Order Form and Statement of Medical Necessity

Tel. 866.ONCOTYPE | oncotypeDX.com

Complete and Fax to 866.444.0640

Genomic Health® | oncotypeDX®

Study Information/Code

TEST & CLINICAL INFORMATION

Invasive Breast Cancer

❑ **Oncotype DX Breast Recurrence Score® Test**

NODAL STATUS:
- ❑ Negative
- ❑ Micromets pNmi (0.2-2.0mm)
- ❑ Positive 1-3
- ❑ Positive 4-9
- ❑ LN Not Tested

Invasive Tumor Size (cm): (based on excisional biopsy pathology report)

___ . ___

The patient is a candidate for Adjuvant Chemotherapy. ❑ Yes ❑ No

Ductal Carcinoma in Situ

❑ **Oncotype DX® DCIS Score™ Test**

DCIS Tumor Size (cm):

___ . ___

Provide accurate tumor size based on excisional biopsy pathology report. Missing or inaccurate tumor size will impact the risk estimates on the report, and you may be contacted.

Colon Cancer

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

Clinical Stage II Patient
(T3 or T4) AND Node Negative

❑ Oncotype DX® Colon Recurrence Score™ (for known MMR Proficient tumors)

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

❑ Oncotype DX Colon Recurrence Score Test

ER STATUS:	PR STATUS:	HER2 STATUS:
❑ Positive	❑ Positive	❑ Positive
❑ Negative	❑ Negative	❑ Negative
❑ Inconclusive by IHC	❑ Inconclusive by IHC	❑ Equivocal
	❑ Not Tested	

PHYSICIAN SIGNATURE AND ATTESTATION

Your signature constitutes a Statement of Medical Necessity (SOMN) and your attestation of the following: 1) accurate clinical information has been entered above, as this informs the risk estimates and clinical interpretation provided on the report. 2) if the diagnosis or exception criteria sections of the form do not indicate otherwise, the patient meets the assay criteria described in the 'Test & Clinical Information' section (see reverse); 3) the test is medically necessary and test results will be used with other clinical data to help determine the appropriate treatment plan for the patient; 4) the patient has consented for this test to be performed, and for Genomic Health Inc. to release test information when necessary to obtain reimbursement. 5) Delegate has the authorization to sign supporting forms and documents on behalf of the Ordering Physician for Genomic Health orders.

Practice Account

Ordering Physician Name Fax

Email

Contact Name Phone

Additional Physician/Report Recipient (Optional) Phone

Fax Email

Ordering Physician Signature Date (mm/dd/yyyy)

Print Physician Name

Exception Criteria/Comments

PATIENT INFORMATION

Patient Name (Last, First, MI)

❑ Female ❑ Male

DOB (mm/dd/yyyy)

Medical Record / Patient # (If applicable)

Address

City State Zip Country

Primary Phone Alternative Phone (Optional)

Multiple Primaries ❑ No ❑ Yes Quantity_____

Multiple Primaries will be run sequentially. See reverse side for details.

BILLING INFORMATION

Submitting Diagnosis ICD-10 Code

Billing Type: COMPLETE the following & attach a copy of patient's insurance card (front/back)

❑ Private Insurance ❑ Medicare ❑ Medicaid ❑ Patient ❑ Bill Pathology Account Contracted accounts only

Hospital Status (Medicare Only) ❑ Hospital Inpatient (>24 hour stay) ❑ Hospital Outpatient ❑ In-Office Procedure

Inpatient Discharge Date_____

Primary Insurance Company Name Member ID

Prior Authorization # (if applicable)

Secondary Insurance Company Name Member ID

SPECIMEN RETRIEVAL

❑ 1) Genomic Health to request specimen from Pathology ❑ 2) Ordering Physician to request specimen from Pathology

Location of Specimen Phone Fax Contact Name

PATHOLOGY AND SPECIMEN INFORMATION — Submit within 24 hours — No substitutions for this assay

Account

Submitting Pathologist Name

Phone Fax

Specimen ID(s) Only one specimen is typically required. The Oncotype DX assay will be completed on the specimens in the order listed below. **For multiple primaries, list the most aggressive tumor first.**

1) _____

2) _____

Date of Collection_____ (MM/DD/YYYY)

Date Block Pulled from Archive_____(Medicare Only)

Specimen Barcode
Affix Specimen barcode here

Block Return Location: (If different from Pathology Account)

Contact Name Phone Address

Specimen Comments

GHI003, Rev #25

REQUISITION FORM INSTRUCTIONS

Online ordering is available at online.genomichealth.com. For assistance in setting up a Portal Account for online ordering, please contact Customer Service at 866-ONCOTYPE or customerservice@genomichealth.com.

STUDY INFORMATION

1. If the order is associated with a Genomic Health involved study, enter the applicable study code.

TEST & CLINICAL INFORMATION

1. Select the requested test and enter clinical information where required.
    a. Invasive Breast Cancer patients
        i. Ensure the ER status and nodal status are accurate, as this information informs the report results.
            1. A specimen submitted for the Oncotype DX Breast Recurrence Score® Test 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.
            2. 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.
        ii. Result reports will include ER, PR, and HER2 scores.
    b. Ductal Carcinoma In Situ patients (no invasive breast cancer present)
        i. Result reports will include ER and PR scores.
        ii. Provide accurate tumor size. Missing or inaccurate tumor size will impact the risk estimates on the report, and you may be contacted.
        iii. The tumor size should be based on the excisional biopsy pathology report. If no residual DCIS was found on the excisional biopsy, use the tumor size determined on the core biopsy pathology report. If the tumor size is not reported, please write "Not Available."
    c. Colon Cancer patients
        i. The use of the test in in clinical stage II MMR-Deficient or in clinical stage III C patients has limited clinical applicability.
2. In some cases, Genomic Health may use additional assessment methods, including confirmatory testing for HER2 status, to verify that the specimen meets the criteria for the Oncotype DX test.
3. Clinical information may be required for payor coverage determinations. If it is not provided, GHI may use the pathology report to obtain this information for reimbursement purposes.

PHYSICIAN INFORMATION

1. Enter the contact information for the Ordering Physician. You may also enter the contact information for another healthcare provider who is treating the patient and should receive a copy of the report.
2. Assay results will be delivered to the Ordering Physician and additional recipients via the secure online portal and/or by fax based on the physicians' report delivery preferences on file at Genomic Health. To establish or change report delivery preferences, please contact Customer Service.

PHYSICIAN SIGNATURE & ATTESTATION

1. The signature must be of an Ordering Physician (treating physician or pathologist) or his/her authorized delegate. Stamped signatures are not acceptable. If this order form is completed by the Physician's representative, the patient's medical record must contain the signed order from the Ordering Physician.
2. If the Requisition Form attestation has been signed and no exception criteria have been entered in the comments section, you attest that the patient meets the requirements for the test:
    a. Invasive Breast Cancer: Newly diagnosed female patients with anatomic Stage I, II, or IIIA (T1-3, N1-2) ER positive breast cancer.
    b. DCIS: Newly diagnosed female patients with DCIS (Stage 0, Tis, N0, M0). For Medicare Beneficiaries, the patient must meet the additional Medicare patient eligibility criteria:
        i. Patient is a candidate for breast conserving surgery or breast conserving surgery plus radiation
        ii. Test results are being used to determine treatment choice between surgery and surgery plus radiation
        iii. Patient has not received and is not planning on receiving a mastectomy.
    c. Colon Cancer: Newly diagnosed Stage II or III A/B colon cancer patients with adenocarcinoma or mucinous carcinoma.

PATIENT INFORMATION

1. Enter the patient information.
2. Indicate whether multiple primaries are being submitted for the patient.
    a. Multiple tumor specimens will be tested sequentially.
    b. For invasive breast cancer tests, if first tumor generates a Recurrence Score® result ≤ 25, the second tumor specimen will be automatically processed. If first tumor generates a Recurrence Score result > 25, Customer Service will contact the ordering physician to determine how to proceed.
    c. If multiple tests are processed, there will be a charge for each test. Contact Customer Service to discuss insurance coverage information.

BILLING INFORMATION

1. Enter the ICD-10 code that will be used for billing and reimbursement purposes.
2. Select the entity to be billed.
    a. If the patient has Medicare Advantage or Managed Medicaid, select "Private Insurance."
    b. If patient is accepting financial responsibility for the cost of the test, Customer Service will contact the Ordering Physician's office to collect payment information.
    c. Before selecting Contracted Account, verify with Genomic Health that you have a contracted account on file.
3. If the patient's insurance is Medicare, enter the hospitalization status. If Inpatient, enter the date of discharge from the hospital. All Medicare patients will have an eligibility check and may be contacted during the process.
4. Complete the Primary and Secondary Insurance Information fields.
5. Include a copy of the front and back of both the primary and secondary insurance cards.
6. GHI will use the statement of medical necessity you provide to expedite insurance appeals.

SPECIMEN RETRIEVAL

1. If indicated, GHI will request the retrieval of the appropriate specimen for the ordered assay on your behalf.
2. If the specimen retrieval section is not completed and the specimen is not submitted with the Order Form and Statement of Medical Necessity, GHI will request the specimen on your behalf. GHI will contact your office to determine the location of the patient's specimen.

PATHOLOGY & SPECIMEN INFORMATION

1. Enter the identification number for the most representative specimen (i.e. the longest linear length of the highest grade tumor) on the appropriate line.
2. If multiple primaries are being submitted, enter the most aggressive tumor on line one; it will be processed first.
3. While the GHI laboratory can accept tumor blocks and unstained slides, blocks are preferred.
4. Include a copy of the pathology report corresponding with the sample planned for evaluation with the Specimen Kit submission box. The pathology report may be used for reimbursement and/or administrative purposes.
5. 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 PREPARATION INSTRUCTIONS

1. For specimen criteria and specimen preparation instructions, visit oncotypeiq.com.
2. Please send either:
    - One fixed paraffin embedded tumor block.
    - Fifteen 5 µm serial unstained slides.
      IMPORTANT: Hand number the serially sectioned slides to indicate the order in which they were cut. Unnumbered slides will be returned.
3. Formalin is the preferred fixative. Tissues processed in other fixatives should not be submitted.
4. Label all specimens with barcode labels from the Specimen Collection and Transportation Kit. Affix a coinciding barcode in the designated area on the Order Form. (Discard any remaining barcodes; do not use for future submissions.)
5. Label the specimens with an additional patient-specific identifier (e.g. patient name, date of birth, hospital number, order number, accession number). All specimens require two patient-specific identifiers for processing.
6. If you have any questions, please contact customer service at the phone number listed on the front side of this form.

DOMESTIC SHIPPING INSTRUCTIONS

1. Before shipping, make a copy of the Order Form and Statement of Medical Necessity and retain it for your records.
2. Place the Oncotype DX Specimen Kit into the FedEx® Clinical Pak.
3. Complete the FedEx US Airbill. The airbill is pre-printed with Genomic Health shipping information.
4. Seal the Clinical Pak by removing the plastic adhesive protector from the white strip and secure.
5. Place the package in the designated FedEx pickup location at your site.
6. If your site does not have standard FedEx pickup, call 800-GO FEDEX (800-463-3339) to arrange for pick up.
7. To order additional kits, email Customer Service at customerservice@genomichealth.com.