

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

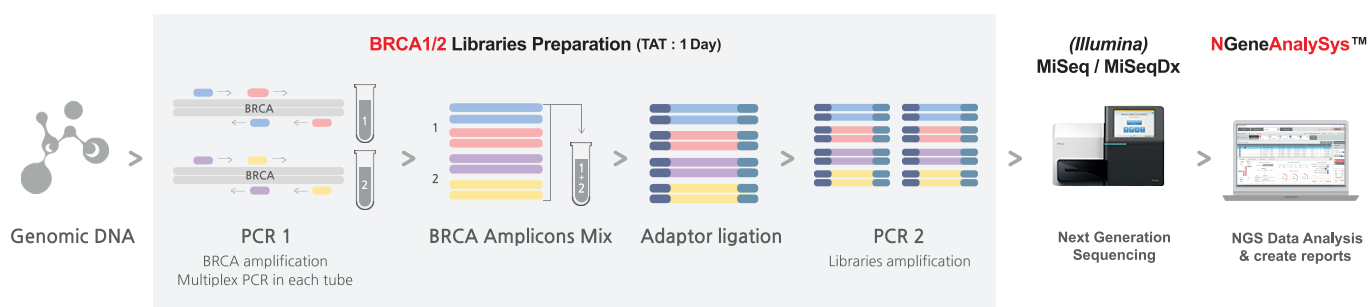
BRCAaccuTest™ is a reagent kit for producing libraries for analyzing the BRCA1/2 genes using the NGS (next-generation sequencing) method, which analyzes genomic DNA derived from blood or FFPE tissues



Product Specification

	BRCAaccuTest™	BRCAaccuTest™ PLUS
certification	CE-IVD, MFDS(KFDA) Class III	CE-IVD
Technique	NGS (Next Generation Sequencing)	
Compatible platforms	Illumina / MiSeq, MiSeqDx	
Target Enrichment	Amplicon-based 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

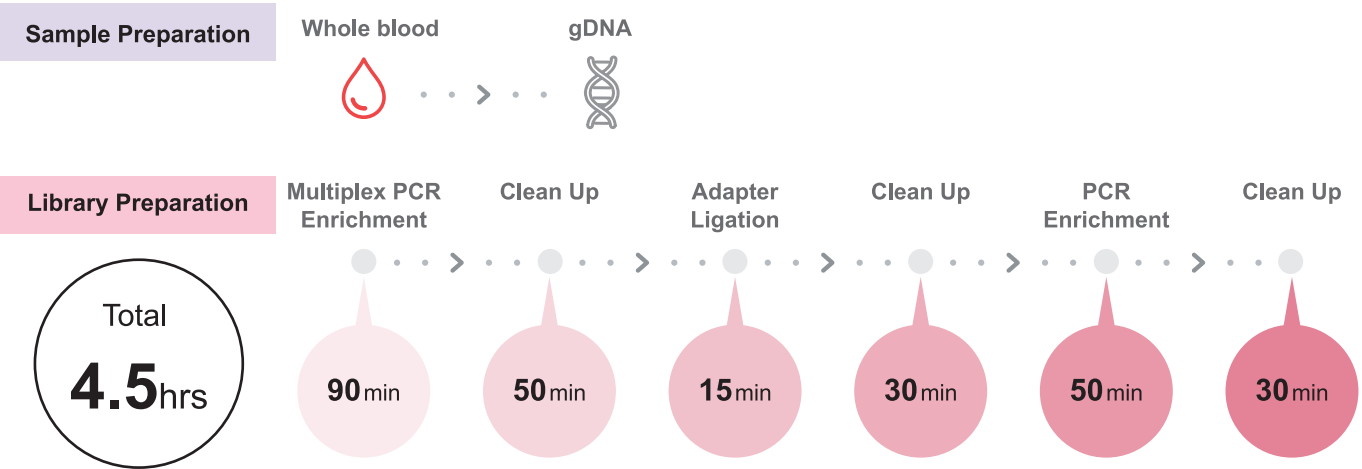


Product Performance

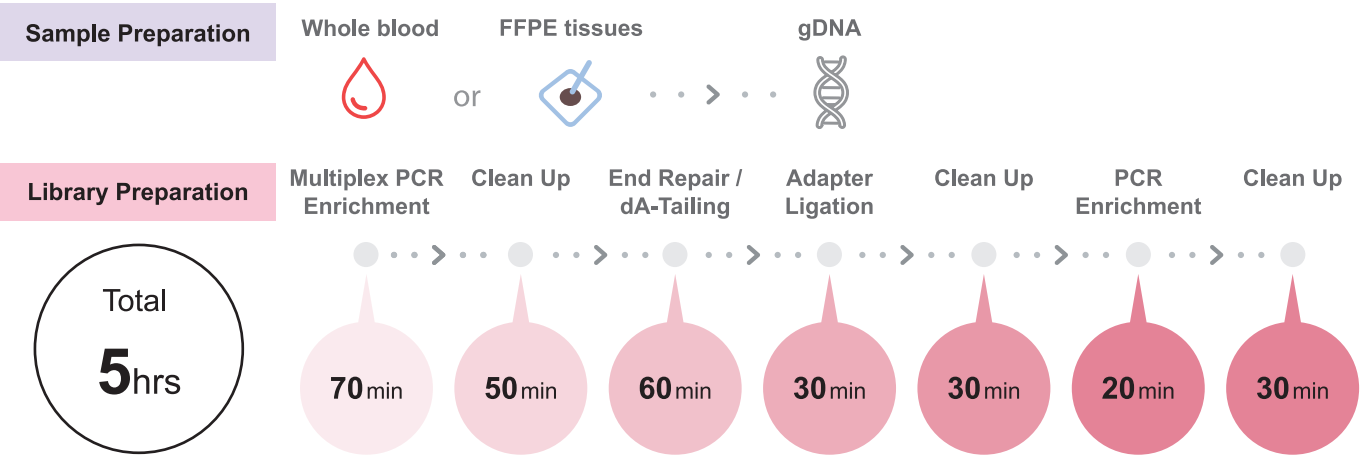
	Germline samples	Somatic samples
Compatible kit	BRCAaccuTest™ / BRCAaccuTest™ PLUS	BRCAaccuTest™ PLUS
Target coverage	Mean coverage 200X Minimum coverage 20X (MiSeq Reagent Nano kit v2, 300cycles / 24 tests)	Mean coverage 1000X Minimum coverage 200X (Using MiSeq Reagent Nano kit v2, 300cycles / 6 tests)
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™



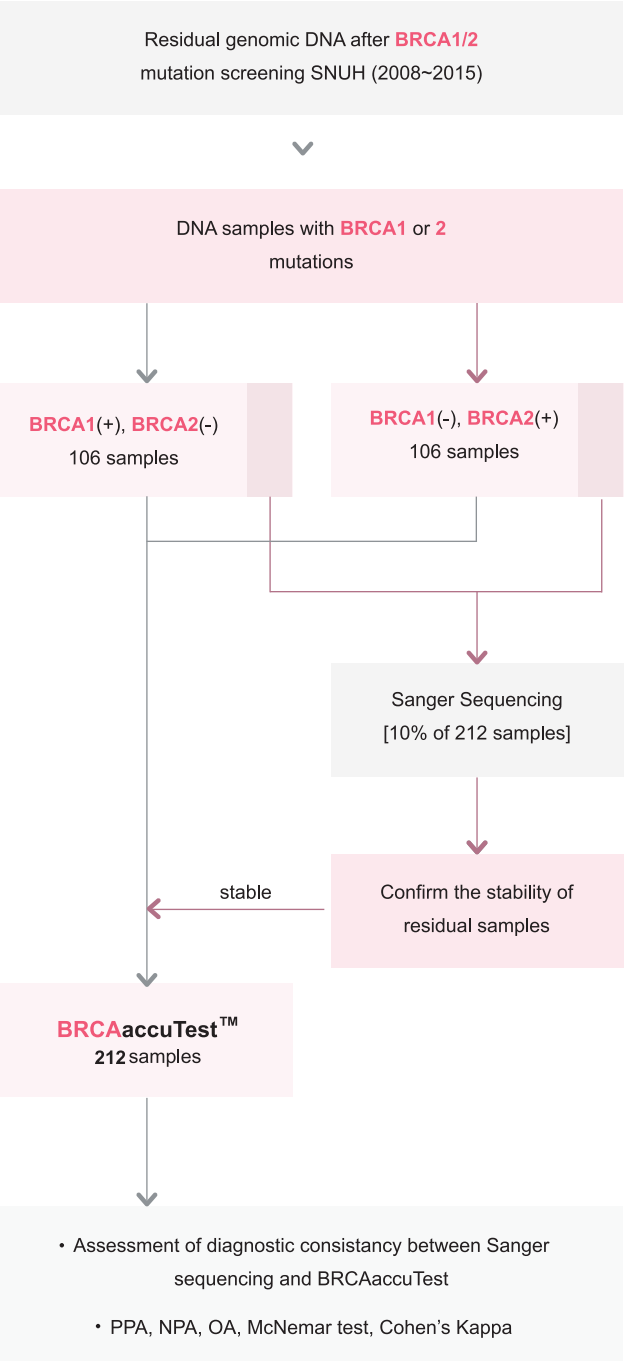
BRCAaccuTest™ PLUS



BRCAaccuTest™ Validation Data

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

Clinical Study Design



Diagnostic agreement : 100%

		Sanger Sequencing	
		P	N
BRCAaccuTest	P	TP	FP
	N	FN	TN
* True Positive (TP), False Positive (FP) * False Negative (FN), True Negative (TN)			

		Sanger Sequencing		
BRCA1 (BRCA2)	BRCAaccuTest	P	N	Sum
		103	0	103
	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 # 8 internal controls included				

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) = $\frac{TP}{TP+FN} \times 100$
* Negative Percent Agreement (NPA) = $\frac{TN}{TN+FP} \times 100$
* Overall Agreement (OA) = $\frac{TP+TN}{TP+FP+FN+TN} \times 100$

Variants agreement : 100%

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

* Number of detected variants

NGeneAnalySys™ Performance

Test Data		Test Number (Variants tested)		Concordance
		Manual Analysis	NGeneAnalySys™	
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
NGB111VIA	BRCAaccuTest™ (CE-IVD registered & KFDA Class III approved) - 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 (CE-IVD registered) - PCR I Ppolymerase - PCR I Buffer - ER Enzyme Mix - ER Buffer - AL Enzyme Mix - AL Enhancer - Adapter (for Illumina) - UDG enzyme - Index PCR Master Mix - Index Primer B01 ~ B12 - Universal Primer - Control DNA	12	-20℃ (box package)
NGB311VWW	NGeneAnalySys™ v.1.1 (Software for only germline analysis) (CE-IVD registered & MFDS(KFDA) Class III approved)		
NGB312VWW	NGeneAnalySys™ v.1.4 (Software for both germline and somatic analysis) (CE-IVD registered)		

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).