BRCAaccuTest& BRCAaccuTest Plus

Genetic testing for BRCA1/2 mutations

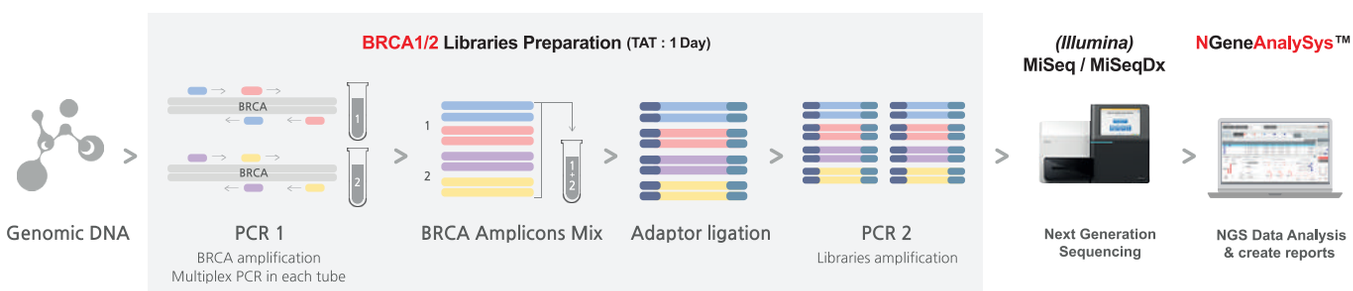
For breast and ovarian cancer patients
For HBOC(Hereditary breast and ovarian cancer syndrome) patients
For family history or the age of breast cancer incidence

BRCAaccuTest™ is a reagent for producing libraries for analyzing the BRCA1/2 genes using the NGS (next-generation sequencing) method, which analyzes genomic DNA derived from blood or FFPE tissues.

Product Specification

	BRCAaccuTest™	BRCAaccuTest™PLUS
certification	CE-IVD, KFDA Class III	CE-IVD
Technique	NGS (Next Generation Sequencing)	
Compatible platforms	Illumina / MiSeq, MiSeqDx	
Target Enrichment	Amplicon method	
Specimen	Blood	Blood and FFPE tissue, tissue biopsy
Quantity	24 test (1 test for control DNA)	6+6 test (1 test each for control DNA)
Target region	19.8 kb (all protein coding region + intron boundary 10 bp)	
Amplicons(primer pairs)	131 (2 pools)	146 (2 pools)
Mean amplicon size	234 bp	207 bp
Hands on time	4.5 hrs	5 hrs

Working Process

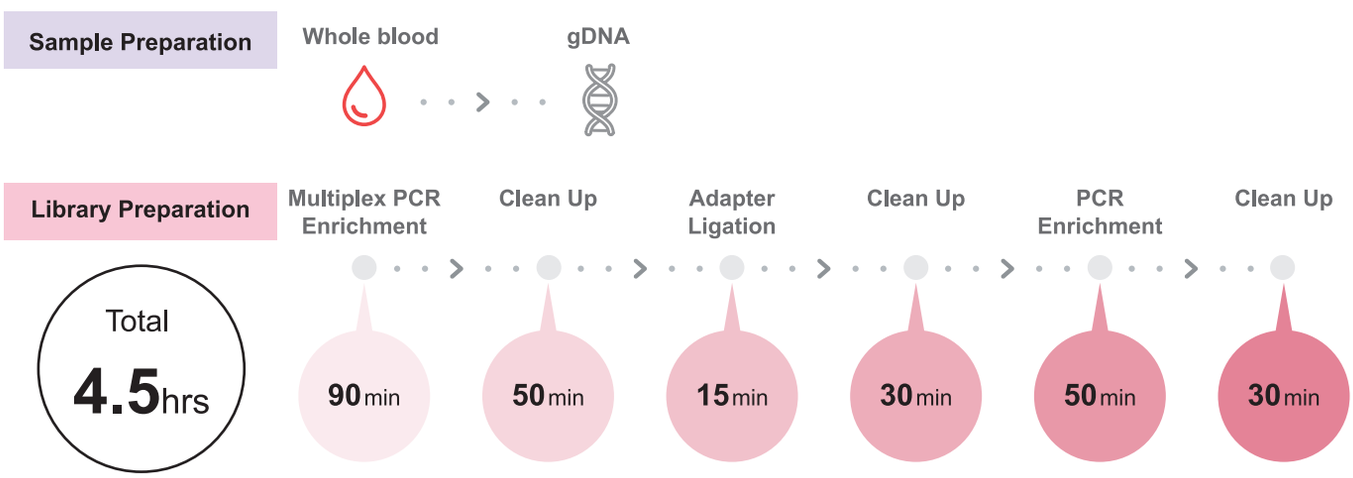


Product Performance

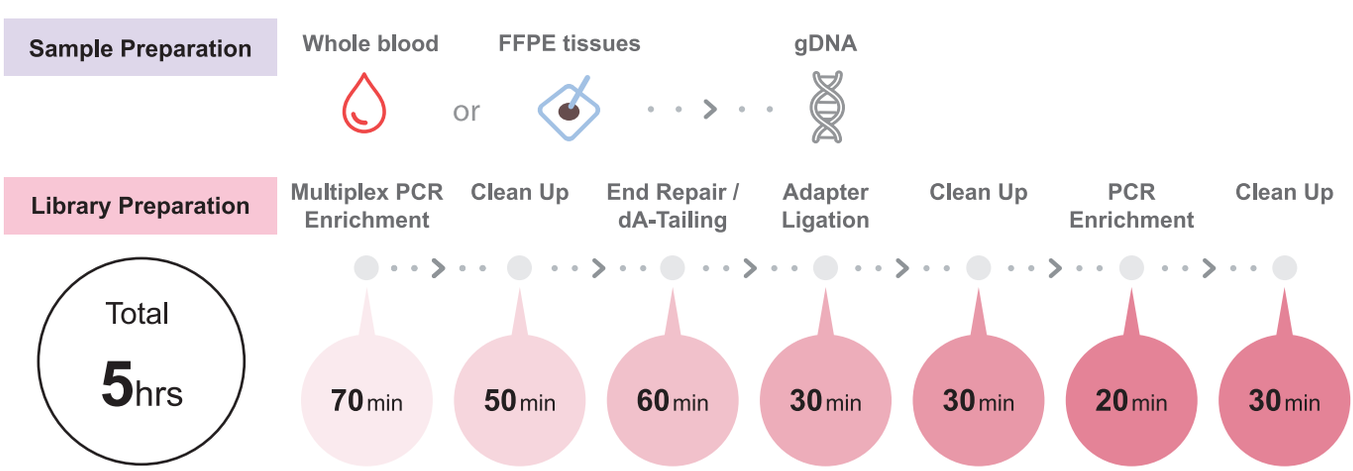
	Germline samples	Somatic samples
Compatible kit	BRCAaccuTest™ / BRCAaccuTest™ PLUS	BRCAaccuTest™ PLUS
Target coverage	Mean coverage 200X Minimum coverage 20X (MiSeq Reagent Nano kit v2, 300cycles / 24 tests)	Mean coverage 1000X Minimum coverage 200X (Using MiSeq Reagent Nano kit v2, 300cycles / 6 tests)
Uniformity	100% detected >0.2x mean coverage	100% detected >0.2x mean coverage
Accuracy	> 99.99%	> 99.99%
Target specificity	> 95% on target read counts	> 95% on target read counts
Sensitivity	Input gDNA 0.5 ng	VAF 5%

BRCAaccuTest™ & BRCAaccuTest™ PLUS Comparison

BRCAaccuTest™



BRCAaccuTest™ PLUS



BRCAaccuTest™ Validation Data

BRCAaccuTest™ gave the positive, negative, and overall diagnostic consistency over 99 % with Sanger sequencing at a significance level of 5%

Clinical Study Design

Residual genomic DNA after BRCA1/2 mutation screening SNUH (2008~2015)

DNA samples with BRCA1 or 2 mutations

BRCA1(+), BRCA2(-)
106 samples

BRCA1(-), BRCA2(+)
106 samples

Sanger Sequencing
[10% of 212 samples]

Confirm the stability of residual samples

stable

BRCAaccuTest™
212 samples

- Assessment of diagnostic consistancy between Sanger sequencing and BRCAaccuTest
- PPA, NPA, OA, McNemar test, Cohen's Kappa

Diagnostic agreement : 100%

		Sanger Sequencing P	Sanger Sequencing N
BRCAaccuTest	P	TP	FP
	N	FN	TN

* True Positive (TP), False Positive (FP)
* False Negative (FN), True Negative (TN)

BRCA1 (BRCA2)		Sanger Sequencing P	Sanger Sequencing N	Sanger Sequencing Sum
BRCAaccuTest	P	103	0	103
	N	0	103	103
	Sum	103	103	206

* Test results in BRCA2 were identical to those in BRCA1
* Tested number of samples

GENE	PPA (95% CI)	NPA (95% CI)	OA (95% CI)
BRCA1	100 (0.9648, 1)	100 (0.9648, 1)	100 (0.9823, 1)
BRCA2	100 (0.9648, 1)	100 (0.9648, 1)	100 (0.9823, 1)

* Positive Percent Agreement (PPA) = [TP/(TP+FN)] x 100
* Negative Percent Agreement (NPA) = [TN/(TN+FP)] x 100
* Overall Agreement (OA) = [(TP+TN)/(TP+FP+FN+TN)] x 100

Variants agreement : 100%

BRCA1 (BRCA2)		Sanger Sequencing SNV	Sanger Sequencing Duplication	Sanger Sequencing Deletion	Sanger Sequencing INDEL
BRCAaccuTest	SNV	1,629	0	0	0
	Duplication	0	12	0	0
	Deletion	0	0	49	0
	INDEL	0	0	0	14

* Number of detected variants

NGeneAnalySys™ Performance

Test Data		Test Number (Variants tested) Manual Analysis	Test Number (Variants tested) NGeneAnalySys™	Concordance
Analytical Validation	Cell lines	277 (219)	277 (219)	100%
	Clinical Samples	80 (78)	80 (78)	100%
Clinical Validation	Clinical Samples	206 (1,704)	206 (1,704)	100%
Sum		**563 (2,001)**	**563 (2,001)**	

Ordering Information

Cat no.	Products	Quantity (T)	Storage
NGB111VKA	**BRCAaccuTest™** (Approved CE-IVD and KFDA Class III) - BRCA Amplicon Primer Mix 1 - BRCA Amplicon Primer Mix 2 - Hot Start PCR I Master Mix - Ligation Mix - Amplicon DNA Adapter - PCR II Barcoded Primer Mix N1~N24 - PCR II Mater Mix - Nuclease-Free Water - Control DNA - Resuspension Buffer - Cleanup Beads	24	**-20℃** (box package) **4℃** (separated component)
NGB112VIA	**BRCAaccuTest™ PLUS** (Approved CE-IVD) - BRCA Primer Mix 1 - BRCA Primer Mix 2 - Hot Start PCR Polymerase - 2X PCR Buffer - End Repair Enzyme mix - End Repair Reaction Buffer - Ligation Master Mix - Ligation Enhancer - Adapter (for Illumina) - Uracil-DNA glycosylase (UDG) - PCR II Mater Mix - Barcoded Primer (Index1~Index12) - Universal Primer - Control DNA	12	**-20℃** (box package)
NGB311VWW	**NGeneAnalySys™ v.1.1** (Software for only germline analysis)		
NGB312VWW	**NGeneAnalySys™ v.1.3** (Software for both germline and somatic analysis)		

This product can be used for *in vitro* diagnostic purpose in authorized countries

All products of NGeneBio Co., Ltd. are manufactured under a strict quality control process. NGeneBio Co., Ltd. warrants the quality of the product during the warranty period (marked on the product).

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