OncoGenomX

Precision Oncology · Molecular Diagnostics

TECHNICAL DATA SHEET · RESEARCHER EDITION

PREDICTION-STAR DX 1.0

Profile the biology that drives ER+ metastatic breast cancer — and match more tumors to the right pathway.

PRODUCT INFO

PRODUCT NAME
PredictionStar DX 1.0

CATALOG #
OGX-PSDX-1.0-RUO

DOCUMENT #
OGX-DS-PSDX1-001 v1.0

EFFECTIVE
01 June 2026

STATUS
Research Use Only (RUO)

Not for use in diagnostic procedures.

FOR TRANSLATIONAL & CLINICAL RESEARCH

The biology-first companion for ER+ MBC research.

Bring tumour biology, not just receptor status, into your next ER+/HER2− metastatic breast cancer research study — using a streamlined DNA + RNA assay built around the genes and pathways that actually drive pathway dependence of tumors.

> Today, biology and pathway dependence match in fewer than 1 of 3 ER+/HER2− metastatic breast cancers. PredictionStar DX 1.0 is engineered to lift that number to better than 1 in 2.

KEY FEATURES

What sets PredictionStar DX 1.0 apart

✓ **Biology-led RNA panel**
41 ERMBC-relevant transcripts — three tumour-typing signatures (ERMBC 1/2/3), five functional pathway readouts, plus a multimodal MSI-equivalent gate.

✓ **Focused DNA hotspots**
Seven actionable genes (PIK3CA, AKT1, PTEN, ESR1, BRCA1/2, TP53) plus five CNV targets — covering the drivers that route patients to CDK4/6, SERD, PI3Kα-i, AKT-i, PARP-i and ADC therapies.

✓ **Single FFPE specimen, single run**
10 unstained 5 µm slides or one FFPE block, <50 ng combined NA. Ion AmpliSeq library on Ion Torrent Genexus DX — 8/16/32-plex, ~48 h end-to-end.

✓ **Decision-ready output**
Per-regimen match probability and supporting evidence via the GCI report (in test phase) — designed to plug into existing molecular tumour boards.

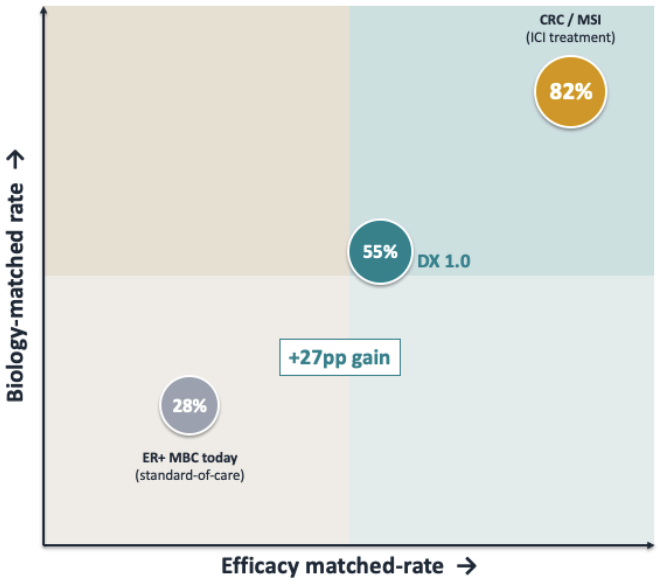
PERFORMANCE AT A GLANCE

OncoGenomX · PredictionStar DX 1.0

From 28 % to 55 % — closing the ERMBC biology-match gap.

biology- / efficacy-matched rate (input) → **predictive yield** (clinical output) · read at 6-month RECIST 1.1 CBR in VA-OGX_RS002a (in preparation).

The biology / efficacy matrix positions PredictionStar DX 1.0 against the molecular tests routinely available to ERMBC researchers today (OGX-1019_P001-17, OncogenomX, data on file).



Biology / Efficacy 2×2 — Efficacy- vs. biology-matched rate. CRC / MSI-H sets the aspirational ceiling for a single biology-matched biomarker. PredictionStar DX 1.0 closes most of the gap from today's ER+ MBC standard of care (28 %) toward that ceiling, reaching a 55 % biology-matched rate (modelled based on literature data in the public domain.

TECHNICAL DATA SPECIFICATION

Indication scope	ER+/HER2− MBC, 1L & 2L, postmenopausal IDBC
Specimen	FFPE block or 10 × 5 µm slides · tumour ≥ 20 %
Input NA	< 50 ng combined DNA + RNA
DNA content	7 hotspot genes + 5 CNV targets · ~150 kb
RNA content	41 ERMBC-relevant transcripts
Platform	All G2-DNA/RNA sequencing solutions
Throughput	8 / 16 / 32 libraries per run
TAT	24 h on-instrument · ~48 h end-to-end
Bioinformatics	Genexus on-instrument + GCI report (test)
Reference genome	GRCh38
Validation	Dual-site (Cincinnati ⇄ WLA VA HCS), RS001
Status	RUO · LDT-track · LVT / CDx in roadmap

BUILT FOR

Researchers who need biology, not just receptor and mutation status.

Academic & translational labs
Tumour collections, biobanks, investigator-initiated studies.

Pharma & biotech R&D
Preclinical hypothesis generation, target validation, companion-style enrichment.

Commercial MDx laboratories
LDT pipeline-in-a-box for ER+ MBC programmes.

CROs & study groups
Standardized biology readouts across multi-centre ERMBC trials.

PROFILE YOUR ER+ BC COLLECTION

Put PredictionStar DX 1.0 to work on your tumors.

Now accepting research partners for a limited cohort of ER+/HER2− MBC tumour collections in 2026–27 — bring your samples, we return biology-led profiles your team can build on.

→ REQUEST A FEASIBILITY CALL

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