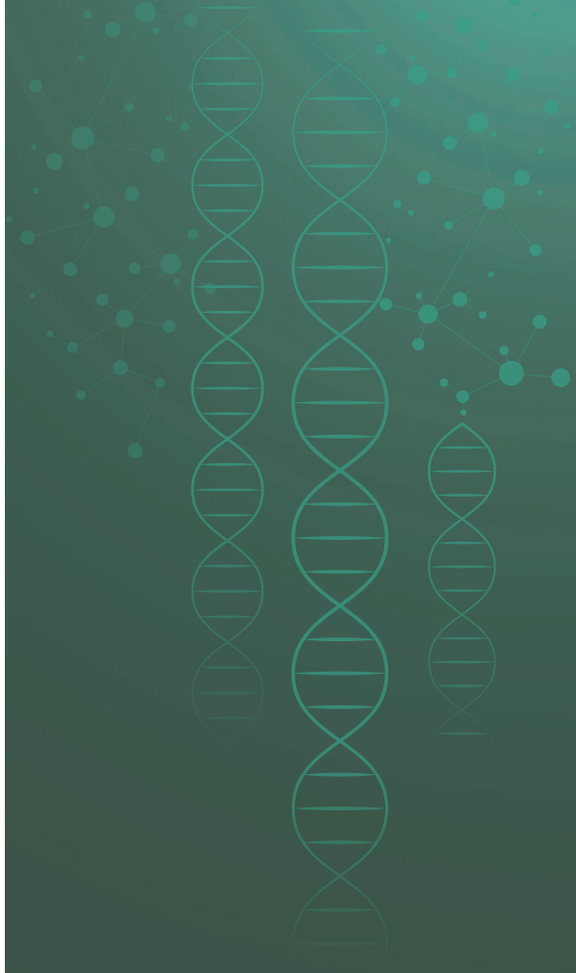
CELEMICS PRODUCT SHEET

Celemics CancerScreen Focus Panel

Accurate Detection of Genetic Markers Associated with Companion Diagnostics

Key Features

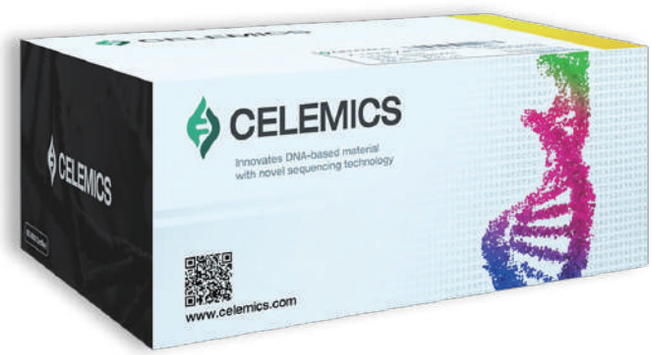
- Includes set of genetic markers applicable for Companion Diagnostics
- Provides options for panel selection depending on the type of marker desired
- Provides genetic information of HRR related genes



CELEMICS

CancerScreen Focus Panel

The CancerScreen Focus Panel is designed to assess the genetic markers for targeted cancer drugs used in companion diagnostics. With Celemics' exclusive technologies, the panel demonstrates high performance not only in genomic DNA (gDNA) samples but also in samples extracted from Formalin-Fixed Paraffin-Embedded (FFPE) tissues and even in low-yield clinical samples. The versatility and robustness of CancerScreen Focus panel can consistently deliver reliable performance even during sample pooling, offering remarkable cost-effectiveness.



Product Specification

Panel	CancerScreen Focus - DNA	CancerScreen Focus - RNA	CancerScreen Focus - HRR
Gene Count	22	9	15
Target size	73.4 Kb	32.1 Kb	69.4 Kb
Covered region	CDS		
Mutation type	SNV, Indel, Rearrangement (RNA Panel)		
Sample type (Amount)	Blood, Fresh-Frozen, FFPE		
Platform	All sequencers from Ilumina, Thermo Fisher, and MGI		
Bioinformatics Support	1. Primary Analysis: FASTQ to annotated VCF 2. Secondary Analysis: CNV, Large Indel 3. Tertiary Analysis: Clinical interpretation, Visualization Curation		

*Gene Add-On Service: Genes can be added by customer's request.

Performance Data

CancerScreen Focus DNA Panel

The CancerScreen Focus DNA Panel is designed to detect genetic mutations associated with companion diagnostics. The panel identifies cancer-related genetic mutations through a patient's genetic profile analysis to support personalized treatment decisions.

Gene	Related Drug	Mutation
KRAS and NRAS	Vectibix	KRAS wild-type and NRAS wild type
PIK3CA	Piqray	C420R, E542K, E545A, E545D, E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y
KIT	Gleevec	D816V
EGFR (HER1)	Erbitux	EGFR (HER1) protein expression
EGFR (HER1)	Exkivity	Exon 20 insertion mutations
MET	Tabrecta	MET single nucleotide variants and indels that lead to MET exon 14 skipping
BRAF	Braftovi in combination with Mektovi	V600E or V600K
BRAF	Cotellic in combination with Zelboraf	V600E or V600K
KRAS	Erbitux	G12A, G12D, G12R, G12C, G12S, G12V, G13D
KRAS	Krazati	KRAS G12C
FLT3 (ITD/TDK)	Xospata	ITD mutations and TKD mutations D835 and I836
BRCA1 and BRCA2	Lynparza	Mutations
BRCA1 and BRCA2	Rubraca	Mutations
TP53	Venclexta	Deletion chromosome 17p (17p-)

Table 1. Example of relation between drugs and genes included in Celemics Focus DNA Panel. Sequencing can be performed by using Celemics Focus DNA Panel for all genes mentioned in the table above as examples of genetic associations for FDA-approved drugs.

Chromosome	Gene	Ref Allele	Alt Allele	Mutation	Reference DNA	CancerScreen Focus DNA
1	NRAS	G	T	Q61K	12.5 %	10.7 %
3	PIK3CA	G	A	E545K	9.0 %	9.5 %
3	PIK3CA	A	G	H1047R	17.5 %	16.9 %
4	KIT	A	T	D816V	10.0 %	8.2 %
4	KIT	G	C	L862	7.5 %	6.4 %
7	EGFR	G	A	G719S	24.5 %	22.2 %
7	EGFR	AGG..AGC	A	ΔE746 - A750	2.0 %	0.5 %
7	EGFR	G	A	Q787Q	15.0 %	11.6 %
7	EGFR	C	T	T790M	1.0 %	0.7 %
7	EGFR	T	G	L858R	3.0 %	2.4 %
7	MET	GT	G	-	7.0 %	6.2 %
7	MET	G	A	A1339A	7.0 %	6.9 %
7	BRAF	A	T	V600E	10.5 %	9.1 %
12	KRAS	C	T	G13D	15.0 %	13.5 %
12	KRAS	C	T	G12D	6.0 %	6.0 %
13	FLT3	GGA	G	-	10.0 %	7.7 %
13	BRCA2	CA	C	K1691Nfs*15	32.5 %	29.3 %
17	TP53	G	C	P72R	92.5 %	92.4 %

Table 2. Detection accuracy results of CancerScreen Focus DNA Panel using reference DNA. Validation experiment is performed by using the CancerScreen Focus DNA Panel with the reference sample of OncoSpan FFPE (Horizon Discovery). The validation results indicate that CancerScreen Focus DNA Panel is able to obtain values closely resembling the allele frequencies of known genetic mutations, and successfully detected all mutations of interest (Sensitivity > 99%; Specificity > 99%).

Performance Data

Available in low-throughput platform

The panel consists of size up to 74kb (DNA Panel), therefore suitable for sequencing even with low-throughput instrument. Sequencing at a depth of 500X for the analysis of mutations at the 1% level using the MiSeq Reagent V2 allows for the analysis of up to 50 samples in a single run.

Sequencing Platform	MiSeq Reagent Kit v2		Ion GeneStudio S5		DNBSEQ-G400	
Throughput	5.1 Gb		15 Gb		55 Gb	
Mean Depth	500 X	1,000 X	500 X	1,000 X	500 X	1,000 X
Sequencing Amount per Sample	100 Mb	200 Mb	100 Mb	200 Mb	100 Mb	200 Mb
Estimated Samples per run	50	25	150	75	500	250

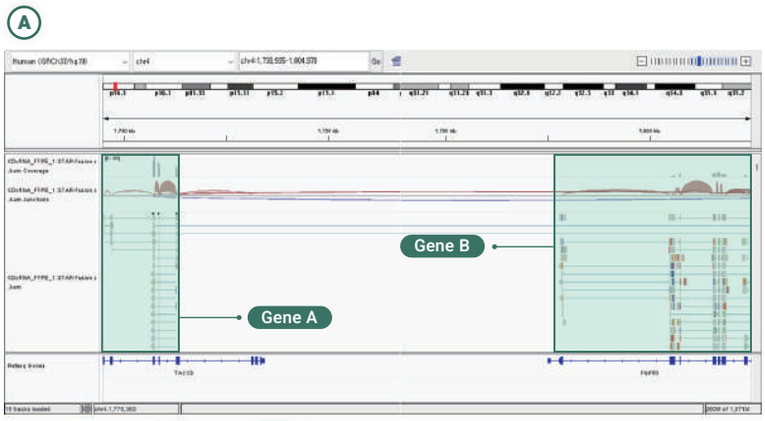
CancerScreen Focus RNA Panel

The CancerScreen Focus RNA Panel is designed to detect fusion mutations associated with companion diagnostics. The panel identifies well-known fusion breakpoints for cancer to support personalized treatment decisions.

Gene	Related Drug	Mutation
ROS1	Rozlytrek	ROS1 fusion
NTRK1, NTRK2, and NTRK3 fusions	Rozlytrek	NTRK1/2/3 fusions
RET	Gavreto	RET fusions

Table 3. Example of fusion genes associated with medication in CancerScreen Focus RNA Panel. Sequencing can be performed by using Celemics Focus RNA Panel for all genes mentioned in the table above as examples of genetic associations for FDA-approved drugs.

(A)



(B)

Gene A	Gene B	Detection
CCDC6	RET	Y
CD74	ROS1	Y
EML4	ALK	Y
ETV6	NTRK3	Y
FGFR3	BAIAP2L1	Y
FGFR3	TACC3	Y
KIF5B	RET	Y
LMNA	NTRK1	Y
NCOA4	RET	Y
SLC34A2	ROS1	Y
TFG	NTRK1	Y
TPM3	NTRK1	Y

Figure 1. Result of gene fusion detection (TACC3 and FGFR3) and list of applicable fusion analysis. Performance data of CancerScreen Focus RNA Panel using Seraseq® FFPE Tumor Fusion RNA v4 Reference Material (SeraCare). (A) The validation experiment result indicate that the panel can successfully detect gene fusion between TACC3 and FGFR3. (B) Other 12 companion diagnostics associated fusion genes known to be present in the reference sample from Seraseq® FFPE Tumor Fusion RNA v4 Reference Material (SeraCare) also successfully detected (Data not shown).

Provision of Genetic Information for Homologous Recombination Repair (HRR)

The CancerScreen Focus HRR Panel is designed to assess the level of genomic instability and homologous recombination deficiency in cancer cells. This specific panel can be beneficial for patients interested in Genomic Instability Assessment, Homologous Recombination Deficiency (HRD), and Tumor Profiling.

Order Information | CancerScreen Focus Panel

Target Enrichment Kit

Cat. No.	Product	Product Unit(Hyb-rxn)
CFDS.HI.ES16/96	CancerScreen Focus DNA Panel; Singleplex; Illumina	16/96
CFDM.HI.EM2/4/8/16	CancerScreen Focus DNA Panel; Multiplex; Illumina	2/4/8/16
CFRS.HI.ES16/96	CancerScreen Focus RNA Panel; Singleplex; Illumina	16/96
CFRM.HI.EM2/4/8/16	CancerScreen Focus RNA Panel; Multiplex; Illumina	2/4/8/16
CFHS.HI.ES16/96	CancerScreen Foucs HRR Panel; Singleplex; Illumina	16/96
CFHM.HI.EM2/4/8/16	CancerScreen Focus HRR Panel; Multiplex; Illumina	2/4/8/16

* CancerScreen Focus for Ion Torrent and MGI are also available.

Library Prep Kit

Cat. No.	Product	Product Unit(Sample)
ILUY016/032/048/096	Illumina; Library Prep Kit; UDI; Short Adapter	16/32/48/96
IEUY016/032/048/096	Illumina; Enzymatic Library Prep Kit; UDI; Short Adapter	16/32/48/96
TLIP016/032/048/096	Ion Torrent; Library Prep Kit; IonXpress	16/32/48/96
TEIP016/032/048/096	Ion Torrent; Enzymatic Library Prep Kit; IonXpress	16/32/48/96
MLAT016/032/048/096	MGI; Library Prep Kit; MGI Single Index	16/32/48/96
MEAT016/032/048/096	MGI; Enzymatic Library Prep Kit; MGI Single Index	16/32/48/96

* For Illumina Prep Kits, more adapter and index options are available. Please inquiry to our sales team.

Accessories

Cat. No.	Product	Product Unit
CMPF-M-500	CLM Polymerase	5 mL
CMSB-M-200/00A	CeleMag™ Streptavidin Bead	2/10 mL
CMCB-M-050/500	CeleMag™ Clean-up Bead	5/50 mL
CNMS-R-16/96	CeleNM™ Bead	16/96 rxn
DSCS-R-16/96	Double Strand cDNA Synthesis Kit	16/96 rxn

* For CeleNM™ Bead and Double Strand cDNA Synthesis Kit, more unit option is available. Please inquiry to our sales team.

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