

118 Gene Panel

SNVs & InDels (117)						CNVs (27)		Fusions (10)	
ABL1	AKT1	AKT2	ALK	APC	AR	ARAF	AKT1	FGFR2	ALK
ARID1A	ATM	BARD1	BRAF	BRCA1	BRCA2	BRIP1	AR	FGFR3	BCR
BTK	CBL	CCND1	CCND2	CCNE1	CD274	CDH1	BRAF	KDR	BRAF
CDK12	CDK4	CDK6	CDKN2A	CEBPA	CHEK1	CHEK2	BRCA1	KIT	EGFR
CSF1R	CTNNB1	DDR2	DPYD	EGFR	ERBB2	ERBB3	CCND1	KRAS	FGFR2
ESR1	FANCL	FBXW7	FGFR1	FGFR2	FGFR3	FLT3	CCND2	MAPK1	FGFR3
GATA3	GNA11	GNAQ	GNAS	HRAS	IDH1	IDH2	CCNE1	MDM2	NTRK1
IGF1R	JAK2	JAK3	KDM6A	KDR	KEAP1	KIT	CD274	MET	NTRK2
KRAS	MAP2K1	MAP2K2	MAPK1	MAPK3	MDM2	MET	CDK12	MYC	RET
MLH1	MPL	MSH2	MSH6	MTOR	MYC	MYCN	CDK4	MYCN	ROS1
NF1	NF2	NFE2L2	NOTCH1	NPM1	NRAS	NTRK1	CDK6	PDGFRA	
NTRK2	NTRK3	PALB2	PDCD1LG2	PDGFRA	PDGFRB	PIK3CA	EGFR	PIK3CA	
PIK3R1	PMS2	PPP2R1A	PPP2R2A	PTEN	PTPN11	RAD51B	ERBB2	RAF1	
RAD51C	RAD51D	RAD54L	RAF1	RB1	RET	RHEB	FGFR1		
RHOA	RIT1	RNF43	ROS1	RUNX1	SETD2	SMAD4			
SMO	STAG2	STK11	TCF7L2	TERT	TOP2A	TP53			
TSC1	TSC2	U2AF1	VHL	UGT1A1					

Sample Requirement

PE/Ascites	Total 40 c.c. (4 STRECK Tubes)
Blood/CSF	Total 20 c.c. (2 STRECK Tubes) 註1 CSF最低至少10 c.c.
Tissue	HE染色片*1 (5 um) & 10片空白片 (10um, tumor content>20%) 註1 空白片數須依檢體大小而定 註2 骨頭檢體需EDTA脫鈣

SNV點突變 (Single nucleotide variation) DNA序列產生單核苷酸變異 (A,T,C,G) (ex. EGFR L858R, KRAS G12C, BRAF V600E...)

InDel短片插入缺失 (insertion / deletion) DNA序列發生短片數十個核苷酸的插入或缺失 (ex. EGFR ex19 del, EGFR ex20 ins...)

CNV拷貝數變化 (Copy number variation) 基因組的某個區域發生複製或缺失的情況 (ex. ERBB2/HER amp, MET amp...)

Fusion基因融合 染色體發生結構重組導致不同的兩個基因序列相連 (ex. EML4-ALK, CD74-ROS1, FGFR3-TACC3...)

MSI微衛星不穩定 (microsatellite instability) 微衛星 (microsatellites) 是遍佈於人類基因組中的短串聯重複序列。與正常細胞相比,腫瘤細胞的微衛星由於複製錯誤引起的簡單重複序列的增加或丟失而導致微衛星長度的改變。

TMB腫瘤突變負荷量 (Tumor Mutation Burden) 在腫瘤基因外顯子編碼區的每一兆鹼基中,發生置換和插入/缺失突變(非同義突變)的總數,可評估免疫治療反應。

5種檢體別 (組織、胸水、腹水、腦脊髓液, 血液)

10個工作天完成產出報告 (實驗室收到合格檢體)

50000x液態切片超深度定序檢測正確找出極微量癌症基因突變

Analytical Performance

AlphaLiquid-100 癌液準®	Reportable Range	AF / CN	Sensitivity
SNVs	≥ 0.03%	≥ 0.1%	95%
InDels	≥ 0.01%	≥ 0.1%	95%
CNVs	≥ 2.2 copies	≥ 2.4 copies	99%
Fusions	≥ 0.05%	≥ 0.2%	95%

AlphaSolid-100 癌克準™	Reportable Range	AF / CN	Sensitivity
SNVs	≥ 1%	≥ 1%	100%
InDels	≥ 1%	≥ 1%	100%
CNVs	≥ 2.6 copies	≥ 2.6 copies	100%
Fusions	≥ 1%	≥ 1%	100%



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查詢報告

癌液準® 癌克準™

Total Solution for NGS



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Total Solution for NGS

癌液準 / 癌克準使用Hybrid-Capture based NGS，根據病人狀況挑選合適檢體，針對癌症相關118基因進行分析。提供早中晚期實體瘤患者的個人化治療策略指引資訊，包括腫瘤基因分型、治療選擇和治療反應監控。

	癌液準®	癌克準™
檢體種類	胸水 / 腹水 / 腦脊髓液 / 血液	腫瘤組織
檢測突變資訊	SNVs / InDels / CNVs / Fusions / MSI / TMB	
檢測極限	0.01%	1%
合適病人	無法取得組織或是需要持續追蹤之患者	可取得足量合格檢體之患者

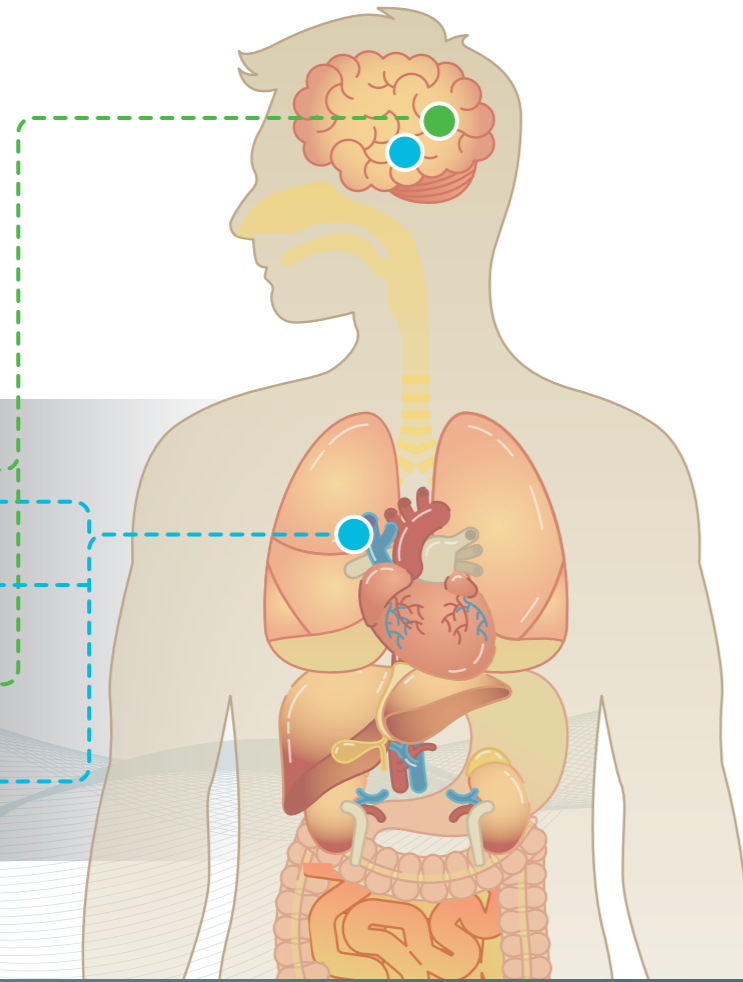
Q: 當病人組織檢體不足時該如何送檢？

A: 依病人狀況不同選擇合適檢體進行NGS檢測

CNS-only progression

Systemic progression

- Tissue
- PE supernatant
- CSF supernatant
- Blood



檢測流程

抗藥 / 追蹤

1st Treatment

2nd Treatment

3rd Treatment

X line Treatment

癌克準™

癌液準®

V

△ (如果組織充足)

△ (如果組織充足)

X

V

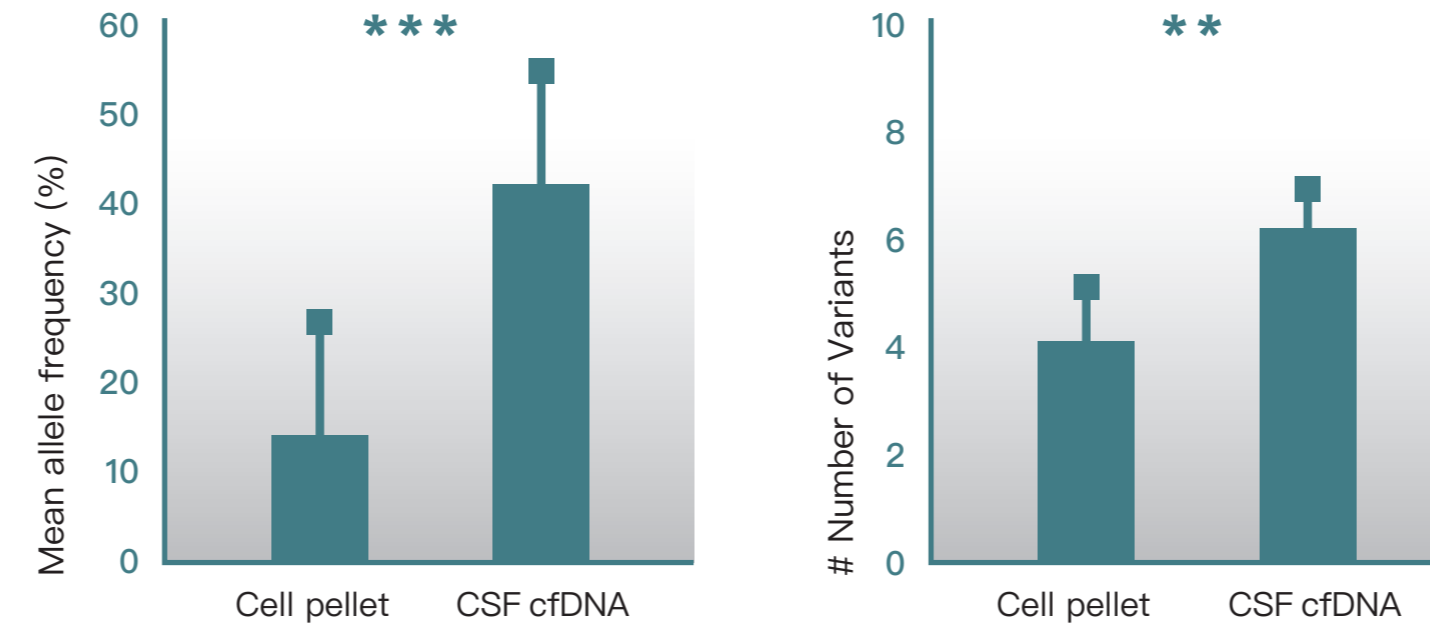
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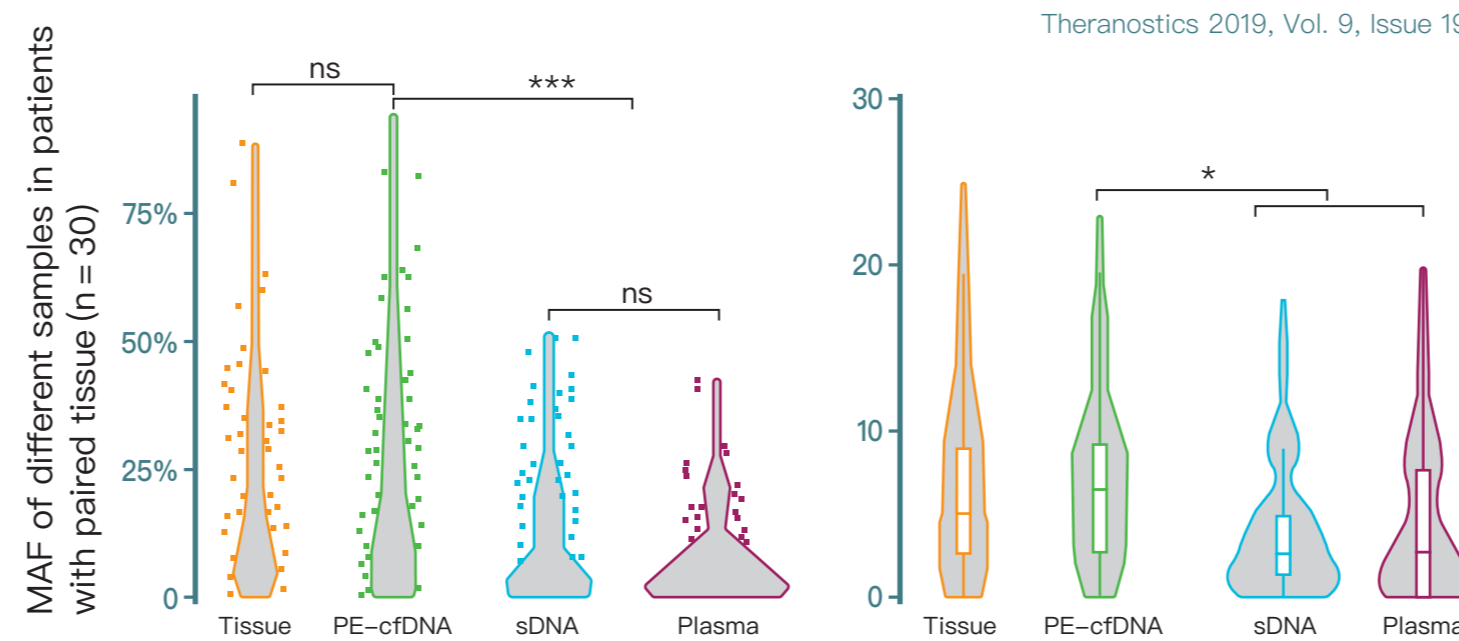
V

除了組織和血液，體液也能進行NGS

J Mol Diagn 2021, 23: 742e752



根據文獻，針對腦/腦膜轉移病人，腦脊髓液上清液檢體比細胞檢體可找出更多基因變異資訊。



根據文獻，病人體液上清液檢體基因變異與組織相近，且更有機會找到更多變異，為病人找尋下一線治療機會。

可用藥變異

根據變異提供FDA/NCCN建議用藥，及相對證據力強弱。同時根據檢測者所在位置提供臨床研究資訊。

Druggable Alterations

Alteration	Therapies	Clinical trials	Page
EGFR L858R 112%	8 FDA approved therapies Afatinib, Bevacizumab + Erlotinib, Carboplatin + Gefitinib + Pemetrexed-Diosodium, Dacomitinib, Erlotinib, Erlotinib + Ramucicromab, Gefitinib, Osimertinib	Yes	p4
EGFR T790M 092%	1 FDA approved therapies Osimertinib	Yes	p7
MET c.2888-1G>A (exon14 skipping) 122%	3 FDA approved therapies Capmatinib, Crizotinib, Tepotinib	Yes	pX
EML4-ALK fusion 108%	5 FDA approved therapies Ceritinib, Crizotinib, Lorlatinib, Alectinib, Brigatinib	Yes	pX
MET amplification 10 CN	3 FDA approved therapies Capmatinib, Crizotinib, Tepotinib	Yes	pX
BRCA D2242F5'2 20%	4 FDA approved in other indication Carboplatin, Cisplatin, Olaparib, Talazoparib	Yes	pX
Micro satellite instability High	1 FDA approved therapies Pembrolizumab	Yes	pX
Tumor mutation burden High (27.7 mut/Mbp)	1 FDA approved therapies Pembrolizumab	Yes	pX

Potentially druggable or functionally effective alterations

- EGFR C797S (1.02%) p9
- TP53 E271K (0.31%) p10

Variant of Uncertain Significance

- SMAD4 R361H (0.85%) ..p11
- ARID1A P1392S (0.29%) ..p12
- BRCA1 T1777K (0.28%) ..p13

Comment

For variants with 40.0% < VAF < 60.0%, we cannot exclude the possibility of their being germline variants

Analytical sensitivity Input DNA: 13ng
Limit of Detection(10ng)
SNV/INDEL | 0.3%
CNA | 2.4 CN
Fusion | 0.5%

Lab. Director
Tae You Kim, M.D., Ph.D.
Electronically signed on March 3, 2022

可能用藥選項

We provide information on detected variants that are either potentially druggable or functionally useful but with which no approved therapy information exists.

檢測敏感度

Limit of Detection (LOD) information is provided based on the original input DNA amount of the sample.

補充註解

Additional sample-specific comments if there is any relevant information that should be noted

臨床研究選項

List of variants that are functionally uncertain or unknown.