

21-GENE RT-QPCR GENOMIC ASSAY

# OncoBreast<sup>2I</sup>

India's first indigenous 21-gene genomic recurrence scoring assay for early-stage breast cancer — delivering personalised chemotherapy guidance validated against global clinical datasets for Indian oncology practice.

**2I**

GENES ANALYSED

**0-100**

RECURRENCE SCORE

**~62%**

CHEMO DE-ESCALATION

**79+**

PGX MARKERS

OVERVIEW

# What is OncoBreast21?

OncoBreast21 is an indigenous, AI-powered laboratory test that analyses the expression of **21 genes** in a breast tumour sample to generate a personalised Recurrence Score (RS 0–100). It guides oncologists on the biological risk of cancer returning and whether chemotherapy will confer meaningful benefit beyond hormone therapy alone.



### Prognostic Value

Quantifies the baseline biological risk of distant recurrence at 10 years, independent of tumour grade or size alone — enabling confident low-risk identification and informed surveillance planning.



### Predictive Value

Predicts the benefit of chemotherapy in addition to endocrine therapy — one of the few assays validated for both prognostic and predictive roles in ER+/HER2- breast cancer globally.



### No Extra Procedure

Uses existing FFPE tumour tissue already collected during surgery or core biopsy — no additional invasive procedure or fresh specimen collection is required.



### Made for India

Indigenously developed to address cost, access, and clinical translation gaps that keep imported genomic assays out of reach for most Indian patients — bringing precision oncology to every oncology centre.

ASSAY COMPOSITION

## The 21-Gene Panel

RT-qPCR measures 16 cancer-related genes across five biological pathways and 5 housekeeping reference genes for normalisation — all from standard FFPE tumour tissue.

ESTROGEN SIGNALLING

ER PR BCL2 SCUBE2

PROLIFERATION

Ki-67 STK15 Survivin CCNB1 MYBL2

HER2 SIGNALLING

HER2 GRB7

INVASION

MMP11 CTSL2

OTHER CANCER GENES

GSTM1 CD68 BAG1

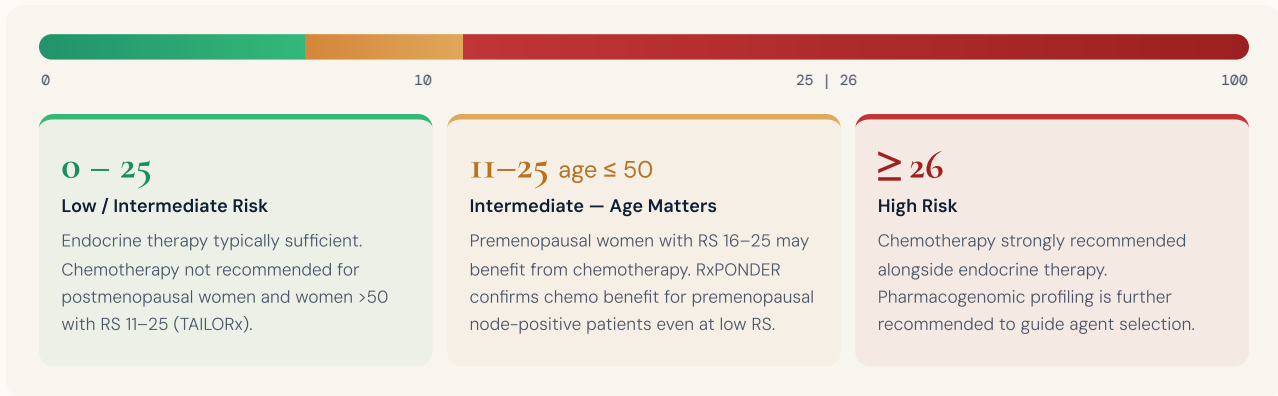
REFERENCE (HK)

ACTB GAPDH RPLP0 GUSB TFRC

CLINICAL INTERPRETATION

# Understanding the Recurrence Score

The Recurrence Score (RS) is stratified based on landmark prospective trials – TAILORx for node-negative and RxPONDER for node-positive disease. Age and menopausal status are critical modifiers.



CLINICAL VALIDATION

## Backed by Landmark Clinical Trials

The 21-gene recurrence score methodology is validated by over 20 years of prospective and retrospective evidence across tens of thousands of patients.

<p><b>NSABP B-14</b> Prognostic Validation</p> <p>Established prognostic utility in tamoxifen-treated, node-negative, ER+ patients. Low RS correlates with excellent 10-year distant recurrence-free survival.</p>	<p><b>NSABP B-20</b> First Chemo-Benefit Prediction</p> <p>Established predictive role – high RS patients derived significant chemotherapy benefit; low RS patients did not, establishing the dual-role assay paradigm.</p>
<p><b>TAILORx</b> TAILORx · NEJM 2018 Prospective Node-Negative (N=10,273)</p> <p>Women &gt;50 with RS 11–25 derived no chemotherapy benefit – enabling safe de-escalation in the majority of patients (~70% chemo safely avoided).</p>	<p><b>RxPONDER</b> Node-Positive Disease Guidance</p> <p>Extended utility to 1–3 node-positive patients. Postmenopausal RS ≤25: no chemo benefit. Premenopausal: benefit even at low RS – likely ovarian suppression effect.</p>

**62.2%** de-escalation rate

**Real-World Evidence — PONDx Survey (2024)**

In 204 real-world patients, introduction of the 21-gene RS test resulted in a 25.5% relative reduction in chemotherapy recommendations. Among patients initially recommended for chemotherapy, 62.2% were successfully de-escalated to endocrine therapy alone – reducing toxicity burden without compromising outcomes.

PATIENT SELECTION

# Who Should Be Tested?

### Indicated Patients

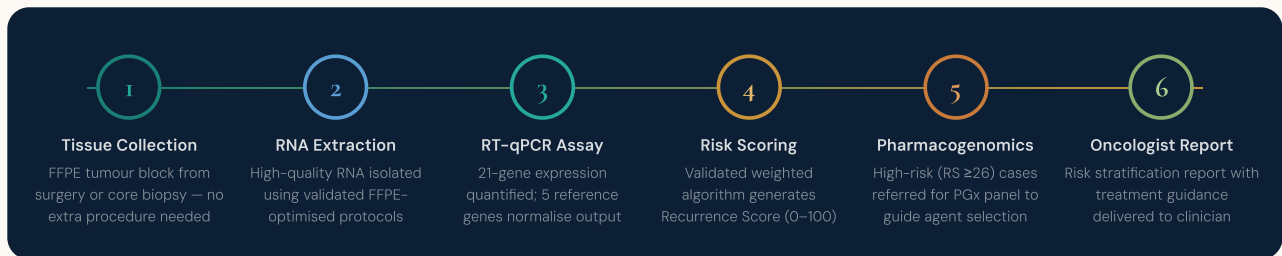
- ✓ Hormone receptor-positive (ER+ / PR+) breast cancer
- ✓ HER2-negative (confirmed by IHC / FISH)
- ✓ Early-stage disease — Stage I or II
- ✓ Node-negative, or limited node-positive (1–3 nodes)
- ✓ FFPE tissue available from surgery or core biopsy
- ✓ Clinical uncertainty between chemotherapy and endocrine therapy alone

### Not Indicated For

- ✗ HER2-positive breast cancer (not validated)
- ✗ Triple-negative breast cancer (TNBC)
- ✗ Advanced / metastatic disease (Stage III–IV)
- ✗ Hormone receptor-negative tumours
- ✗ Cases where clinical decision is already clearly determined
- ✗ Post-neoadjuvant chemotherapy setting

LABORATORY WORKFLOW

# From Sample to Clinical Decision



# Pharmacogenomics — Precision Beyond Recurrence Scoring

For patients receiving a High-Risk Recurrence Score ( $\geq 26$ ), OncoBreast21 strongly recommends pharmacogenomic profiling. Understanding how each patient metabolises and responds to chemotherapy agents is essential for selecting the most effective and safest treatment regimen.

### Effectiveness Identification

Identifies which chemotherapy agents will be most effective based on the patient's own genomic profile of drug-metabolising enzymes and tumour targets.

### Toxicity Risk Prediction

Detects inherited variants in CYP450 enzymes, ABC transporters, and uptake genes that elevate toxicity risk — enabling proactive dose adjustment.

### Optimal Dosing Guidance

Determines the precise dose at which chemotherapy will be most effective and safe — reducing the trial-and-error approach to treatment selection.

#### COMPREHENSIVE 79+ MARKER PANEL

Recommended for High RS ( $\geq 26$ ) OncoBreast21 cases · Includes hereditary risk, drug metabolism, and therapeutic target genes

### Category 1

#### Hereditary Risk & DNA Repair

High-penetrance susceptibility genes and DNA damage response markers relevant to PARP inhibitor eligibility and surgical decisions.

ATM · BARD1 · BRCA1 · BRCA2 · BRIP1 · CDH1 · CDKN2A · CHEK2 · MSH2 · MSH6 · PMS2 · EPCAM · PTEN · RAD51C · RAD51D · NF1 · PALB2 · STK11 · TP53 · FANCC · MRE11 · MUTYH · NBN · RAD50 · RECQL · RINT1 · SLX4 · SMARCA4 · XRCC2 · HOXB13

### Category 2

#### Drug Metabolism, Transport & Toxicity

CYP450 enzyme variants, ABC transporters, and uptake genes determining tamoxifen activation, anthracycline clearance, and taxane response.

CYP2C19 · CYP2B6 · CYP1B1 · CYP2D6 · RNF8 · ABCG2 · SLC22A16 · NQO2 · GSTP1 · NQO1 · ABCB1 · ALDH3A1 · ABCC2 · ERCC1 · CBR1 · XRCC1 · NOS3 · CBR3 · SOD2 · NUDT15 · UGT1A4 · SLC01B1 · FGFR4 · NCOA1

### Category 3

#### Therapeutic Targets & Pathway Markers

Actionable oncogenic drivers including PIK3CA, KRAS, FGFR family, NTRK family, BRAF, and MTOR for targeted therapy eligibility.

VEGFA · TNFRSF11B · FCGR3A · FCGR2A · AKT1 · ESR1 · KRAS · NRG1 · PIK3CA · PIK3R2 · ARID1A · CDK12 · FGFR1 · MET · NTRK1 · BRAF · FGFR2 · MTOR · NTRK2 · FGFR3 · NTRK3 · ERBB2 · ERBB3

## Book the Pharmacogenomics Panel Test


Available for High-Risk OncoBreast21 cases · Hyderabad, India

BOOK NOW →

[bookmytest.peacewise.in](https://bookmytest.peacewise.in)

COMPETITIVE LANDSCAPE

# Genomic Assay Comparison

TEST	PLATFORM	OUTPUT	DUAL ROLE	AI-POWERED	INDIA ACCESS
OncoBreast21 	RT-qPCR + Hybrid AI	Score 0–100	✓ Both	✓ TCGA + METABRIC	Indigenous
Oncotype DX (USA)	RT-PCR	Score 0–100	✓ Both	—	High cost / Import
MammaPrint (NL)	Microarray	Binary (Low/High)	Prognostic only	—	Very limited
Prosigna / PAM50	Gene expression	Risk + Subtype	Prognostic only	—	Very limited

MARKET OPPORTUNITY

## India's Breast Cancer Landscape

India faces a growing breast cancer epidemic with severely limited access to precision genomic testing. OncoBreast21 is positioned to address this critical unmet clinical need at scale.

~230K

NEW CASES / YEAR

Breast cancer is the most common cancer among Indian women, with incidence rising annually.

~60%

ER+ SUBSET

Majority of breast cancers are hormone receptor-positive — the exact OncoBreast21 indication.

<5%

GENOMIC TESTING RATE

Current penetration of genomic assays in India remains extremely low — dominated by high-cost imports.

Addressable Market Gap

₹ 95%

Approximately 95% of eligible ER+/HER2- early-stage breast cancer patients in India currently have no access to genomic recurrence scoring. OncoBreast21 is the first indigenous assay designed to close this gap at an accessible price point for Indian oncology centres.

PRECISION ONCOLOGY · MADE IN INDIA · FOR INDIA

# Bringing Precision Oncology to Every Indian Oncologist

OncoBreast21 is the next step in democratising genomic medicine in India — giving oncologists the AI-powered evidence they need to make confident, personalised treatment decisions for their patients.

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#### IMPORTANT MEDICAL DISCLAIMER

OncoBreast21 is a clinical decision-support tool only. The Recurrence Score is intended to assist qualified oncologists and must not be used as a standalone basis for any treatment decision. Only a licensed and qualified oncologist is responsible for interpreting the score in the context of the individual patient's full clinical picture. The test is validated for ER+/PR+, HER2-negative, early-stage (I-II) breast cancer only and is not validated for HER2-positive, triple-negative, advanced, or metastatic breast cancer. Results must always be used in conjunction with multidisciplinary tumour board evaluation. Pharmacogenomic testing results must similarly be interpreted by qualified pharmacologists and oncologists. Patients are strongly advised not to self-interpret any genomic or pharmacogenomic report.