

遺伝子パネル検査における標準物質としての 変異細胞株パネルの作製

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* 発表に際し、開示すべきCOI情報はありません

規制科学の観点から

「変異 X については臨床検体に存在しなかったため確認できないが、
合成DNAを用いた実験から検出可能であると考えられる」



低頻度なので仕方ないが、本当に大丈夫？

次世代シーケンサーの信頼性確保の重要性



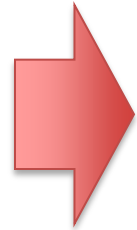
サンプル調整からデータ解析結果を得るまでのステップが非常に複雑なため標準物質を用いた精度管理が重要

機器としての信頼性

どのくらい正確に対象物質(DNA, RNA)を測定できているか？



“標準物質（合成DNA, RNA）”
を用いて精度管理可能



診断の信頼性

どのくらい正確に遺伝子変異を検出できているか？

問題点：検体間差（腫瘍の割合）、サンプル間差（DNA抽出、ライブラリー作製）、遺伝子間差（変異タイプや遺伝子領域ごとのリードdepthの変動）



“標準細胞（明確なアレル頻度）”
を用いて精度管理が望ましい！？

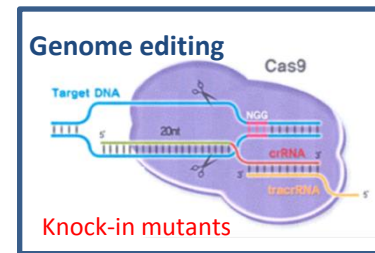
標準品配布の構想

- 安定供給可能な細胞としての標準品。
- 一定の割合で複数の細胞株を混合した標準品も提供
- NCCオンコパネルの全遺伝子を網羅する変異スタンダード細胞パネルの作製。
- 定量的に扱える標準品として、感度試験、同等性試験、定量試験に使用可能とする。

がん遺伝子パネルに対する標準変異細胞株パネルの作製



NCC Oncopanel (90 gene)					
ABL1	CCND1	FGFR1	KRAS	NRAS	RET
AKT1	CDK4	FGFR2	MAGI3	NRG1	ROS1
AKT2	CDKN2A	FGFR3	MAP2K1	NTSC2	SETD2
AKT3	CHEK2	FGFR4	MAP2K4	PALB2	SMAD4
ALK	CREBBP	FLT3	MAP3K1	PBRM1	SMARCA4
APC	CTNNB1	HRAS	MAP3K4	PDGFRA	SMO
ARID1A	CUL3	IDH1	MDM2	PDGFRB	STAT3
ARID2	DDR2	IDH2	MET	PIK3CA	STK11
ATM	EGFR	IGF1R	MTOR	PIK3R1	TP53
AXIN1	ENO1	IGF2	MYC	PTCH1	TSC1
BAP1	EP300	IL7R	MYCN	PTEN	VHL
BARD1	ERBB2	JAK1	NF1	RAC1	
BCL2L1	ERBB3	JAK2	NFE2L2	RAC2	
BRAF	ERBB4	JAK3	NOTCH1	RAD51C	
BRCA1	EZH2	KEAP1	NOTCH2	RAF1	
BRCA2	FBXW7	KIT	NOTCH3	RB1	

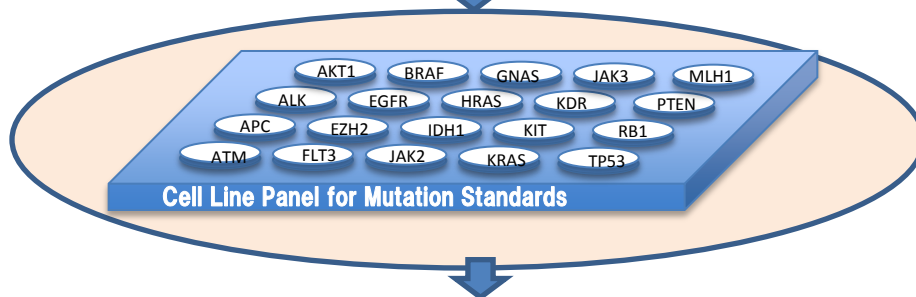


既存細胞における
COSMIC搭載変異の確認

Prepare mutants for 90 genes in NCC oncopanel

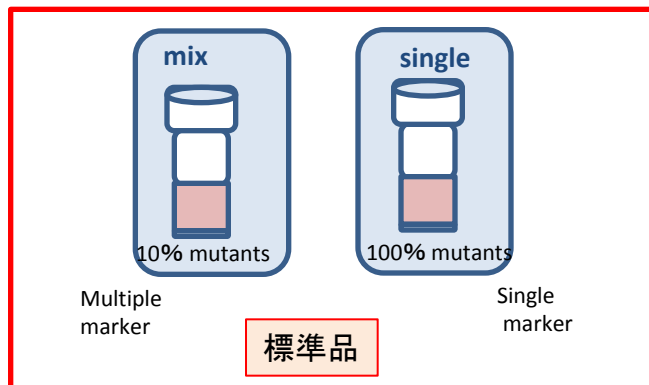
既存細胞で育えない変異遺
伝子を持つ細胞の作製

シーケンス情報



細胞株パネルの維持と
供給

Mix cells of interest



標準品

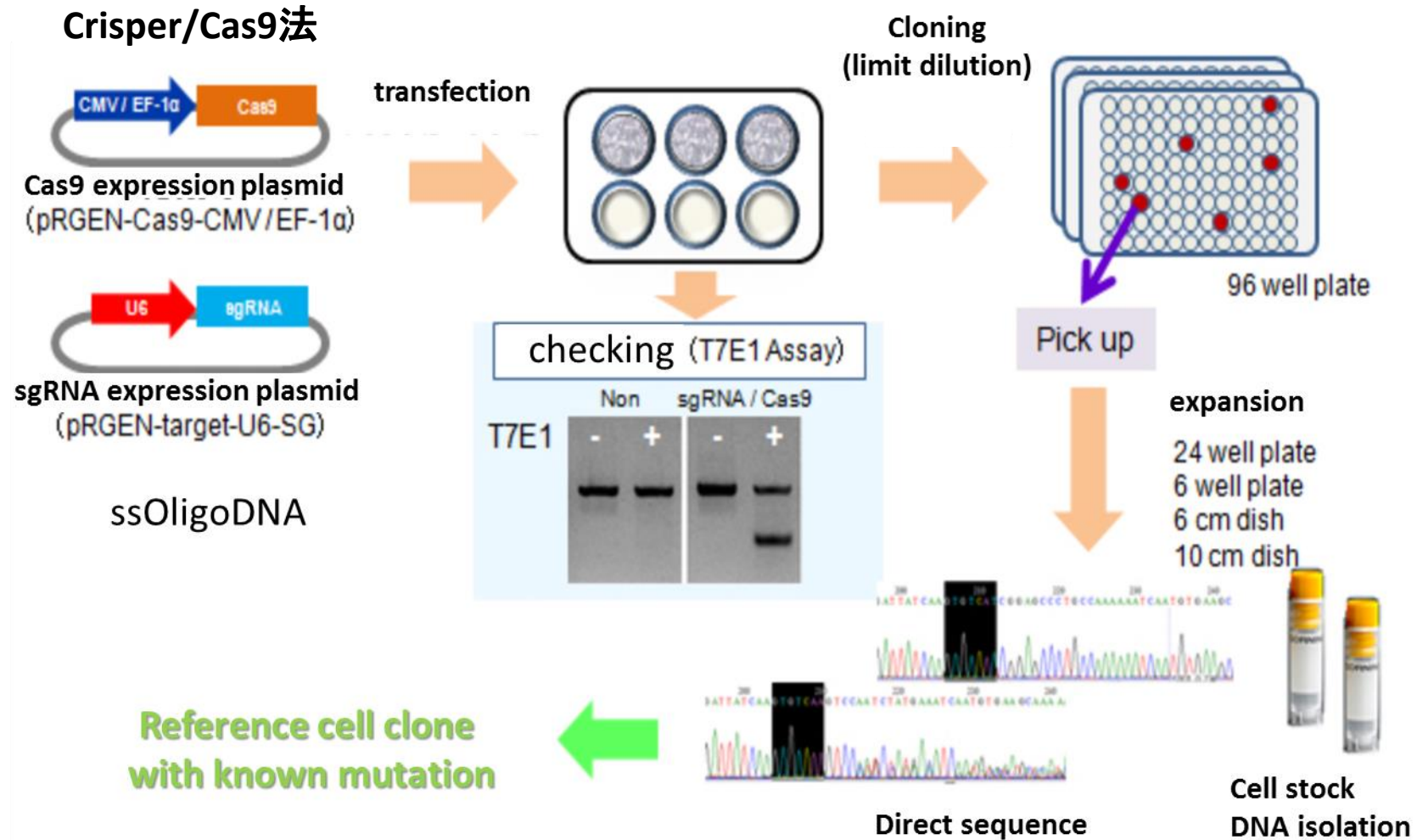
診断薬メーカー

開発過程におけるバリデーション

病院、検査機関

臨床検査におけるバリデーション

Scheme of genome editing in HEK293T/17 cell



2~5クローンを選択

約150クローンを解析

(タカラバイオに委託)

ゲノム編集の対象遺伝子と標的変異(各種がん遺伝子パネルへの搭載)

Gene	NCC Oncopanel (ver 2)	Thermo Fisher Oncomine Dx Test	Personails ACE CancerPlus ™ Test	Illumina Trusight Tumor 26	Ion AmpliSeq Cancer Hotspot Panel v2	No of mutations in COSMIC	COSMIC_ID	CDS Mutation	FATHMM
AKT1	*	*	*	*	*	975	COSM33765	c.49G>A	Pathogenic (score 1.00)
AKT3	*		*			269	COSM242892	c.232C>A	Pathogenic (score 0.99)
ALK	*	*	*	*	*	1522	COSM28056	c.3824G>A	Pathogenic (score 0.98)
BAP1	*		*			1221	COSM110721	c.178C>T	Pathogenic (score 0.98)
BCL2L11 (BIM)	*		*			116	COSM389356	c.585G>C	Pathogenic (score 0.98)
BRAF	*	*	*	*	*	27630	COSM476	c.1799T>A	Pathogenic (score 0.99)
BRAF'	*	*	*	*	*	4	COSM1137	c.1817G>A	Pathogenic (score 0.98)
CDK4	*	*	*			101	COSM1677139	c.70C>T	Pathogenic (score 0.98)
CDKN2A (p16)	*	*	*		*	5911	COSM12475	c.238C>T	Pathogenic (score 0.88)
CTNNB1 (β -catenin)	*	*	*	*	*	7307	COSM5664	c.121A>G	Pathogenic (score 0.98)
DNMT3A		*	*			3679	COSM52944	c.2645G>A	Pathogenic (score 0.98)
ERBB2 (HER2)	*	*	*	*	*	1596	COSM48358	c.929C>T	Pathogenic (score 0.97)
ERBB3	*	*	*			900	COSM20710	c.310G>A	Pathogenic (score 0.88)
EZH2	*	*	*		*	1273	COSM37028	c.1937A>T	Pathogenic (score 0.99)
FBXW7	*	*		*	*	1972	COSM22975	c.1513C>T	Pathogenic (score 0.94)
FGFR3	*	*	*		*	4354	COSM715	c.746C>G	Pathogenic (score 0.96)
FOXL2		*		*		933	COSM33661	c.402C>G	Pathogenic (score 0.95)
HRAS	*	*	*		*	2023	COSM502	c.183G>T	none (score 0.53)
IDH2	*	*	*		*	2430	COSM33733	c.515G>A	Pathogenic (score 0.99)
IGF2	*					132	COSM1561457	c.293C>T	Pathogenic (score 0.97)
JAK2	*	*	*		*	50556	COSM12600	c.1849G>T	Pathogenic (score 0.94)
KIT	*	*	*	*	*	8856	COSM1314	c.2447A>T	Pathogenic (score 0.99)
KNSTRN		*				118	COSM140056	c.71C>T	Neutral (score 0.00)
KRAS	*	*	*	*	*	43548	No ID	c.124G>A	-
MAGOH		*				43	COSM535605	c.410T>C	Pathogenic (score 0.99)
MAP2K1	*	*	*	*		496	COSM235614	c.370C>T	Pathogenic (score 0.99)
MAPK1		*	*			173	COSM461148	c.964G>A	Pathogenic (score 0.98)
MDM2	*		*			110	COSM431747	c.994C>T	Pathogenic (score 0.91)
MET	*	*	*	*	*	1142	COSM707	c.3029C>T	Pathogenic (score 0.98)
MTOR	*	*	*			1195	COSM20417	c.6644C>A	Pathogenic (score 1.00)
MYCN	*					305	COSM35624	c.131C>T	Pathogenic (score 0.96)
NOTCH1	*	*	*		*	3921	COSM12771	c.4799T>C	Pathogenic (score 0.99)
NRAS	*	*	*	*	*	6676	COSM5930625	c.112G>A	Pathogenic (score 0.99)
PDGFRA	*	*	*	*	*	2354	COSM736	c.2525A>T	Pathogenic (score 0.99)
PIK3CA	*	*	*	*	*	13613	COSM775	c.3140A>G	Pathogenic (score 0.96)
PTCH1	*	*	*			1331	COSM1638394	c.3944C>T	Pathogenic (score 1.00)
PTEN	*	*	*	*	*	4778	No ID	c.697C>T	-
SMO	*	*	*		*	593	COSM216037	c.1234C>T	Pathogenic (score 0.96)
STAT3	*	*				805	COSM1155743	c.1919A>T	Pathogenic (score 0.97)
TP53 (p53)	*	*	*	*	*	39196	COSM10662	c.743G>A	Pathogenic (score 0.98)

ゲノム編集にて得られたノックイン細胞クローン数

Method	Gene	Mutation	bp from PAM	Total Clones	Homo Knock-in	Hetero Knock-in	Success Rate (%)
Vector	KRAS	35 G>A	4	160	0	2	1.3
Vector	NRAS	35 G>A	1	157	2	0	2.5
Vector	PIK3CA	1633 G>A	10	161	0	1	0.6
Vector	PTEN	697 C>T	7	156	0	1	0.6
Vector	TP53	743 G>A	5	159	2	2	3.8
Vector	JAK2	1849 G>T	8	164	3	1	4.3
Vector	FGFR3	746 C>G	1	167	0	1	0.6
Vector	KIT	2447 A>T	7	172	3	12	10.5
Vector	CTNNB1	121 A>G	6	164	1	0	1.2
Vector	CDKN2A	238 C>T	2	156	5	2	7.7
Vector	HRAS	183 G>T	2	172	2	5	5.2
Vector	KNSTRN	71 C>T	1	161	1	0	1.2
Vector	MAPK1	964 G>A	4	169	0	0	0.0
Vector	MAGOH	410 T>C	4	160	0	5	3.1
Vector	MDM2	994 C>T	6	171	0	2	1.2
Vector	EZH2	1937 A>T	7	153	4	0	5.2
Vector	IDH2	515 G>A	2	155	0	7	4.5
Vector	PDGFRA	2525 A>T	7	176	7	6	11.4
Vector	STAT3	1919 A>T	5	161	0	1	0.6
Vector	MTOR	6644 C>A	8	182	2	9	7.1
Vector	FBXW7	1513 C>T	2	167	0	0	0.0
Vector	MET	3029 C>T	5	154	1	1	1.9
Vector	SMO	1234 C>T	8	157	8	7	14.6
Vector	NOTCH1	4799 T>C	9	167	0	2	1.2
Vector	ERBB3	310 G>A	4	171	0	1	0.6
Vector	AKT1	49 G>A	1	177	0	0	0.0
Vector	DNMT3A	2645 G>A	6	149	0	1	0.7
Vector	BAP1	178 C>T	5	183	0	12	6.6
Vector	ALK	3824 G>A	4	190	4	5	6.8
Vector	MAP2K1	370 C>T	1	177	1	0	1.1
Protein	BRAF	1817 G>A	1	172	1	16	10.5
Protein	AKT3	232 C>A	2	192	0	5	2.6
Protein	BIM	585 G>C	1	192	6	9	10.9
Protein	IGF2	293 C>T	2	192	0	6	3.1
Protein	MYCN	1132 G>A	1	192	10	26	24.0

作製したゲノム編集株リスト (HEK293T/17 cell)

Target Gene	Cell Clone Name (ID)	Mutation detail
JAK2	170214_01-1_1_JAK2-F_B01	1849G>T(COSM12600)Homo
	170214_01-2_1_JAK2-F_H06	1849G>T(COSM12600)Hetero
FGFR3	170214_02-2_2_FGFR3-F2_B02	752insA Homo
	170214_02-2_2_FGFR3-F2_H02	746C>G(COSM715)Hetero
KIT	170214_03-2_3_KIT-R_A10	2447A>T(COSM1314)Homo
	170214_03-2_3_KIT-R_D02	2447A>T(COSM1314)Hetero
CTNNB1	170217_04-2_4_CTNNB1-F_A09	121A>G(COSM5664)Homo+del116-9&112G>A+del114-9
	170217_04-2_4_CTNNB1-F_F06	121A>G(COSM5664)Homo
CDKN2A	170217_05-1_5_CDKN2A-F_D02	238C>T(COSM12475)Hetero
	170217_05-2_5_CDKN2A-F_H07	238C>T(COSM12475)Homo
HRAS	170217_07-1_7_HRAS-F_D09	183G>T(COSM502)Homo
	170217_07-2_7_HRAS-F_C07	183G>T(COSM502)Hetero
KNSTRN	170221_08-1_C07	71C>T(COSM140056) Homo
	170221_08-1_G03	71C>T(COSM140056) &Del67-9 Homo
MAPK1	170221_09-2_C06	960insG Homo
	170221_09-2_C11	del962-8 Hetero(7bp)+del962-9&4bp Hetero(12bp)+del926-69&69bp Hetero(113bp)
MAGOH	170303_10-1_D01	410T>C(COSM535605)Hetero
	170303_10-1_D06	410T>C(COSM535605)&407delT Hetero
MDM2	170221_11-1_B09	995insG Homo
	170221_11-1_C08	994C>T(COSM431747)Hetero
EZH2	170222_12-2_D02	1937A>T(COSM37028)Homo+1852(-)21T>C
	170222_12-2_G04	1937A>T(COSM37028)Homo
IDH2	170222_13-1_G08	515G>A(COSM33733)Hetero+512G>A(COSM86960)
	170222_13-2_C08	515G>A(COSM33733)Hetero
PDGFRA	170221_14-1_A09	2525A>T(COSM736)Homo

35遺伝子に対して合計88変異株を単離し、JCRB細胞バンクに寄託済み

既存33細胞株におけるCOSMIC変異の確認

Cell ID	Cell Name	COSMIC Mutated Genes	COSMIC Mutations	Sequenced Mutated Genes	Sequenced Mutations	Positive rate
JCRB0618	TGW	7	8	5	5	50
JCB0034	RPMI8226	7	7	7	7	57.1
JCRB0042	HEC-1	34	51	28	37	64.7
JCRB0118	SKM-1	5	5	7	7	0
JCRB0711	T-24	5	5		low quality data	
JCRB0062	HEL	4	4	3	3	50
JCRB1003	KASUMI-1	6	6	5	5	66.7
JCRB0170	LU-135	9	9	4	4	44.4
IFO50368	no-10	5	6	2	2	33.3
JCRB0076	A549	5	5	4	4	0
JCRB0019	K-562	6	6	4	4	50
JCRB0829	LK-2	9	11	10	10	54.5
JCRB0044	LU-99A	6	6	5	5	66.7
JCRB0822	NUGC-3	14	14	7	7	28.6
JCRB0814	VMRC-LCD	5	5	5	5	40
JCRB0114					10	36.4
JCRB0114					5	40
JCRB0114					29	59.5
JCRB0115	SCC-3	5	6	5	5	50
JCRB0066	Mewo	28	40	12	14	35
JCRB0611	KATO III	5	5		low quality data	
JCRB0252	MKN1	4	4	3	3	50
JCRB0101	A3-KAW	9	15	5	5	33.3
JCRB1087	KYSE-270	9	10	4	4	30
JCRB0614	NY	4	4	3	3	50
JCRB1010	KMRC-1	5	5	2	2	40
<i>Additional cell lines</i>						
IFO50412	CCRF-CEM	21	23	17	19	56.5
JCRB0074	VMRC-MELG	5	5	5	5	60
JCRB0098	KURAMOCHI	6	8	6	6	50
JCRB0403	HuH-7	4	4	2	3	25
JCRB0126.1	KOSC-2 cl3-43	5	6	4	4	33.3
JCRB1479	HCT-15-Luc#1	53	84	15	20	18.1
JCRB9068	293	No data	No data	1	1	No data
average positive rate						42.4

確認できたCOSMIC変異は半分以下

シーケンス解析の結果既存細胞で変異が確認できた遺伝子

Gene Name	No. of Cell lines	Cell line with mutations	Gene Name	No. of Cell lines	Cell line with mutations
ABL1	2	HEC-1 CCK-81	KEAP1	1	HEC-1
AKT1	1	KOSC-2 cl3-43	KIT	4	TGW Kasumi-1 SBC-3 HCT-15-Luc#1
AKT2	1	VMRC-LCD	KRAS	4	RPMI8226 HEC-1 LU99A HCT-15-Luc#1
AKT3	1	K562	MAP2K1	1	SCC-3
ALK	2	RPMI8226 CCRF-CEM	MAP2K4	1	VMRC-LCD
APC	6	HEL LK-2 LU99A A3/KAW CCK-81 HCT-15-Luc#1	MAP3K1	6	HEC-1 HEL P30-OHK NUGC-3 CCK-81
ARID1A	4	HEC-1 CCRF-CEM A3/KAW NY	MAP3K4	4	SCC-3 SKM-1 A3/KAW HCT-15-Luc#1
ARID2	2	Mewo NUGC-3	MDM2	0	none
ATM	3	HEC-1 P30-OHK KURAMOCHI	MET	3	HEC-1 Mewo VMRC-MELG HCT-15-Luc#1
AXIN1	1	KURAMOCHI	MTOR	1	KOSC-2 cl3-43
BAP1	3	HEC-1 A3/KAW CCK-81	MYC	1	A3/KAW
BARD1	0	none	MYCN	0	none
BIM	1	LK-2	NF1	7	HEC-1 P30-OHK SKM-1 KURAMOCHI A3/KAW KYSE-270 NY
BRAF	2	VMRC-MELG CCK-81	NFE2L2	4	K562 HEC-1 SKM-1 LK-2
BRCA1	4	SKM-1 Lu-135 CCK-81 VMRC-LCD	NOTCH1	5	RPMI8226 HEC-1 Mewo VMRC-MELG HCT-15-Luc#1
BRCA2	8	HEC-1 P30-OHK SKM-1 KMRC-1 SBC-3 KURAMOCHI A3/KAW CCK-81	NOTCH2	1	CCRF-CEM
CCND1	1	CCRF-CEM	NOTCH3	4	HEC-1 Mewo CCK-81 HCT-15-Luc#1
CDK4	1	NUGC-3	NRAS	0	none
CDKN2A	3	A549 LK-2 KOSC-2 cl3-43	NRG1	3	HEC-1 Mewo P30-OHK
CHEK2	3	293 CCK-81 HCT-15-Luc#1	NT5C2	2	P30-OHK Kasumi-1
CREBBP	4	HuH-7 NUGC-3 LU99A CCRF-CEM	PALB2	5	LK-2 VMRC-MELG CCK-81 KYSE-270 HCT-15-Luc#1
CTNNB1	1	CCK-81	PBRM1	4	NUGC-3 KMRC-1 CCRF-CEM A3/KAW
CUL3	3	HEC-1 P30-OHK SKM-1	PDGFRA	4	Mewo KMRC-1 A3/KAW CCK-81
DDR2	1	CCRF-CEM	PDGFRB	2	HEC-1 LK-2
EGFR	4	RPMI8226 CCRF-CEM CCK-81 KYSE-270	PIK3CA	5	P30-OHK MKN1 LU99A CCK-81 HCT-15-Luc#1
ENO1?	1	LU99A	PIK3R1	1	NY
EP300	3	SKM-1 LU99A CCK-81	PTCH1	1	SKM-1
ERBB2	1	HEC-1	PTEN	1	P30-OHK
ERBB3	4	HEC-1 SCC-3 KMRC-1 KYSE-270	RAC1	2	TGW HCT-15-Luc#1
ERBB4	5	RPMI8226 HEC-1 Lu-135 TGW CCRF-CEM CCK-81	RAC2	1	HEC-1
EZH2	2	NUGC-3 CCRF-CEM	RAD51C	1	SBC-3
FBXW7	2	MKN1 CCK-81	RAF1	1	no.10
FGFR1	3	Mewo P30-OHK HCT-15-Luc#1	RB1	2	SKM-1 Lu-135
FGFR2	2	Mewo SBC-3	RET	1	Mewo
FGFR3	1	CCRF-CEM	ROS1	6	K562 Mewo A549 HuH-7 LK-2 A3/KAW
FGFR4	1	SCC-3	SETD2	1	KURAMOCHI
FLT3	2	HEC-1 A3/KAW	SMAD4	1	HEC-1
HRAS	1	HEC-1	SMARCA4	4	P30-OHK NUGC-3 CCK-81 HCT-15-Luc#1
IDH1	0	none	SMO	1	Mewo
IDH2	0	none	STAT3	1	TGW
IGF1R	3	Mewo Kasumi-1 CCRF-CEM	STK11	1	A549
IGF2	0	none	TP53	15	no.10 RPMI8226 HEC-1 Mewo SKM-1 Lu-135 TGW LK-2 HCT-15-Luc#1 Kasumi-1 VMRC-MELG CCRF-CEM CCK-81 VMRC-LCD KOSC-2 cl3-43
IL7R	2	SKM-1 A3/KAW	TSC1	2	SBC-3 CCRF-CEM
JAK1	1	CCK-81	VHL	1	Mewo
JAK2	1	HEL			
JAK3	1	HCT-15-Luc#1			

変異が見つからなかった遺伝子

Reference cell lines for 90 genes in Oncopanel (ver. 2)

No.	Cell Line	Genes	Gene Name
1	A3-KAW	2	IL7R MYC
2	A549	1	STK11
3	CCK-81	11	BRAF JAK1 BRCA1 SMARCA4 CHEK2 EGFR PIK3CA MAP3K1 FBXW7 ABL1 CTNNB1
4	CCRF-CEM	5	FGFR3 ALK CCND1 NOTCH2 DDR2
5	HCT-15-Luc#1	4	RAC1 JAK3 PALB2 KIT
6	HEC-1	16	AKT2 CUL3 KEAP1 PDGFRB ERBB3 NOTCH1 HRAS ARID1A RAC2 SMAD4 ATM FLT3 KRAS BAP1 NOTCH3 ERBB2
7	HEL	2	APC JAK2
8	K562	1	AKT3
9	KOSC-2_cl3-43	3	AKT1 MTOR CDKN2A
10	KURAMOCHI	2	TP53 AXIN1
11	LK-2	3	BCL2L1 ROS1 NFE2L2
12	LU99A	3	CREBBP ENO1 EP300
13	Mewo	9	SMO PDGFRA FGFR1 FGFR2 MET NRG1 RET VHL
14	no-10	1	RAF1
15	NUGC-3	4	PBRM1 EZH2 ARID2 CDK4
16	NY	1	PIK3R1
17	P30-OHK	2	PTEN NT5C2
18	SBC-3	2	TSC1 RAD51C
19	SCC-3	3	FGFR4 MAP2K1 MAP3K4
20	TGW	2	STAT3 ERBB4
21	SKM-1	6	BRCA2 RB1 PTCH1 NF1 SETD2 MAP2K4
22	HL60	7	IDH1 BIRD1 ALK ERBB2 FLT3 NOTCH1 CDKN2A
23	HEK293T/IDH2	1	IDH2
24	HEK293T/NRAS	1	NRAS
25	HEK293T/MDM2	1	MDM2
26	HEK293T/IGF2	1	IGF2
27	HEK293T/MYCN	1	MYCN

27 cell lines can cover all 90 gene's mutations

< Additional cell line

→ Creation by genome editing

Confirmed mutations in JCRB cell lines registered in COSMIC database
 Created mutations in missing genes by genome editing in HEK293T/17 cell

NCC Oncopanel (ver4) 114遺伝子への対応

List of COSMIC-registered JCRB cell lines with known mutations in additional 24 genes on the new NCC Oncopanel (ver4)

Gene	JCRB cell lines with mutations															
ACTN4	MeWo	HSC-4	IM95													
ARAF	CCK-81	NUGC81														
AXL	HEC-1	KHH-2	NB1													
CD274/PD-L1	HEC-1	KURAMOCHI	P30-OHK	JHH-7	KYM-1	KYSE-270										
CRKL	Jurkat*															
ESR1/ER	CCK-81	JHH-2	MeWo	TASK-1												
GNA11	KURAMOCHI															
GNAQ	KON															
GNAS	HEC-1	KURAMOCHI	P30OHK													
KDM6A/UTX	HEC-1	T-24	OVMIU	RPM1-8206												
MAP2K2/MEK	HEC-1	HuCCT1														
MDM4	CCK-81	HEC-1	JHH-1	LU-99A												
MLH1	CCK-81	CCRF-CEM	HSC4	MIAPaCa2	MeWo	P30-OHK	RD	YKG-1								
MSH2	A3-KAW	CCK-81	JHH-7	IM95	KON	LU-65	OCUM-1	SKM-1								
NTRK1	BE2-M17	FU-97	HCC56	MeWo												
NTRK2	A3-KAW	A4-FuK	KYM-1													
NTRK3	ASH3	KP2	KURAMOCH	SAT	SBC-3											
PIK3R2	HEC-1	JHH-4	KG1	SBC-1												
POLD1	HEC-1	JHH-4	KM-H2	KOSC-2	MeWo	NEC8T-24	YMB-1-B									
POLE	A549	ABC-1	CCK-81	HEC-1	KMRC-1	KMS-12-BM	LU-65	LU-99A	MKN28	NUGC-3	NY	P30-OHK	P32-ISH	SAT	TT	TYK-nu
PRKCI	HUH-7	KP-4	P30-OHK	T98G												
RHOA	CCK-81	IM-95	KOSC-2													
SETBP1	A4-Fuk	CCK-81	HARA	HEC-1	HSC-4	KATOIII	KON	MRK-nu-1	MeWo	NY	TASK-1					
SMARCB1	KMRC-1	P32-ISH														

Cell lines used for 90 genes
 Additionally required cell lines

NCC Oncopanel is updated to have 114 genes (ver. 4)

* JCRB cell line but not registered at COSMIC

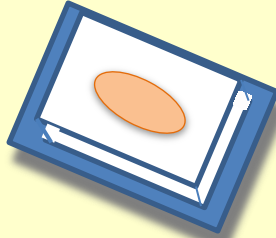
Three additional cell lines will be added!

今後の方向性

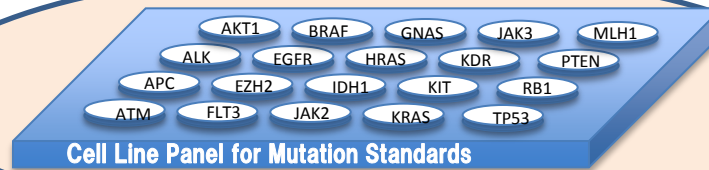
パネル検査用
ALL-in-one標準品



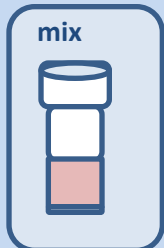
FFPEサンプルの作製



新規変異の機能解析



感度試験用標準品



A遺伝子変異 + B遺伝子変異 + C遺伝子変異 + D遺伝子変異 — — —
(20%) (10%) (5%) (1%)

謝 辞



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Japan Agency for Medical Research and Development

医薬品等規制調和・評価研究事業

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「コンパニオン診断薬の臨床性能のブリッジング
のための評価手法に関する研究」