



SOFIVA Cancer Monitor-Breast Cancer

Assessments for FDA-approved drug for Breast cancer, Specimen type could be tissue and body fluid.

Gene list (26 genes)

AKT1 🔍	CCND1 O	FBXW7 🗕	MSH6 –	RB1 🔴
AKT2 🔴	CDK4 😐	FGFR1 🗕	NTRK1 🗕 🗕	TP53 😑
AR 🕘	CDK6 😑	FGFR2 🗕 🔴	PIK3CA 😑	
BRAF 😑	CSF1R 😑	GATA3 🔴	PMS2	
BRCA1 😐	ERBB2 🔍 🔍	MLH1 📃	PTEN 😐	
BRCA2 😐	ESR1 O	MSH2 🗕	RET 🛛 🔴	

SNV and InDel analysis; Fusion analysis – / CNV analysis –

Specification

-		
Specimen	Blood,Body fluid(ctDNA)	FFPE
Technology	Hybrid capture-based NGS + Sanger Sequencing*	
Average reads	>6,000x	>3,600x
Analytical variants	SNV / InDel / CNV / Fusion	
Sensitivity	99.0%	
Turnaround time	10 working days**	

* To clarify whether a mutation is a germline mutation or a somatic mutation. **10 working days after qualified specimens are collected.

Features

NGS Testing of Breast Cancer	SOFIVA Cancer Monitor -Breast Cancer	Advantages
Specimen	 • FFPE ✓ • Blood (ctDNA) ✓ • Body fluid (pleural fluid, pleural effusion, etc.,ctDNA) 	ctDNA is suitable for SNV / InDel / CNV / Fusion analysis.
Technology	¥ Hybrid capture-based NGS	High overlapping probe is used to comprehensively detect possible gene variations.
Tested genes	26 genes	This item could help doctors determine the treatment strategy of FDA-approved drug for breast cancer for their patients.
Analytical variants	SNV / InDel / CNV / Fusion	Multiple specimen types, tissue or ctDNA could be analyzed.
Turnaround time	10 working days	Report is got quickly.
 Patient condition: Insufficient tissue specimens Unable to re-sampling 	ctDNA analysis using liquid biopsy is available and the specimens could be blood, pleural fluid, pleural effusion, etc.	, NGS testing is available even if there is not enough tumor tissue in last stage patient.

SOFIVA Cancer Monitor-Breast Cancer

Features and Procedure

Information for targeted therapy : NGS panel tests can evaluate multiple genes simultaneously



Specimen type could be tissue and blood.



Multi-gene detection is time-saving and instant.



Both germline and somatic mutation can be detected.

SOFIVA Cancer Monitor-Breast Cancer: assessments for FDA-approved drug

Breast Cancer	Targeted therapies listed in NCCN guideline ¹	
BRCA1/2	Olaparib, Talazoparib	
ERBB2	Ado-Trastuzumab, Emtansine, Lapatinib,Margetuximab, Neratinib(Nerlynx),Trastuzumab, Trastuzumab Deruxtecan	
ESR1	Elacestrant	
PICK3CA	Alpelisib	
Solid Tumors		

BRAF V600E Mutation	Dabrafenib+Trametinib(Not indicated for colorectal cancer)
NTRK Fusion	Entrectinib, Larotrectinib
RET Rearrangement	Selpercatinib

Panel selection

Accurate and complete drug-related gene panel

SOFIVA Cancer Monitor -Breast Cancer 26 genes

Covers genes associated with targeted therapies for patients with breast cancer.
Common mutations in breast cancer.
MMR genes. 14 genes Breast Cancer v1.0

SOFIVA Cancer Monitor v1.0

31 genes

• Covers genes associated with common targeted therapies for patients with solid tumors.

SOFIVA Cancer Monitor v2.1- 77 genes: targeted therapies, potential clinical trial SOFIVA Cancer Monitor v3.0- 249 genes: targeted therapies, potential clinical trial, monitoring SOFIVA CGP – 324 genes + TMM +MSI : targeted therapies, immunotherapy, potential clinical trial

Procedure

Physician/ nurses explain procedures and contents Sign the consent form and collect blood and FFPE specimen

Send specimen to SOFIVA GENOMICS Analysis of experimental data

Report is produced in 10 working days

Reference:

1. NCCN Guidelines Breast Cancer Version 4. 2023



SOFIVA GENOMICS Medical Laboratory

T +886-2-2382-6615 ext.7 F +886-2-2382-6617 No.27, Baoqing Rd., Zhongzheng Dist., Taipei City 100, Taiwan www.sofivagenomics.com

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SOFIVA GENOMICS BANGKOK

T +66-2-258-5168 F +66-2-258-5368 888 Polaris Tower, 4th Floor, Soi Sukhumvit 20, Sukhumvit Road, Khlong Toei, Bangkok 10110, Thailand www.sofivagenomics.com