insurance company to verify coverage and coverage amounts. GHI will use the statement of medical necessity you provide to expedite insurance appeals.

SECTION VII. SPECIMEN RETRIEVAL INFORMATION

- A. If requested, GHI will request the retrieval of the appropriate specimen for the *Oncotype DX* assay on your behalf.

NOTE: If the specimen retrieval section is not completed and the specimen was 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 VIII. PHYSICIAN SIGNATURE & SPECIMEN STATUS — REQUIRED

- A. **SIGNATURE:** Sign and date the Requisition Form and print your name. The signature must be of an ordering physician (treating physician or pathologist) or their authorized representative.
- 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 *Oncotype DX* 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 breast assay or colon assay section below, the patient's test report will indicate, where appropriate, that the clinical interpretation of the Recurrence Score® (RS) is unknown or adjusted. In all cases, it is the treating physician's responsibility to determine whether and how the RS should be used in determining a treatment plan for that patient.

GHI will run the assay and report an RS 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.

- C. **BREAST ASSAY — ADDITIONAL INFORMATION:** 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 Stage I, II, or III (T3, N1) ER positive breast cancer.

Enter the nodal status for the patient in the designated area. The nodal status is required to determine the extent of the clinical experience information to be included in the report for your patient. If the nodal 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 nodal status is not specified, GHI may use the pathology report, if provided, to determine the nodal status for reimbursement purposes.

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, an RS will not be reported to the patient and the patient / payer will not be billed. All *Oncotype DX* Breast Cancer Assay result reports will include ER, PR and HER2 scores.

- D. **COLON ASSAY — ADDITIONAL INFORMATION:** 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. Enter the T4 and MSI/MMR status if known.

NOTE: MSI-H: microsatellite instability-high phenotype; **MMR-D:** mismatch repair-deficient (specimens with a negative immunohistochemistry score for either MLH1 or MSH2).

SECTION IX. PATHOLOGY INFORMATION

- A. If the first specimen submitted is not sufficient to complete the assay, GHI will use the specimens in the order listed to complete the test.
- B. While the GHI laboratory can accept tumor blocks and unstained slides, blocks are preferred due to the frequent requirement for manual microdissection of the specimen consistent with clinical trial experience.
- 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 identifying Specimen Barcode (S Barcode) and check YES for multiple primaries. Complete one Requisition Form per cancer type for each patient. There will be a charge for each 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).**OR**
 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: The *Oncotype 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.

DOMESTIC SHIPPING INSTRUCTIONS

- A. Materials and equipment
 1. *Oncotype DX* Specimen Kit containing the patient specimen, pathology report and *Oncotype DX* Requisition Form.
 2. FedEx® US 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 *Oncotype 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)**