

SELECT A TEST

Invasive Breast Cancer
Oncotype DX Breast Recurrence Score® Test

Ductal Carcinoma in Situ
Oncotype DX Breast DCIS Score® Test

Colon Cancer

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

CLINICAL INFORMATION

Invasive Breast Cancer

ER Status: Positive, Negative, Inconclusive by IHC
PR Status: Positive, Negative, Inconclusive by IHC, Not Tested
HER2 Status: Positive, Negative, Equivocal

Nodal status: Negative, Positive 1-3, Positive 4-9, Unknown

Menopausal Status*
*required for positive nodal status

Postmenopausal, Premenopausal, Unknown
The patient is a candidate for Adjuvant Chemotherapy.

Ductal Carcinoma in Situ

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.

Tumor grade: Grade 1, Grade 2, Grade 3, Unknown

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

Oncotype DX Colon Recurrence Score® Test

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

Oncotype DX Colon Recurrence Score® Test

PROVIDER 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 Exact Sciences 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 Provider for Exact Sciences orders.

PROVIDER INFORMATION

Ordering Provider Name, Provider NPI #, Practice Account, Address, Email, Phone, Fax, Contact Name, Additional Report Recipient (optional), Fax

Ordering Provider Signature, Date (mm/dd/yyyy), Print Provider Name

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

Primary Cancer Diagnosis, ICD-10 Code, Billing Type: COMPLETE the following & attach a copy of patient's insurance card (front/back), Insurance/Medicare/Medicaid, Patient Self-pay, Account Bill, Hospital Status (Medicare Only), Hospital Inpatient (>24 hours 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) Exact Sciences to request specimen from Pathology
2) Ordering Provider to request specimen from Pathology

Location of Specimen, Phone, Fax, Contact Name

PATHOLOGY AND SPECIMEN INFORMATION

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 Collection: (If different from Pathology Account)

Contact Name, Phone, Address

Specimen Comments

SELECT A TEST

Online ordering is available at online.genomichealth.com. For assistance in setting up a Portal Account for online ordering, please contact Customer Service at 866-662-6897 or oncotype@exactsciences.com.

STUDY INFORMATION

1. If the order is associated with a Exact Sciences 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, PR 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 hormone receptor positive (HR+) by an immunohistochemical study for the estrogen receptor (ER) and/or the progesterone receptor (PR) by a referring laboratory or the quantitative RT-PCR method used by Exact Sciences. If Exact Sciences determines that the submitted specimen is negative for both ER and PR by IHC and RT-PCR, a result will not be reported and the patient/payer will not be billed.
 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.
 - iii. Premenopausal status is <6 months since last menstrual period (LMP) and postmenopausal status as prior bilateral oophorectomy or >12 months since LMP with no prior hysterectomy. If these definitions do not apply, participants are categorized as premenopausal if age <50 or postmenopausal if age ≥50.
 - 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, Exact Sciences 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, Exact Sciences may use the pathology report to obtain this information for reimbursement purposes.

PROVIDER INFORMATION

1. Enter the contact information for the Ordering Provider. 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 Provider and additional recipients via the secure online portal and/or by fax based on the Providers' report delivery preferences on file at Exact Sciences. To establish or change report delivery preferences, please contact Customer Service.

PROVIDER SIGNATURE & ATTESTATION

1. The signature must be of an Ordering Provider (treating Provider or pathologist) or his/her authorized delegate. Stamped signatures are not acceptable. If this order form is completed by the Provider's representative, the patient's medical record must contain the signed order from the Ordering Provider.
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) hormone receptor positive (HR+) 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 Provider 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. For patients with coverage, select 'Insurance/Medicare/Medicaid.' Exact Sciences will bill the insurer.
 - b. If the patient accepts financial responsibility for the test, select 'Patient self-pay.' Customer Service will reach out to the Ordering Provider or the patient for payment info.
 - c. Select 'Account bill' if you have an account with Exact Sciences. Please confirm that you have a contracted account before doing so.
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. Exact Sciences will use the statement of medical necessity you provide to expedite insurance appeals.

SPECIMEN RETRIEVAL

1. If indicated, Exact Sciences 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, Exact Sciences will request the specimen on your behalf. Exact Sciences 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 Exact Sciences 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). Exact Sciences is not responsible for selecting the order in which specimens will be run. Exact Sciences will use the specimens in the order listed to complete the test.

SPECIMEN PREPARATION INSTRUCTIONS

1. For specimen criteria and specimen preparation instructions, visit precisiononcology.exactsciences.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.
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 oncotype@exactsciences.com.

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