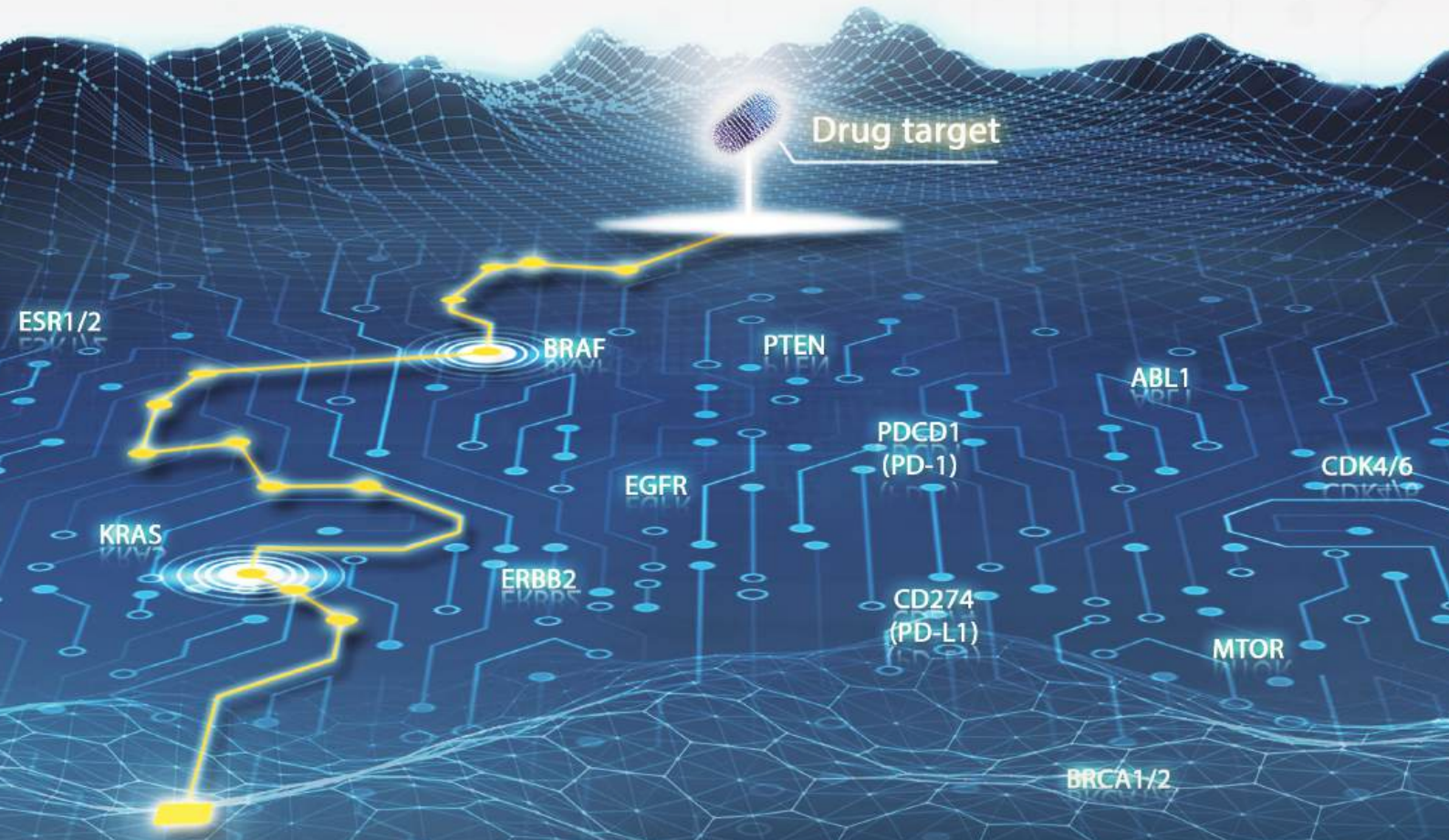
精準找出更多治療選擇

ACT Onco® +

癌安克® 癌症基因檢測

廣泛檢測>400個癌症相關基因
完整分析腫瘤訊息傳遞路徑



ACT GENOMICS®

ACT Onco® + 檢測規格

檢體需求
石蠟包埋切片
5-20片未染色切片(5 μm/片)
1片H&E染色玻片(5 μm)

* 體液檢體(如肋膜積水、腹水或心包膜積水)需要將懸浮細胞離心後製成FFPE才可送件，且建議至少需含1x10^6細胞。
* 檢測會因檢體腫瘤含量(Tumor Purity)之差異而無法提供檢測結果。ACT Onco®+ 腫瘤含量需≥30% 檢體腫瘤含量若小於30%，CNV, TMB and MSI可能無法提供。

免疫治療預測
腫瘤突變負荷 (TMB)
微衛星不穩定性檢測(MSI)

檢測位點
> 1Mb 組基因位點

完整外顯子定序
>400個癌症相關基因

NGS平均定序深度
≥ 500x

癌融克® 癌症基因檢測
腫瘤RNA檢測，29個臨床重要融合基因

檢測時間
8個工作天

ACT Onco® +
提供更多治療選擇

適用實體腫瘤

局部晚期、轉移或復發 — 全面性了解基因突變，選擇合適用藥

標準治療效果不佳 — 標準治療後發現效果有限，透過基因突變找到更多用藥選擇

初次診斷 — 在治療前廣泛了解基因突變選擇合適用藥

ACT Onco® + 檢測優勢

根據腫瘤訊息傳遞路徑提供治療建議

檢測涵蓋>400個與腫瘤訊息傳遞路徑相關的基因，分析單核苷酸變異 (SNV)、插入/缺失 (InDel)、拷貝數變異 (CNV)與融合基因變異 (Fusion Gene)，針對藥物敏感及抗藥基因分析，提供更精準解讀與用藥選擇。

提供免疫抑制劑治療反應評估

整合腫瘤突變負荷(TMB)、微衛星不穩定性(MSI)與免疫相關基因資訊，提供更精準免疫治療建議。

8個工作天提供專業解決方案

8個工作天檢測時程符合臨床需求。(從實驗室收到合格檢體起開始計算)

國際品質認證

檢測皆在美國CAP認證實驗室進行，並獲得台灣TFDA精準醫療分子檢測實驗室(認證編號LDT0001)

提供醫師報告諮詢服務

每份個人化檢測報告都提供一對一諮詢服務，詳細解說分析結果。

提供藥物基因體學資訊

治療反應可能會受遺傳基因變異(基因多型性)影響，藥物基因體學資訊可協助醫師為病患選擇適當藥物。

整合性生物醫藥資訊分析

臨床經驗豐富之專業團隊整合腫瘤生物學、醫學、分子生物學、細胞生物學、免疫學、生物資訊、大數據分析及藥學等專業領域，提供整合性用藥建議。

檢測具高靈敏度

使用具高靈敏度之次世代定序技術(NGS)可因應臨床檢體需求以及腫瘤高異質性的問題。

適用實體腫瘤

局部晚期、轉移或復發
全面性了解基因突變
選擇合適用藥

標準治療效果不佳
標準治療後發現效果有限
透過基因突變找到更多用藥選擇

初次診斷
在治療前廣泛了解基因突變
選擇合適用藥

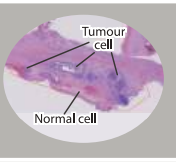
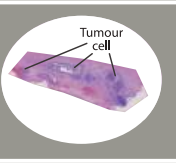
一次提供資訊

- 標靶治療
- 化學治療
- 免疫治療
- 荷爾蒙治療

精準臨床應用優勢

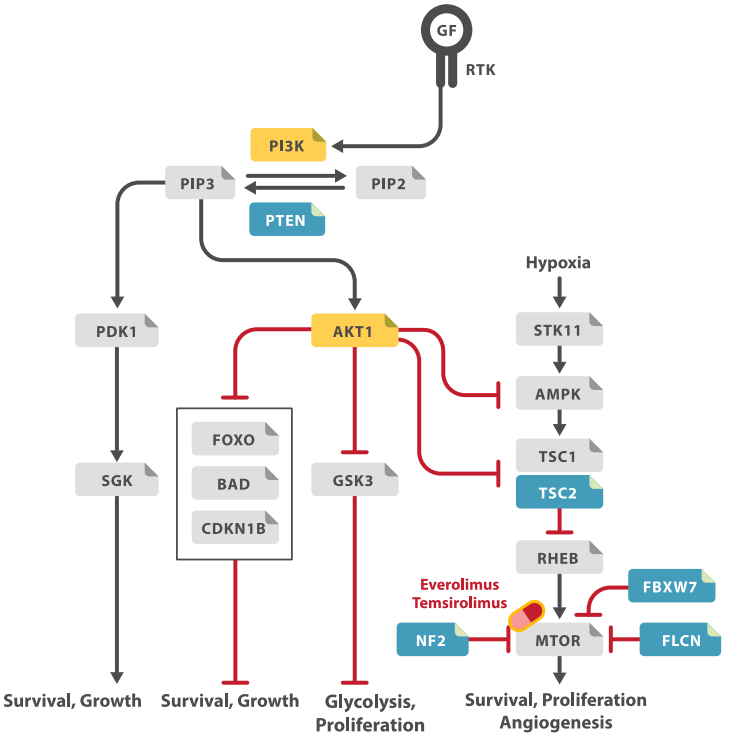
腫瘤檢體處理 (Macrodissection)提供準確拷貝數變異分析

以癌症細胞的ERBB2基因擴增成8個為例，當萃取出的腫瘤DNA比例從20%到70%時，計算出的拷貝數變異(CNV)數量從3.2上升到6.2，可更準確的預測使用Herceptin治療效果。

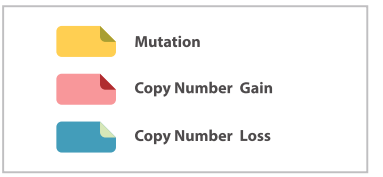
手工刮取	處理前	處理後
腫瘤檢體範圍		
萃取出腫瘤DNA比例	20%	70%
計算出 *ERBB2* CNV 數量	3.2 = 8*0.20 + 2*0.80	6.2 = 8*0.70 + 2*0.30


實驗室人員正在進行手工刮取(Macrodissection)

結合腫瘤訊息傳遞路徑 (Signal Pathway)分析提供個人化治療策略



將廣泛檢測出的癌症基因突變進行腫瘤訊息傳遞路徑分析，找出突變基因之間的關聯性，再從基因上下游網絡中辨識出正確的突變源頭，以利生物資訊進行系統性的用藥分析，協助醫師制定更精準的治療策略。

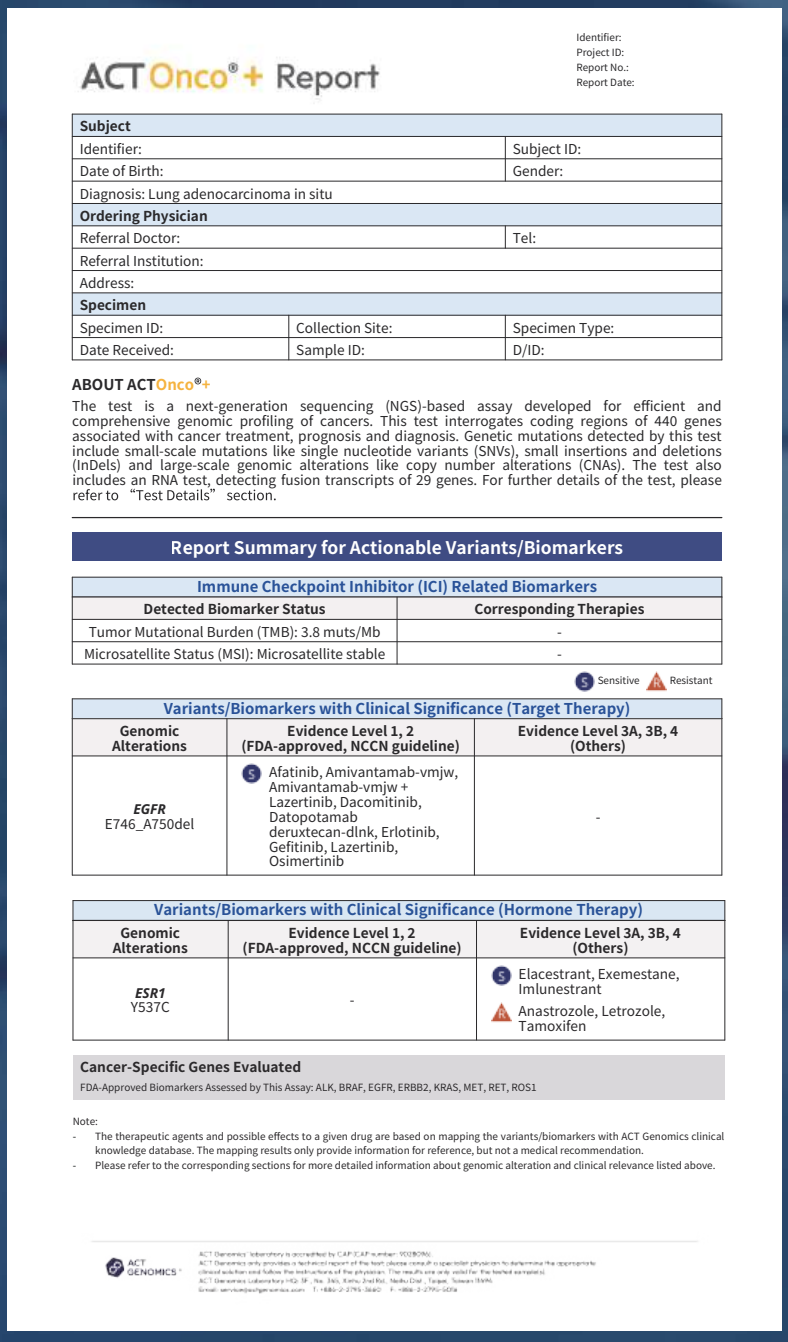


生物與醫藥資訊分析(Bioinformatics)將數據轉換成實際治療方針

基因檢測除了DNA定序外，更重要的是從錯綜複雜的基因數據中解析出具臨床意義的資訊。行動基因的生資與醫資團隊整合國內國外大型資料庫，準確辨識癌症相關變異，再透過基因與藥物資訊的比對，完整提供具醫療價值的檢測報告。

生物與醫藥資訊分析主要流程:

- **變異辨認(Variant Calling):**
  正確辨識出定序數據內的變異基因
- **數據註釋(Data Annotation):**
  註釋與篩選與癌症相關之變異基因
- **醫藥解析(Clinical Interpretation)**
  依據文獻找出具有臨床意義之變異基因，提供醫師選擇用藥指引



ACT Onco®+ Report

Identifier:
Project ID:
Report No.:
Report Date:

Subject		
Identifier:		Subject ID:
Date of Birth:		Gender:
Diagnosis: Lung adenocarcinoma in situ		
Ordering Physician		
Referral Doctor:		Tel:
Referral Institution:		
Address:		
Specimen		
Specimen ID:	Collection Site:	Specimen Type:
Date Received:	Sample ID:	D/ID:

ABOUT ACTOnco®+

The test is a next-generation sequencing (NGS)-based assay developed for efficient and comprehensive genomic profiling of cancers. This test interrogates coding regions of 440 genes associated with cancer treatment, prognosis and diagnosis. Genetic mutations detected by this test include small-scale mutations like single nucleotide variants (SNVs), small insertions and deletions (InDels) and large-scale genomic alterations like copy number alterations (CNAs). The test also includes an RNA test, detecting fusion transcripts of 29 genes. For further details of the test, please refer to "Test Details" section.

Report Summary for Actionable Variants/Biomarkers

Immune Checkpoint Inhibitor (ICI) Related Biomarkers	
Detected Biomarker Status	**Corresponding Therapies**
Tumor Mutational Burden (TMB): 3.8 muts/Mb	-
Microsatellite Status (MSI): Microsatellite stable	-

S Sensitive R Resistant

Variants/Biomarkers with Clinical Significance (Target Therapy)		
Genomic Alterations	**Evidence Level 1, 2 (FDA-approved, NCCN guideline)**	**Evidence Level 3A, 3B, 4 (Others)**
EGFR E746_A750del	S Afatinib, Amivantamab-vmjw, Amivantamab-vmjw + Lazertinib, Dacomitinib, Datopotamab deruxtecan-dlnk, Erlotinib, Gefitinib, Lazertinib, Osimertinib	-

Variants/Biomarkers with Clinical Significance (Hormone Therapy)		
Genomic Alterations	**Evidence Level 1, 2 (FDA-approved, NCCN guideline)**	**Evidence Level 3A, 3B, 4 (Others)**
ESR1 Y537C	-	S Elacestrant, Exemestane, Imlunestrant R Anastrozole, Letrozole, Tamoxifen

Cancer-Specific Genes Evaluated

FDA-Approved Biomarkers Assessed by This Assay: ALK, BRAF, EGFR, ERBB2, KRAS, MET, RET, ROS1

Note:
- The therapeutic agents and possible effects to a given drug are based on mapping the variants/biomarkers with ACT Genomics clinical knowledge database. The mapping results only provide information for reference, but not a medical recommendation.
- Please refer to the corresponding sections for more detailed information about genomic alteration and clinical relevance listed above.

ACT GENOMICS

註：由於檢測技術限制及個體腫瘤基因差異等因素，即使檢測人員已確實執行標準操作程序，仍可能發生無法提供檢測特定基因或特定生物標記之情形或未發生任何異常。本檢測及其結果僅供醫師參考用途，不得被視為對任何人提供的診斷或醫學治療建議。受檢測者針對任何檢測結果的臨床上解讀，應諮詢其醫師。

拷貝數變異
CNV

拷貝數變異發生於長度在1kb以上的DNA片段[1]，會造成基因增幅(Amplification)、異型接合子缺失(Heterozygous Deletion)或同型接合子缺失(Homozygous Deletion)。

[1] Zack TI et al., Pan-cancer patterns of somatic copy number alterations. Nature Genetics 45: 1134-1140, 2013

ACTFusion™
癌融克®癌症基因檢測結果

融合基因
FUSION GENE

融合基因是不同區間的基因發生染色體異位(Translocation)、缺失(Deletion)或染色體反轉(Chromosomal Inversion)而連接在一起，可能造成基因失去正常調控狀態而導致癌症。

腫瘤突變負荷
TMB

腫瘤突變負荷是一種定量的生物標記，呈現檢體中基因突變數量的多寡，以每一百萬鹼基(Megabase,MB)的非同義變異(Nonsynonymous Mutations)數量表示。評估免疫檢查點抑制劑治療(Checkpoint Inhibitortherapy)是否適用於該病患。

完整醫藥報告

深入解讀基因資訊

單核苷酸變異
SNV

DNA序列中的核苷酸(Nucleotide)產生單一位點突變時，可能造成致癌基因不受調控而持續活化，或造成抑癌基因失去功能。

基因突變頻率
LEVEL OF MUTATION FREQUENCY

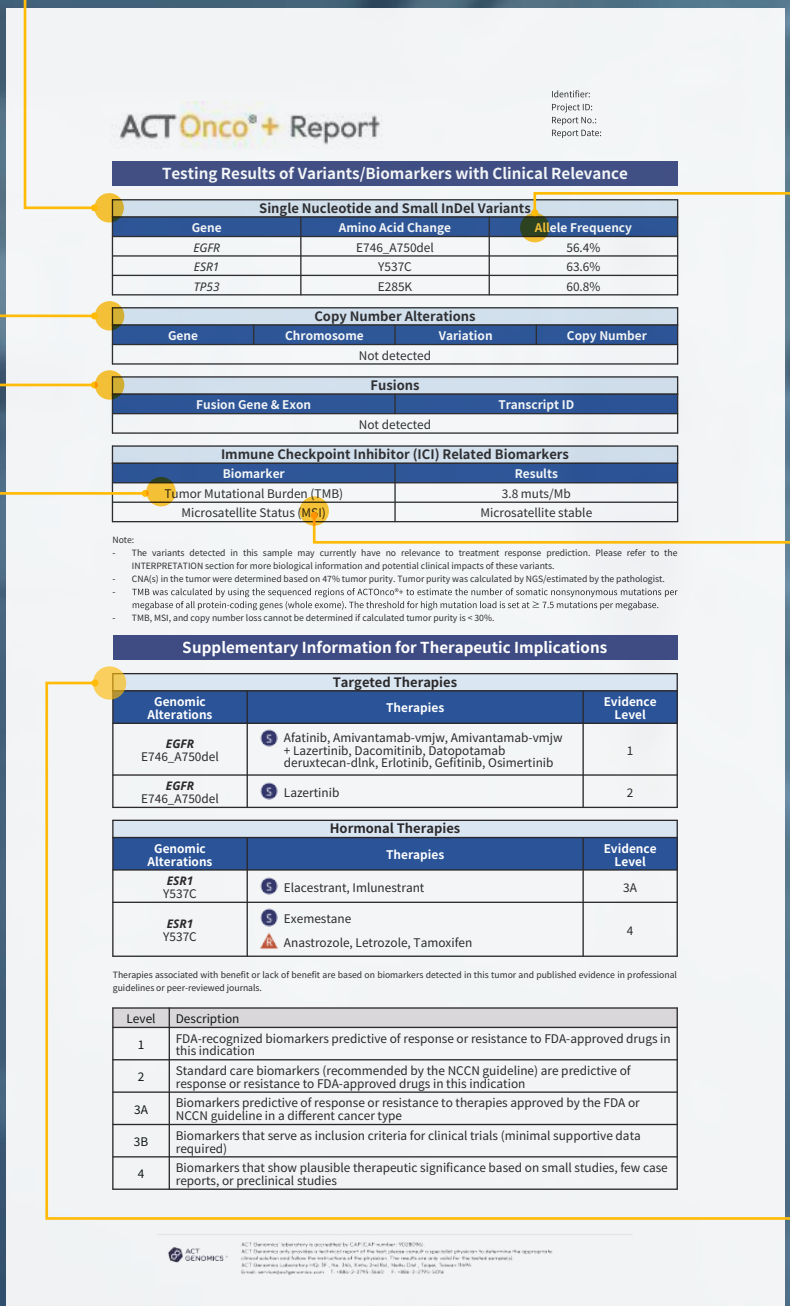
基因突變頻率能夠提供與腫瘤生成有關的突變比例資訊。

微衛星不穩定性檢測
MSI

在基因組內有一些重複的序列區域，會因細胞的序列配對修補機制(Mismatch repair system)異常，在細胞複製時容易發生插入或缺失等序列變異，呈現基因組不穩定的狀況。病患若檢測到帶有微衛星不穩定性或序列配對修補機制異常，可使用免疫檢查點抑制劑進行治療。

治療建議
THERAPEUTIC IMPLICATIONS

依據基因突變資訊提供醫師與病患多種治療選擇。



ACT Onco®+ Report

Identifier:
Project ID:
Report No.:
Report Date:

Testing Results of Variants/Biomarkers with Clinical Relevance

Single Nucleotide and Small InDel Variants

Gene	Amino Acid Change	Allele Frequency
EGFR	E746_A750del	56.4%
ESR1	Y537C	63.6%
TP53	E285K	60.8%

Copy Number Alterations

Gene	Chromosome	Variation	Copy Number
Not detected			

Fusions

Fusion Gene & Exon	Transcript ID
Not detected	

Immune Checkpoint Inhibitor (ICI) Related Biomarkers

Biomarker	Results
Tumor Mutational Burden (TMB)	3.8 muts/Mb
Microsatellite Status (MSI)	Microsatellite stable

Note:
- The variants detected in this sample may currently have no relevance to treatment response prediction. Please refer to the INTERPRETATION section for more biological information and potential clinical impacts of these variants.
- CNA(s) in the tumor were determined based on 47% tumor purity. Tumor purity was calculated by NGS/estimated by the pathologist.
- TMB was calculated by using the sequenced regions of ACTOnco®+ to estimate the number of somatic nonsynonymous mutations per megabase of all protein-coding genes (whole exome). The threshold for high mutation load is set at ≥ 7.5 mutations per megabase.
- TMB, MSI, and copy number loss cannot be determined if calculated tumor purity is < 30%.

Supplementary Information for Therapeutic Implications

Targeted Therapies

Genomic Alterations	Therapies	Evidence Level
EGFR E746_A750del	S Afatinib, Amivantamab-vmjw, Amivantamab-vmjw + Lazertinib, Dacomitinib, Datopotamab deruxtecan-dlnk, Erlotinib, Gefitinib, Osimertinib	1
EGFR E746_A750del	S Lazertinib	2

Hormonal Therapies

Genomic Alterations	Therapies	Evidence Level
ESR1 Y537C	S Elacestrant, Imlunestrant	3A
ESR1 Y537C	S Exemestane A Anastrozole, Letrozole, Tamoxifen	4

Therapies associated with benefit or lack of benefit are based on biomarkers detected in this tumor and published evidence in professional guidelines or peer-reviewed journals.

Level	Description
1	FDA-recognized biomarkers predictive of response or resistance to FDA-approved drugs in this indication
2	Standard care biomarkers (recommended by the NCCN guideline) are predictive of response or resistance to FDA-approved drugs in this indication
3A	Biomarkers predictive of response or resistance to therapies approved by the FDA or NCCN guideline in a different cancer type
3B	Biomarkers that serve as inclusion criteria for clinical trials (minimal supportive data required)
4	Biomarkers that show plausible therapeutic significance based on small studies, few case reports, or preclinical studies

ACT GENOMICS

基因列表

ACT Onco® + 檢測基因 （◆ SNV / InDel ■ CNV ）

ABCB1 ◆	CBFB ◆■	DPYD ◆■	GNAQ ◆■	MAX ◆■	PIK3CG ◆■	SF3B1 ◆■
ABCC2 ◆	CBL ◆■	DTX1 ◆■	GNAS ◆■	MCL1 ◆■	PIK3R1 ◆■	SGK1 ◆■
ABCG2 ◆	CCNA1 ◆■	E2F3 ◆■	GREM1 ◆■	MDM2 ◆■	PIK3R2 ◆■	SH2D1A ◆
ABL1 ◆■	CCNA2 ◆■	EGFR ◆■	GRIN2A ◆■	MDM4 ◆■	PIK3R3 ◆■	SLC19A1 ◆
ABL2 ◆■	CCNB1 ◆■	EP300 ◆■	GSK3B ◆■	MED12 ◆■	PIM1 ◆■	SLC22A2 ◆
ADAMTS1 ◆■	CCNB2 ◆■	EPCAM ◆■	GSTP1 ◆	MEF2B ◆■	PMS1 ◆■	SLCO1B1 ◆
ADAMTS13 ◆■	CCNB3 ◆■	EPHA2 ◆■	GSTT1 ◆	MEN1 ◆■	PMS2 ◆■	SLCO1B3 ◆
ADAMTS15 ◆■	CCND1 ◆■	EPHA3 ◆■	HGF ◆■	MET ◆■	POLB ◆■	SMAD2 ◆■
ADAMTS16 ◆■	CCND2 ◆■	EPHA5 ◆■	HIF1A ◆■	MITF ◆■	POLD1 ◆■	SMAD3 ◆■
ADAMTS18 ◆■	CCND3 ◆■	EPHA7 ◆■	HIST1H1C ◆	MLH1 ◆■	POLE ◆■	SMAD4 ◆■
ADAMTS6 ◆■	CCNE1 ◆■	EPHB1 ◆■	HIST1H1E ◆	MPL ◆■	PPARG ◆■	SMARCA4 ◆■
ADAMTS9 ◆■	CCNE2 ◆■	ERBB2 ◆■	HNF1A ◆■	MRE11 ◆■	PPP2R1A ◆■	SMARCB1 ◆■
ADAMTSL1 ◆■	CCNH ◆■	ERBB3 ◆■	HR ◆■	MSH2 ◆■	PRDM1 ◆■	SMO ◆■
ADGRA2 ◆■	CD19 ◆■	ERBB4 ◆■	HRAS ◆	MSH6 ◆■	PRKAR1A ◆■	SOCS1 ◆
ADH1C ◆	CD274 ◆■	ERCC1 ◆■	HSP90AA1 ◆■	MTHFR ◆	PRKCA ◆■	SOX2 ◆
AKT1 ◆■	CD58 ◆■	ERCC2 ◆■	HSP90AB1 ◆■	MTOR ◆■	PRKCB ◆■	SOX9 ◆■
AKT2 ◆■	CD70 ◆	ERCC3 ◆■	HSPA4 ◆■	MUC16 ◆■	PRKCG ◆■	SPEN ◆■
AKT3 ◆■	CD79A ◆■	ERCC4 ◆■	HSPA5 ◆■	MUC4 ◆■	PRKCI ◆■	SPOP ◆■
ALDH1A1 ◆	CD79B ◆■	ERCC5 ◆■	IDH1 ◆■	MUC6 ◆■	PRKCQ ◆■	SRC ◆■
ALK ◆■	CDC73 ◆■	ERG ◆■	IDH2 ◆■	MUTYH ◆■	PRKDC ◆■	STAG2 ◆■
AMER1 ◆■	CDH1 ◆■	ESR1 ◆■	IFNL3 ◆	MYC ◆■	PRKN ◆■	STAT3 ◆■
APC ◆■	CDK1 ◆■	ESR2 ◆■	IGF1 ◆■	MYCL ◆■	PSMB8 ◆■	STK11 ◆■
AR ◆■	CDK12 ◆■	ETV1 ◆■	IGF1R ◆■	MYCN ◆■	PSMB9 ◆■	SUFU ◆■
ARAF ◆■	CDK2 ◆■	ETV4 ◆■	IGF2 ◆■	MYD88 ◆■	PSME1 ◆■	SYK ◆■
ARID1A ◆■	CDK4 ◆■	EZH2 ◆■	IKBKB ◆■	NAT2 ◆	PSME2 ◆■	SYNE1 ◆■
ARID1B ◆■	CDK5 ◆■	FAM46C ◆■	IKBKE ◆■	NBN ◆■	PSME3 ◆■	TAF1 ◆■
ARID2 ◆■	CDK6 ◆■	FANCA ◆■	IKZF1 ◆■	NEFH ◆■	PTCH1 ◆■	TAP1 ◆■
ASXL1 ◆■	CDK7 ◆■	FANCC ◆■	IL6 ◆■	NF1 ◆■	PTEN ◆■	TAP2 ◆■
ATM ◆■	CDK8 ◆■	FANCD2 ◆■	IL7R ◆■	NF2 ◆■	PTGS2 ◆■	TAPBP ◆■
ATR ◆■	CDK9 ◆■	FANCE ◆■	INPP4B ◆■	NFE2L2 ◆■	PTPN11 ◆■	TBX3 ◆■
ATRX ◆■	CDKN1A ◆■	FANCF ◆■	INSR ◆■	NFKB1 ◆■	PTPRD ◆■	TEK ◆■
AURKA ◆■	CDKN1B ◆■	FANCG ◆■	IRF4 ◆■	NFKBIA ◆■	PTPRT ◆■	TERT ◆■
AURKB ◆■	CDKN2A ◆■	FANCL ◆■	IRS1 ◆■	NKX2-1 ◆	RAC1 ◆■	TET1 ◆■
AXIN1 ◆■	CDKN2B ◆■	FAS ◆■	IRS2 ◆	NOTCH1 ◆■	RAD50 ◆■	TET2 ◆■
AXIN2 ◆■	CDKN2C ◆■	FAT1 ◆■	JAK1 ◆■	NOTCH2 ◆■	RAD51 ◆■	TGFBR2 ◆■
AXL ◆■	CEBPA ◆	FBXW7 ◆■	JAK2 ◆■	NOTCH3 ◆■	RAD51B ◆■	TMSB4X ◆
B2M ◆■	CHEK1 ◆■	FCGR2B ◆■	JAK3 ◆■	NOTCH4 ◆■	RAD51C ◆■	TNF ◆■
BAP1 ◆■	CHEK2 ◆■	FGF1 ◆	JUN ◆	NPM1 ◆■	RAD51D ◆■	TNFAIP3 ◆■
BARD1 ◆■	CIC ◆■	FGF10 ◆■	KAT6A ◆■	NQO1 ◆	RAD52 ◆■	TNFRSF14 ◆■
BCL10 ◆■	CREBBP ◆■	FGF14 ◆■	KDM5A ◆■	NRAS ◆■	RAD54L ◆■	TNFSF11 ◆■
BCL2 ◆	CRKL ◆■	FGF19 ◆	KDM5C ◆■	NSD1 ◆■	RAF1 ◆■	TOP1 ◆■
BCL2L1 ◆■	CRLF2 ◆■	FGF23 ◆■	KDM6A ◆■	NTRK1 ◆■	RARA ◆■	TP53 ◆■
BCL2L2 ◆	CSF1R ◆■	FGF3 ◆■	KDR ◆■	NTRK2 ◆■	RB1 ◆■	TPMT ◆
BCL6 ◆■	CTCF ◆■	FGF4 ◆	KEAP1 ◆■	NTRK3 ◆■	RBM10 ◆■	TSC1 ◆■
BCL9 ◆■	CTLA4 ◆■	FGF6 ◆■	KIT ◆■	PAK3 ◆■	RECQL4 ◆■	TSC2 ◆■
BCOR ◆■	CTNNA1 ◆■	FGFR1 ◆■	KMT2A ◆■	PALB2 ◆■	REL ◆■	TSHR ◆■
BIRC2 ◆■	CTNNB1 ◆■	FGFR2 ◆■	KMT2C ◆■	PARP1 ◆■	RET ◆■	TYMS ◆■
BIRC3 ◆■	CUL3 ◆■	FGFR3 ◆■	KMT2D ◆■	PAX5 ◆■	RHOA ◆■	U2AF1 ◆■
BLM ◆■	CYLD ◆■	FGFR4 ◆■	KRAS ◆■	PAX8 ◆■	RICTOR ◆■	UBE2A ◆
BMPR1A ◆■	CYP1A1 ◆	FH ◆■	LCK ◆■	PBRM1 ◆■	RNF43 ◆■	UBE2K ◆■
BRAF ◆■	CYP2B6 ◆	FLCN ◆■	LIG1 ◆■	PDCD1 ◆■	ROS1 ◆■	UBR5 ◆■
BRCA1 ◆■	CYP2C19 ◆	FLT1 ◆■	LIG3 ◆■	PDCD1LG2 ◆■	RPPH1 ◆■	UGT1A1 ◆
BRCA2 ◆■	CYP2C8 ◆	FLT3 ◆■	LMO1 ◆■	PDGFRA ◆■	RPTOR ◆■	USH2A ◆■
BRD4 ◆■	CYP2D6 ◆■	FLT4 ◆■	LRP1B ◆■	PDGFRB ◆■	RUNX1 ◆■	VDR ◆
BRIP1 ◆■	CYP2E1 ◆	FOXL2 ◆	LYN ◆■	PDIA3 ◆■	RUNX1T1 ◆■	VEGFA ◆■
BTG1 ◆	CYP3A4 ◆	FOXP1 ◆■	MALT1 ◆■	PGF ◆■	RXRA ◆■	VEGFB ◆■
BTG2 ◆	CYP3A5 ◆	FRG1 ◆■	MAP2K1 ◆■	PHOX2B ◆	SDHA ◆■	VHL ◆■
BTK ◆■	DAXX ◆■	FUBP1 ◆■	MAP2K2 ◆■	PIK3C2B ◆■	SDHB ◆■	WT1 ◆■
BUB1B ◆■	DCUN1D1 ◆■	GATA1 ◆■	MAP2K4 ◆■	PIK3C2G ◆■	SDHC ◆■	XIAP ◆■
CALR ◆■	DDR2 ◆■	GATA2 ◆■	MAP3K1 ◆■	PIK3C3 ◆■	SDHD ◆■	XPO1 ◆■
CANX ◆■	DICER1 ◆■	GATA3 ◆■	MAP3K7 ◆■	PIK3CA ◆■	SERPINB3 ◆■	XRCC2 ◆■
CARD11 ◆■	DNMT3A ◆■	GNA11 ◆■	MAPK1 ◆■	PIK3CB ◆■	SERPINB4 ◆■	ZNF217 ◆■
CASP8 ◆■	DOT1L ◆■	GNA13 ◆■	MAPK3 ◆■	PIK3CD ◆■	SETD2 ◆■	

ACT Onco® + 檢測之融合基因 (Fusion Gene)

AKT3	ALK	AR	BRAF	EGFR	ERBB2	ERBB4
ERG	ESR1	FGFR1	FGFR2	FGFR3	KIT	MET
NRG1	NRG2	NTRK1	NTRK2	NTRK3	NUTM1	PAX8
PIK3CA	PPARG	RAF1	RET	ROS1	RSPO2	TFE3
TMPRSS2						

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