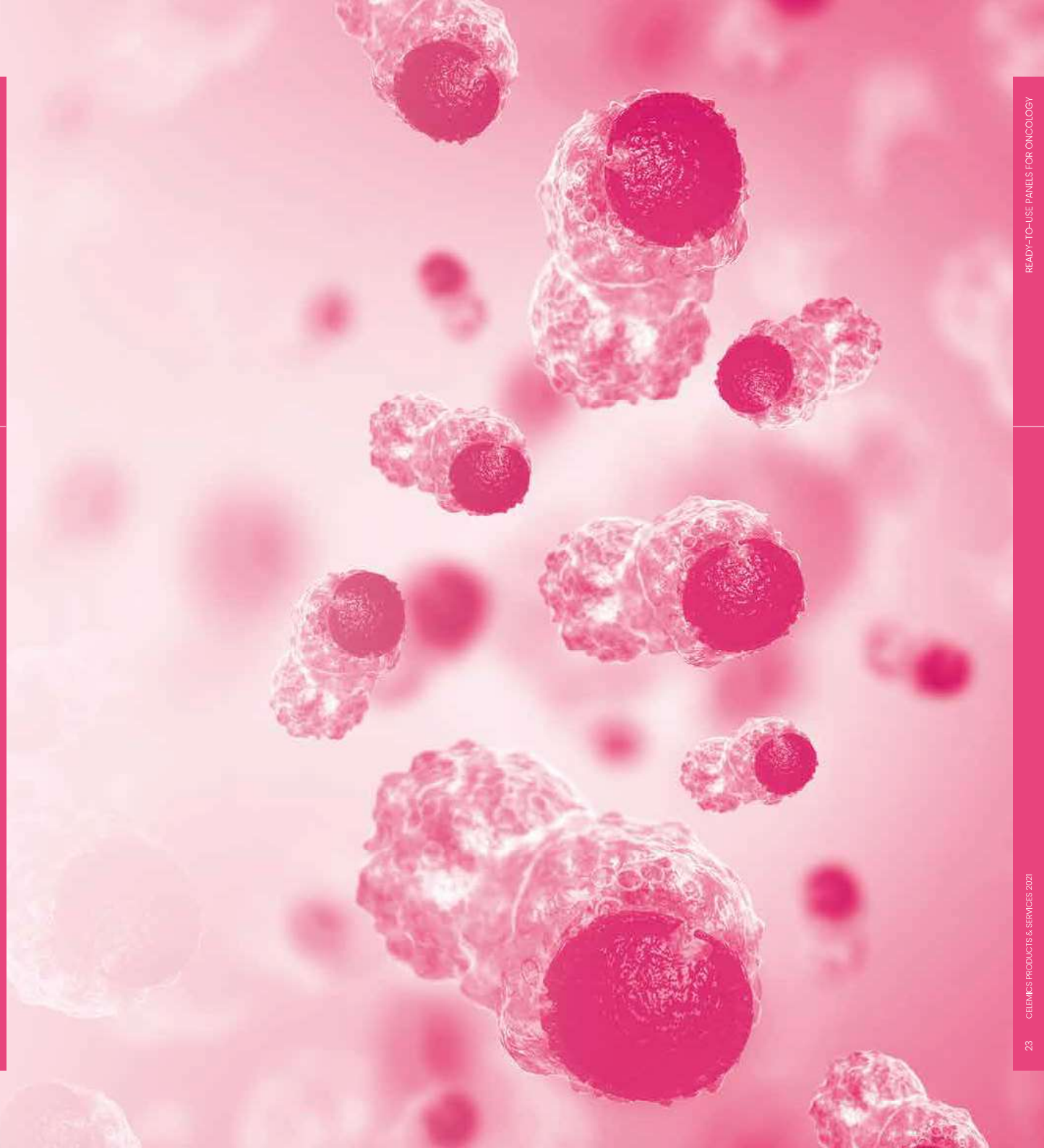
READY-TO-USE PANELS FOR ONCOLOGY

CELEMICS PRODUCTS & SERVICES 2021

BRCA 1/2 Panel
OncoRisk Panel
CancerScreen Panel - Core / 50 / 100 / 400
CancerMaster Panel

CELEMICS

Palex
Constant Improvement



BRCA 1/2 Panel

Germline and Somatic Cancer

KEY FEATURES

1. Targets the whole CDS (+/- 40) and promoter regions of BRCA 1/2 with high specificity	Target regions not only covering the CDS regions but expanded to +40 and -40 of CDS to detect splicing site variants Probes specifically designed for detecting deletion, duplication, and large rearrangement
2. Compatible with a variety of sample types	No compromise on panel performance even with of using DNA from challenging specimen types such as blood and FFPE
3. Market-leading panel performance in uniformity and coverage	Designed to target whole exon regions of BRCA 1, 2 gene with 100% coverage (RefSeq) and validated to yield 100% coverage

SPECIFICATION

Gene count*	BRCA 1/2 genes
Covered region	Whole CDS (+/- 40bp), UTR, Promoter
Target size	23 kb
Mutation type	SNV, Indel, CNV
Sample type(amount)	Blood (> 50 ng of fragmented DNA), FFPE
Platform	All sequencers from Illumina, Thermo Fisher, MGI, PacBio, and Oxford Nanopore
Sensitivity	> 95% for all variant types at 5% VAF
Specificity	99.9% (SNV), 99.5% (Indel)
Bioinformatics pipeline	Primary, Secondary and Tertiary analysis result (FASTQ to VCF, VCF to Clinical report)

* Gene Add-on Service: Genes can be added or removed by customer demand

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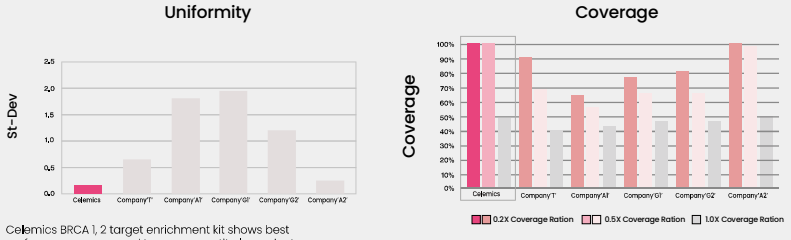
PANEL PERFORMANCE

1. Superior Panel Performance Compared to Competitor Product

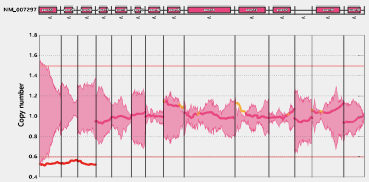


Celemics BRCA 1, 2 target enrichment kit shows best performance compared to our competitor's products

2. SNV, CNV Analysis

BRCA1, S1556G & S1389S / BRCA2, N372H & L1521L / BRCA1 CNV plot

Gene	Mutation Type	Amino AcidC hange	Sequencing			Variant Allele Frequency
			Total	Ref.	Alt.	
BRCA1	Non-SYN	p.S1556G	634	315	301	48.71%
BRCA1	SYN	p.S1389S	876	501	370	42.48%
BRCA2	Non-SYN	p.N372H	396	213	181	45.94%
BRCA2	SYN	p.L1521L	289	0	281	99.29%



PACKAGE COMPOSITION

Package name	Compositions		
Target Enrichment	Target capture Probe	-	
Standard	Target Enrichment reagents	Library prep Kit	-
All-In-One			Beads / Polymerase

Package option	Options	
Pooling method	Single Reaction	Pre-capture Pooling
Library Preparation kits	Standard Kit	EP-kit
Hybridization Enhancer	Included	Not included

OncoRisk Panel

Hereditary Cancer
(Germline cancer risk)

KEY FEATURES

1. Comprehensive analysis of oncogenes	Analyze 31 oncogenes associated with inherited cancer and precisely selected from contract research organizations and numerous research studies
2. Robust bioinformatics system for large deletion analysis	Receive bioinformatics results for large deletion analysis provided by Celemics proprietary bioinformatics analysis system
3. Used for Homologous Recombination Deficiency (HRD) testing	Provides information for HDR grade computation to aid precision medicine for tumor treatment

SPECIFICATION

Gene count*	31 genes
Covered region	Whole CDS
Target size	96 kb
Mutation type	SNV, Indel, CNV, Rearrangment
Sample type(amount)	Blood (> 50 ng of fragmented DNA), FFPE
Platform	All sequencers from Illumina, Thermo Fisher, MGI, PacBio, and Oxford Nanopore
Sensitivity	> 95% for all variant types at 5% VAF
Specificity	99.90% (SNV), 99.50% (Indel)
Bioinformatics pipeline	Primary, Secondary and Tertiary analysis result (FASTQ to VCF, VCF to Clinical report)

* Gene Add-on Service: Genes can be added or removed by customer demand

GENE LIST

OncoRisk Panel	APC	ATM	BARD1	BLM	BMPR1A	BRCA1	BRCA2	BRIP1	CDH1	CDK4	CDKN2A	CHEK2	EPCAM
	MLH1	MRE11A	MSH2	MSH6	MUTYH	NBN	PALB2	PMS2	PRSS1	PTEN	RAD50	RAD51C	RAD51D
	SLX4	SMAD4	STK11	TP53	VHL								

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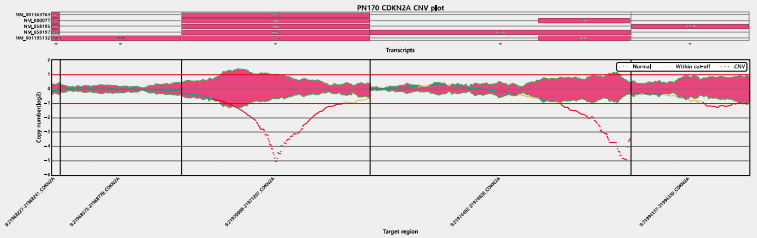
PANEL PERFORMANCE

1. SNV Analysis Example

Gene	Mutation Type	Amino Acid Change	Total Depth	REF Depth	ALT Depth	Variant Allele Frequency
APC	SYN	p.S1738S	1008	590	415	41.17%
ATM	Non-SYN	p.D1853N	417	200	217	52.04%
BARD1	Non-SYN	p.R658C	829	435	394	47.53%
BMPR1A	Non-SYN	p.P2T	621	309	311	50.08%
BRCA1	SYN	p.S1389S	802	460	342	42.64%
BRCA2	SYN	p.V2171V	1026	0	1026	100%
BRIP1	SYN	p.Y1137Y	844	3	840	99.53%
PMS2	Non-SYN	K541E	686	0	646	100%
PRSS1	SYN	p.N246	921	0	921	100%
RAD51D	Non-SYN	p.L152IL	971	0	971	100%

2. CNV Analysis Example

Higher sequencing depths in the target regions, enabling accurate CNV analysis



PACKAGE COMPOSITION

Package name	Compositions		
Target Enrichment	Target capture Probe		-
Standard	Target Enrichment reagents	Library prep Kit	-
All-In-One			Beads / Polymerase

Package option	Options	
Pooling method	Single Reaction	Pre-capture Pooling
Library Preparation kits	Standard Kit	EP-kit
Hybridization Enhancer	Included	Not included

CancerScreen Panel

Core/50/100/400

Somatic Cancer

KEY FEATURES

1. Optimized panel for solid cancer	Assess DNA, RNA, and the whole CDS regions (RefSeq) of up to 407 genes and rearrangement regions associated with solid cancer
2. High sensitivity and specificity	Detect low-frequency and rare variants with high sequencing depths Capture the GC rich and homologous regions with Celemics proprietary design technology
3. Cost-effective sequencing	Lower sequencing costs for 3 Gb sequencing amount compared to competitor product
4. Assess all variant types	Detect all mutation types including SNV, Indel, Large Indel, CNV, Rearrangement, MSI, and TMB in a single assay

SPECIFICATION

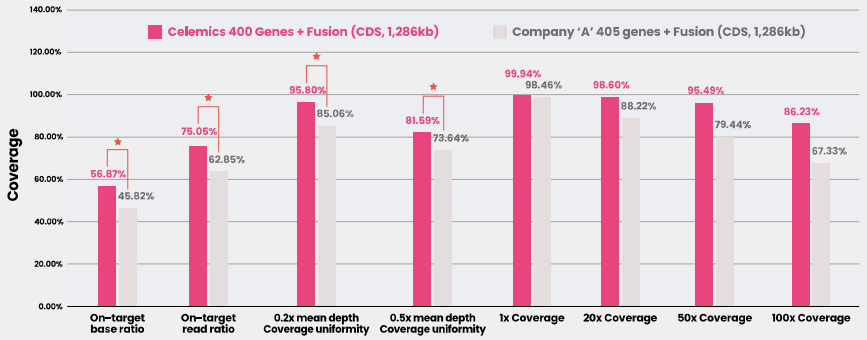
Gene count*	13 / 54 / 99 / 407 genes
Target size	61 / 197 / 299 / 1,123 kb + Rearrangement
Mutation type	SNV, Indel, CNV, Rearrangement, MSI, TMB
Sample type	FFPE, frozen tissue, cfDNA, RNA
Platform	All sequencers from Illumina, Thermo Fisher, MGI, PacBio, and Oxford Nanopore
Bioinformatics pipeline	Primary, Secondary and Tertiary analysis result (FASTQ to VCF, VCF to Clinical report)

* Gene Add-on Service: Genes can be added or removed by customer demand

PANEL PERFORMANCE

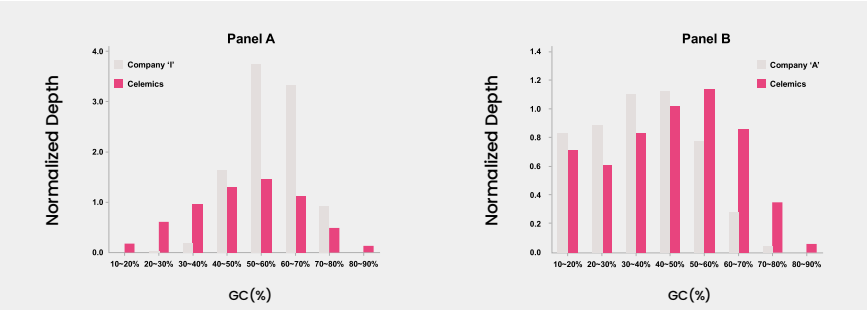
Performance Comparison with Competitor Product

Higher on-target ratio, uniformity, and coverage at 100X compared to competitor product over the target regions including exons and introns (Compared with the same sequencing depth)



Performance Comparison over GC-rich Regions

Higher uniform read depths over GC-rich regions compared to competitor product (Compared with the same sequencing depth)



PACKAGE COMPOSITION

Package name	Compositions		
Target Enrichment	Target capture Probe	-	
Standard	Target Enrichment reagents	Library prep Kit	-
All-In-One			Beads / Polymerase

Package option	Options	
Pooling method	Single Reaction	Pre-capture Pooling
Library Preparation kits	Standard Kit	EP-kit
Hybridization Enhancer	Included	Not included

CancerScreen Panel Core

DESCRIPTION

CancerScreen Panel Core is an NGS assay designed to detect all types of variants in 13 genes associated with somatic cancer. Targeting the selected genes with high sensitivity and specificity enables saving cost and effort. The report consists of the primary, secondary, and tertiary results for the In-depth understanding and interpretation of sequencing data.

GENE LIST

CancerScreen Panel Core	**ALK**	APC	BRAF	EGFR	ERBB2	KRAS	MET	NRAS	PIK3CA	**RET**	**ROS1**	SMAD4	TP53

* Genes in bold indicate fusion analysis

CancerScreen Panel 50

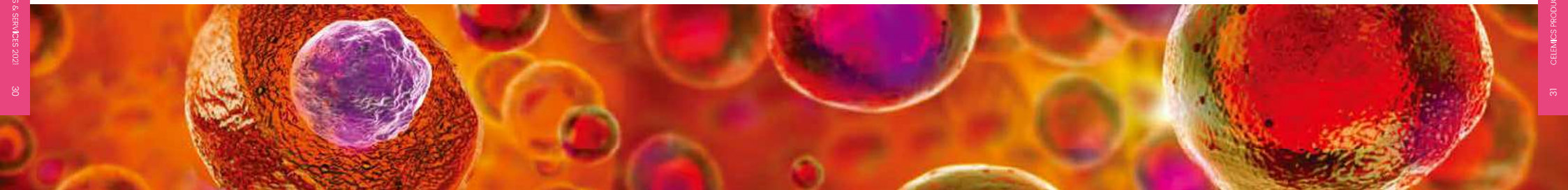
DESCRIPTION

CancerScreen Panel 50 is an expanded NGS assay designed to detect all types of variants in over 50 genes associated with somatic cancer. Targeting the selected genes with high sensitivity and specificity enables saving cost and effort. The report consists of the primary, secondary, and tertiary results for the In-depth understanding and interpretation of sequencing data.

GENE LIST

CancerScreen Panel 50	ABL1	AKT1	**ALK**	APC	ATM	BRAF	BRCA1	BRCA2	CDH1	CDK4	CDK6	CDKN2A	CSF1R
	CTNNB1	DDR2	EGFR	ERBB2	ERBB4	ESR1	FGFR1	FGFR2	FGFR3	GNA11	GNAQ	GNAS	HRAS
	IDH1	IDH2	JAK2	KDR	KIT	KRAS	MAP2K1	MET	MLH1	MTOR	MYC	MYCN	NOTCH1
	NRAS	**NTRK1**	PDGFRA	PIK3CA	PTCH1	PTEN	PTPN11	RB1	**RET**	**ROS1**	SMAD4	SMO	SRC
	STK11	TP53											

* Genes in bold indicate fusion analysis



CancerScreen Panel 100

DESCRIPTION

CancerScreen Panel 100 is an NGS assay for the comprehensive analysis of around 100 genes associated with somatic cancer. All types of variants are detected with high sensitivity and specificity. The report consists of the primary, secondary, and tertiary results for the In-depth understanding and interpretation of sequencing data.

GENE LIST

CancerScreen Panel 100	ABL1	AKT1	AKT2	AKT3	ALK	APC	ARID1A	ARID1B	ARID2	ATM	ATRX	AURKA	AURKB
	BARD1	BCL2	BLM	BMPR1A	BRAF	BRCA1	BRCA2	BRIP1	CDH1	CDK4	CDK6	CDKN2A	CHEK2
	CSF1R	CTNNB1	DDR2	EGFR	EPCAM	EPHB4	ERBB2	ERBB3	ERBB4	EZH2	FBXW7	FGFR1	FGFR2
	FGFR3	FLT3	GNA11	GNAQ	GNAS	HNF1A	HRAS	IDH1	IDH2	IGF1R	ITK	JAK1	JAK2
	JAK3	KDR	KIT	KRAS	MDM2	MET	MLH1	MPL	MRE11	MSH2	MSH6	MTOR	MUTYH
	NBN	NF1	NOTCH1	NPM1	NRAS	NTRK1	PALB2	PDGFRA	PDGFRB	PIK3CA	PIK3R1	PMS2	PRSS1
	PTCH1	PTCH2	PTEN	PTPN11	RAD50	RAD51C	RAD51D	RB1	RET	ROS1	SLX4	SMAD4	SMARCB1
	SMO	SRC	STK11	SYK	TERT	TOP1	TP53	VHL					

CancerScreen Panel 400

DESCRIPTION

CancerScreen Panel Core is an NGS assay designed to detect all types of variants in over 400 genes associated with somatic cancer. Targeting the selected genes with high sensitivity and specificity enables saving cost and effort. The report consists of the primary, secondary, and tertiary results for the In-depth understanding and interpretation of sequencing data.

CancerScreen Panel 400

GENE LIST

CancerScreen Panel 400	ABL1	ABL2	ADGRA2	AKT1	AKT2	AKT3	ALK	AMER1	APC	APCDD1	APEX1	APOB	APOBEC1
	AR	ARAF	ARFRP1	ARID1A	ARID1B	ARID2	ASXL1	ATM	ATP1B	ATR	ATRX	AURKA	AURKB
	AXIN1	AXL	B2M	B3GAT1	BACH1	BAP1	BARD1	BCL2	BCL6	BCL9	BCOR	BCR	BIRC2
	BIRC3	BLM	BRAF	BRCA1	BRCA2	BRD2	BRD3	BRD4	BRIP1	BTG1	BTK	BTLA	CARD11
	CASP5	CASP8	CBFB	CBL	CDK12	CDK4	CDK6	CDK8	CDKN1A	CDKN1B	CDKN2A	CDKN2B	CDKN2C
	CDX2	CEBPA	CHD1	CHD2	CHD4	CHEK1	CHEK2	CHUK	CIC	CRBN	CREBBP	CRKL	CRLF2
	CSF1R	CSF2	CSF2RA	CSF2RB	CSNK2A1	CTCF	CTLA4	CTNNA1	CTNNB1	CUL3	CUL4A	CUL4B	CXCL10
	CXCL11	CXCL9	CXCR3	CYLD	CYP17A1	DAXX	DCUN1D1	DDR2	DICER1	DIS3	DNMT1	DNMT3A	DOCK2
	DOT1L	EGFR	ELMO1	EML4	EMSY	EP300	EPHA3	EPHA5	EPHA6	EPHA7	EPHB1	EPHB4	EPHB6
	ERBB2	ERBB3	ERBB4	ERCC1	ERCC2	ERG	ERRFI1	ESR1	ETV1	ETV4	ETV5	ETV6	EWSR1
	EYA2	EZH2	FANCA	FANCC	FANCD2	FANCE	FANCF	FANCG	FANCI	FANCL	FANCM	FAS	FAT1
	FAT3	FBXW7	FGF1	FGF10	FGF12	FGF14	FGF19	FGF2	FGF23	FGF3	FGF4	FGF6	FGF7
	FGFR1	FGFR2	FGFR3	FGFR4	FH	FLCN	FLT1	FLT3	FLT4	FOXA1	FOXL2	FOXO3	FOXP3
	FRS2	FUBP1	GABRA6	GAS6	GATA1	GATA2	GATA3	GATA4	GATA6	GID4	GLI1	GNA11	GNA13
	GNAQ	GNAS	GRIN2A	GRM3	GSK3B	GUCY1A2	GZMA	GZMB	GZMH	H3F3A	HGF	HIST1H3B	HNF1A
	HOXA3	HRAS	HSD3B1	HSP90AA1	IDH1	IDH2	IDO1	IDO2	IFITM1	IFITM3	IFNA1	IFNB1	IFNG
	IGF1	IGF1R	IGF2	IGF2R	IKBKE	IKZF1	IL12A	IL12B	IL2	IL23A	IL6	IL7R	INHBA
	INPP4B	INSR	IRF2	IRF4	IRS2	ITGAE	ITK	JAK1	JAK2	JAK3	JUN	KAT6A	KDM5A
	KDM5C	KDM6A	KDR	KEAP1	KEL	KIT	KLF4	KLHL6	KMT2A	KMT2B	KMT2C	KNSTRN	KRAS
	LAG3	LMO1	LRP1B	LRP6	LTK	LYN	LZTR1	MAGI2	MAGOH	MAML1	MAP2K1	MAP2K2	MAP2K4
	MAP3K1	MAP3K13	MAPK1	MAX	MCL1	MDM2	MDM4	MED12	MEF2B	MEN1	MET	MITF	MLH1
	MPL	MRE11	MSH2	MSH6	MTOR	MUTYH	MYB	MYC	MYCL	MYCN	MYD88	MYO18A	NCOA3
	NCOR1	NF1	NF2	NFE2L2	NFKBIA	NOTCH1	NOTCH2	NOTCH3	NOTCH4	NPM1	NRAS	NSD1	NSD3
	NTRK1	NTRK2	NTRK3	NUP93	NUTM1	PAK3	PAK5	PALB2	PARP1	PARP2	PARP3	PARP4	PAX5
	PBRM1	PDCD1	PDCD1LG2	PDGFRA	PDGFRB	PDK1	PGR	PHF6	PHLPP2	PIK3C2B	PIK3C3	PIK3CA	PIK3CB
	PIK3CG	PIK3R2	PKHD1	PLCG1	PLCG2	PMS2	PNP	PNRC1	POLD1	POLE	PPARG	PPP2R1A	PRDM1
	PREX2	PRF1	PRKAR1A	PRKC1	PRKDC	PRPF40B	PRSS8	PTCH1	PTCH2	PTEN	PTK2	PTPN11	PTPRC
	PTPRD	QKI	RAB35	RAC1	RAC2	RADI7	RAD50	RAD51	RAD52	RAD54L	RAF1	RANBP2	RARA
	RB1	RBM10	REL	RET	RHEB	RHOA	RHOB	RICTOR	ROBO1	ROBO2	ROS1	RPA1	RPS6KB1
	RPTOR	RUNX1	RUNX1T1	RUNX3	SDHA	SDHB	SDHC	SDHD	SEMA3A	SEMA3E	SET	SETBP1	SETD2
	SF3A1	SF3B1	SH2B3	SKP2	SLIT2	SMAD2	SMAD3	SMAD4	SRSF2	SRSF7	STAG2	STAT3	STAT4
	TERT	TET2	CD274	TP53									

CancerMaster Panel

Somatic Cancer

DESCRIPTION

The CancerMaster panel is designed to detect all variant types and the I-O markers, microsatellite instability (MSI) and tumor mutational burden (TMB), which are crucial biomarkers for cancer immunotherapy. For CNV analysis, different cut-off is applied according to the ratio of cancer cells. The panel is also designed to detect Epstein-Barr virus (EBV) and Human Papillomaviruses (HPV) allowing for comprehensive analysis of cancer associated genes.

KEY FEATURES

1. Comprehensive analysis of cancer associated genes	A broad range of targeting elements including somatic variants, IO-signatures (TMB, MSI), EBV and HPV, for clinical diagnoses of different cancer types and precision medicine
2. Extensive validation studies	Robust panel performance supported by extensive validation tests with Reference and clinical specimens

SPECIFICATION

Gene count*	524 genes
Covered region	Whole CDS, custom regions of oncogenes, immune response genes, and EBV & HPV viruses
Target size	2.5 Mb
Mutation type	SNV, Indel, CNV, Rearrangment, TMB, MSI, EBV, HPV
Sample type	FFPE, Fresh frozen tissue (> 50 ng of fragmented DNA)
Platform	All sequencers from Illumina, Thermo Fisher, MGI, PacBio, and Oxford Nanopore
Bioinformatics pipeline	Primary, Secondary and Tertiary analysis result (FASTQ to VCF, VCF to Clinical report)
Publication	Molecular Characterization of Biliary Tract Cancer Predicts Chemotherapy and PD-1/PD-L1 Blockade Responses, Hepatology, 2021

*Gene Add-on Service: Genes can be added or removed by customer demand

GENE LIST

OncoRisk Panel	ABL1	ALK	PDGFRA	ROS1	FGFR2	FGFR3	NTRK1	NTRK2	NTRK3	FGFR1	MET	PPARG	RET
	AKT3	BRAF	BRCA1	EGFR	ERBB2								

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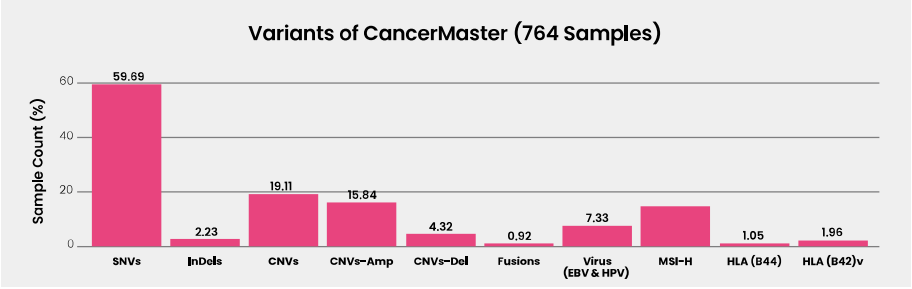
PANEL PERFORMANCE

The probes are designed to include the intron regions as well as clinically significant biomarkers. By conducting extensive validation studies with clinical samples, the panel was examined to show its performance with high sensitivity and specificity in detecting the variants in cancer-associated genes.

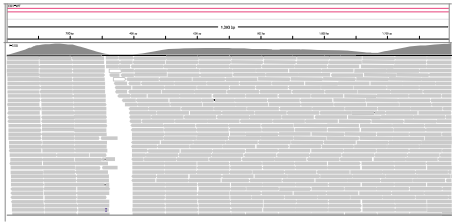


ANALYSIS OF EBV & HPV

EBV (Epstein-Barr Virus)

- Related disease – Lymphoma
- Genes – EBV type 1 (EBNA-2)

Validation for detection of EBV type 1 (EBNA-2) in control specimens



HPV (Human Papillomavirus)

- Related disease – Cervical cancer
- Genes – HPV L1 gene
  (Analysis of a total of 24 types is possible)

Analysis of the following 11 types of HPV types was completed using clinical specimens

Human infection HPV list
Human papillomavirus type 178
Human papillomavirus type 136
Human papillomavirus type 140
Human papillomavirus type 154
Human papillomavirus type 156
Human papillomavirus type 179
Human papillomavirus type 201
Human papillomavirus type 49
Human papillomavirus type 9
Human papillomavirus type 92
Human papillomavirus type 96

PACKAGE COMPOSITION

Package name	Compositions		
Target Enrichment	Target capture Probe	-	
Standard	Target Enrichment reagents	Library prep Kit	-
All-In-One			Beads / Polymerase

Package option	Options	
Pooling method	Single Reaction	Pre-capture Pooling
Library Preparation kits	Standard Kit	EP-kit
Hybridization Enhancer	Included	Not included