CE IVD

ctDNA Breast

NGS Panel

NGS Clinical Panels

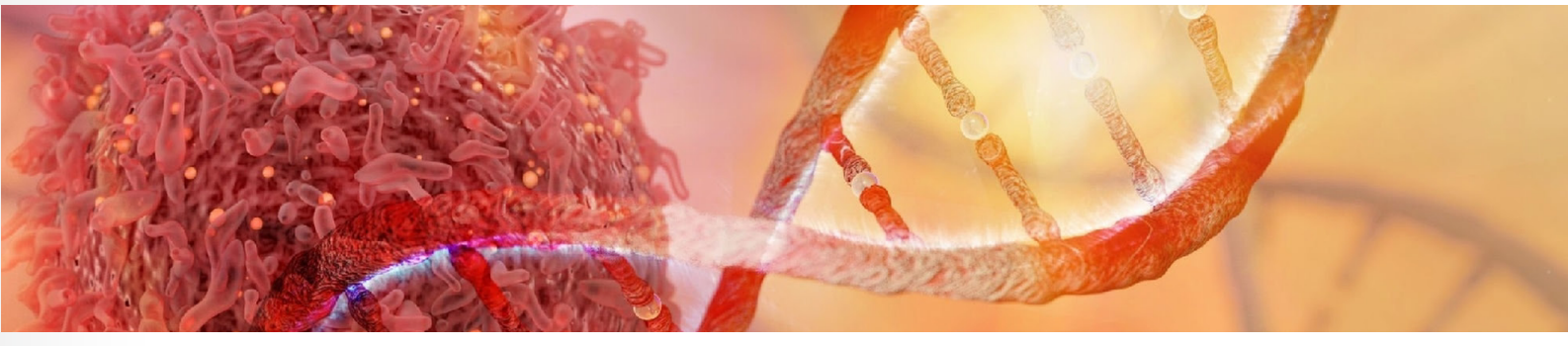
The Genes 2Me ctDNA Breast Panel is a hybridization based solution for targeted sequencing employing NGS. With a fast turnaround time this product provides detection and identification of 36 clinically relevant genes spanning 115 Kb of genome size (whole coding sequence) that covers all major mutations like SNV and InDels linked to breast cancer.

Focused Comprehensive Panel: Targets all the specific genes encapturing ultra-low VAF mutations

Low Input: Process compatible with low input quality compromised samples

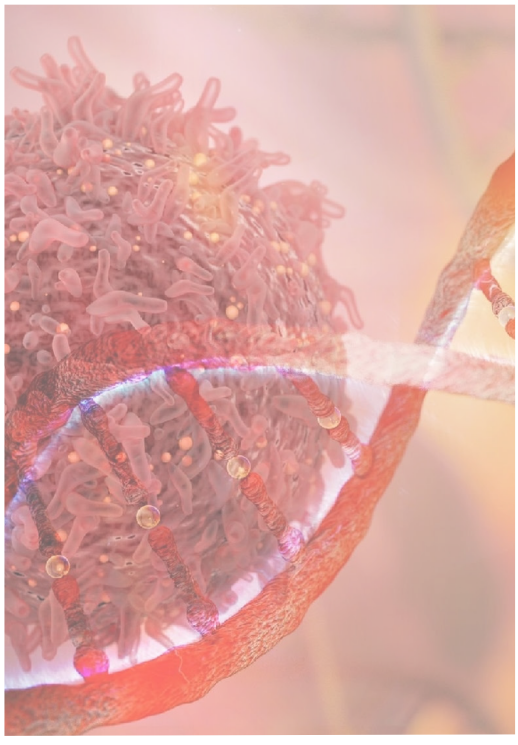
Robust and Rapid Workflow: Hybridization enhancer technology and enzyme based library preparation enables quick turn around time.

CliSeq Interpreter: User friendly companion software for automated & cloud based analysis and reporting.



ctDNA Breast

NGS Panel



The steady increase in breast cancer incidence since the mid-2000s has become a major issue in oncology, as it translates to more than 2 million new cases annually around the globe. Liquid biopsies refer to the isolation and analysis of tumor-derived biological material from body fluids, most commonly blood, in order to provide clinically valuable information for the management of cancer patients. Their non-invasive nature allows to overcome the limitations of tissue biopsy and complement the latter in guiding therapeutic decision-making. In the past years, several studies have demonstrated that circulating tumor DNA (ctDNA) detection can be used in the clinical setting to improve patient prognosis and monitor therapy response, especially in metastatic cancers. With the advent of significant technological advances in assay development, ctDNA can now be accurately and reliably identified in early-stage cancers despite its low levels in the bloodstream.

No. of Genes	36
Gene count /family	~29
Covered region	Whole CDS, Hotspots, DNA Fusions
Target size	115 Kb
Mutation type	SNVs/InDels/CNVs
Sample type	Blood/Plasma

The Genes 2Me ctDNA Breast Panel screens Breast cancer causing genes to identify somatic mutations in DNA from blood. It provides comprehensive detail of the cancer and helps to decide the best course of treatment. The screening method involves using circulating tumor cells that are used as biomarkers to detect Breast cancer. Circulating tumor DNA (ctDNA) is released from tumor cells. Applications of ctDNA in Breast cancer include early diagnosis and detection, prognosis prediction, detecting mutations and structural alterations, minimal residual disease, tumor mutational burden, and tumor evolution tracking.

Gene List

AKT1	APC	AR	BRCA1	BRCA2	CCND1#	CDH1	EGFR	ERBB2#
ESR1	FBXW7	FGFR1#	FGFR2#	GATA3	IGF1R#	KIT	KRAS	MAP2K4
MAP3K1	MDM2#	MYC#	NF1	PIK3CA	PIK3R1	PTEN	RB1	SF3B1
TOP2A#	TP53							

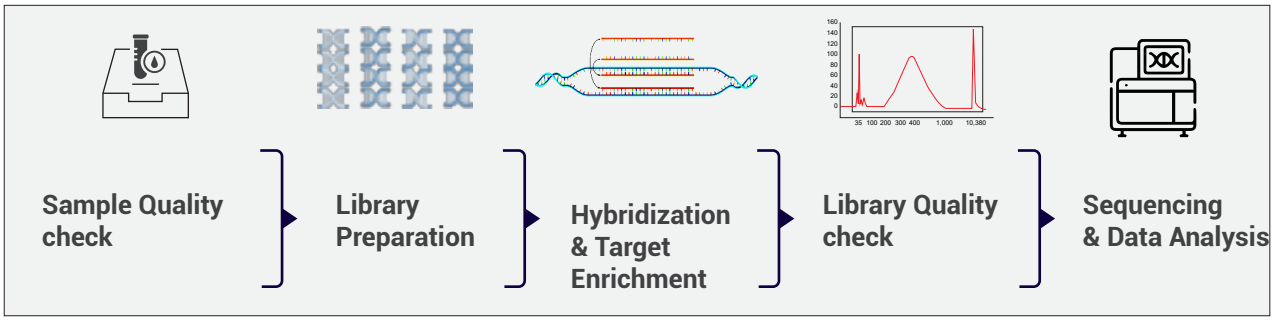
Specifications

Starting Material (DNA)	Library preparation time	Bioinformatics analysis	Databases used for Annotation
10-20 ng circulating tumor DNA	1.5 days (including Target Capture & Enrichment) for manual process With **G2M Auto EzyPrep automated NGS Library preparation system:** Minimum Hands-on required	Within 24hrs (Raw data to CSM report)	COSMIC, TCGA, ICGC, FusionDB, OncoDB, ClinVar, OMIM, gnomAD 1000Genome, dbSNP

Process Workflow

A. Platform Agnostic

Sequencing on multiple platforms (Illumina, MGI and Element Biosciences)



B. Bioinformatics Solutions

Data Analysis and Interpretation using Genes 2Me Cliseq Interpreter software

Panel Performance

Features	Illumina	MGI
Coverage uniformity	97%	98%
Precision	93%	93%
Reproducibility	98%	98%
Sensitivity	<1% VAF at 95%	<1% VAF at 95%
On Target Ratio	88-95 %	87-95%

Scan for Sample Report

Gene & Drug details

Type of Cancer	Gene	Drug
Breast cancer, Metastatic Castrate Resistant Prostate Cancer, Ovarian Cancer	BRCA1	Olaparib, Rucaparib, Niraparib + Abiraterone acetate
Ovarian Cancer, Breast cancer	BRCA2	Talazoparib
Breast Cancer	ERBB2	Trastuzumab, Pertuzumab, Ado-trastuzumab emtansine
Breast Cancer	ESR1	Elacestrant (Orserdu)

References

- https://www.cdc.gov/cancer/breast/basic_info/risk_factors.htm(1).
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- Sircoulomb, F., Bekhouche, I., Finetti, P. et al. Genome profiling of ERBB2-amplified breast cancers. BMC Cancer 10, 539 (2010).
- Abu-Helalah, M., Azab, B., Mubaidin, R. et al. BRCA1 and BRCA2 genes mutations among high risk breast cancer patients in Jordan. Sci Rep 10, 17573 (2020).
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Ordering Details

Commercial Name	Cat No.	Pack Size
ctDNA Breast Panel	G2MCTBP12001-ill	96T
	G2MCTBP12001-MG	96T

CE IVD

MAKE IN INDIA

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