ALMAC

Partnering to Advance Human Health

Almac Diagnostics

Clinical Trial Assay

Illumina TruSight™ Tumor 170 Panel

A Next Generation Sequencing (NGS) assay that targets DNA and RNA variants from the same solid tumour FFPE sample. The assay covers 170 common cancer genes including key actionable mutations across multiple cancers.

Assay	
Assay intended use	For prospective use in Clinical Trials
Quality & regulatory	CLIA Compliant
Technology & platform	NGS Technology- Illumina NextSeq 500 and Illumina NextSeq 550
Assay type	Central laboratory based test
Disease indication	
Disease indication	Multiple cancer indications
Gene targets	170 common cancer genes *See gene list overleaf
Variants	Targets all coding exons, per the current RefSeq database, in 170 genes. The content includes 55 genes for fusions and splice variants, 148 for SNVs and Indels, and 59 for CNV * (CNV - RUO Assay Only)
Sample requirements	
Tissue type	Formalin Fixed Paraffin Embedded (FFPE) tissue
Recommended tissue requirements	≥ 1mm^3 tissue
Minimum viable tumour cells	25%
Input material	DNA and RNA
Recommended input requirements	120ng DNA and 85ng RNA
Detection rate	
Performance	High levels of accuracy and precision from FFPE suitable for clinical trial use. (See assay validation performance specification for detailed information)
Turnaround time	
TAT	9 days from sample receipt, inclusive of pathology review for small sample numbers within a prospective clinical trial. For batch retrospective testing - turnaround time agreed on a per project basis
Reporting	
Raw data provided	Yes
Customisable reporting	Yes
Results interpretation	Almac data filtering and reporting
Bioinformatics applications	Illumina TruSight™ Tumor 170 Basespace App Bespoke Almac Basespace Apps for deterministic downsampling and QC
Added value	
Added value to client	Almac Diagnostics' experience in prospective clinical trials under a CLIA compliant testing environment. Bespoke Almac bioinformatics pipeline. Clear locked results and RUO data provision for other use

Key benefits:

- Evaluate multiple biomarkers on one panel from one sample
- Works from minimal tissue input
- Rapid turnaround time
- Access to raw data
- Powerful reporting and interpretation services
- Bespoke Almac bioinformatics pipeline providing enhanced variant call reproducibility, accuracy and QC
- Highly competitive price

Gene list:

SNVs and Indels (from DNA)									
AKT1	BRIP1	CREBBP	FANCI	FGFR2	JAK3	MSH3	PALB2	RAD51D	TSC1
AKT2	BTK	CSF1R	FANCL	FGFR3	KDR	MSH6	PDGFRA	RAD54L	TSC2
AKT3	CARD11	CTNNB1	FBXW7	FGFR4	KIT	MTOR	PDGFRB	RB1	VHL
ALK	CCND1	DDR2	FGF1	FLT1	KMT2A(MLL)	MUTYH	PIK3CA	RET	XRCC2
APC	CCND2	DNMT3A	FGF2	FLT3	KRAS	MYC	PIK3CB	RICTOR	
AR	CCNE1	EGFR	FGF3	FOXL2	MAP2K1	MYCL1	PIK3CD	ROS1	
ARID1A	CD79A	EP300	FGF4	GEN1	MAP2K2	MYCN	PIK3CG	RPS6KB1	
ATM	CD79B	ERBB2	FGF5	GNA11	MCL1	MYD88	PIK3R1	SLX4	
ATR	CDH1	ERBB3	FGF6	GNAQ	MDM2	NBN	PMS2	SMAD4	
BAP1	CDK12	ERBB4	FGF7	GNAS	MDM4	NF1	PPP2R2A	SMARCB1	
BARD1	CDK4	ERCC1	FGF8	HNF1A	MET	NOTCH1	PTCH1	SMO	
BCL2	CDK6	ERCC2	FGF9	HRAS	MLH1	NOTCH2	PTEN	SRC	
BCL6	CDKN2A	ERG	FGF10	IDH1	MLLT3	NOTCH3	PTPN11	STK11	
BRAF	CEBPA	ESR1	FGF14	IDH2	MPL	NPM1	RAD51	TERT	
BRCA1	CHEK1	EZH2	FGF23	INPP4B	MRE11A	NRAS	RAD51B	TET2	
BRCA2	CHEK2	FAM175A	FGFR1	JAK2	MSH2	NRG1	RAD51C	TP53	
Amplifications (from DNA) * RUO Assay Only									
AKT2	BRCA2	CHEK1	ERCC2	FGF5	FGF14	FGFR4	MDM4	NRG1	RAF1
ALK	CCND1	CHEK2	ESR1	FGF6	FGF19	JAK2	MET	PDGFRA	RET
AR	CCND3	EGFR	FGF1	FGF7	FGF23	KIT	MYC	PDGFRB	RICTOR
ATM	CCNE1	EDBB2	FGF2	FGF8	FGFR1	KRAS	MYCL1	PIK3CA	RPS6KB1
BRAF	CDK4	ERBB3	FGF3	FGF9	FGFR2	LAMP1	MYCN	PIK3CB	TFRC
BRCA1	CDK6	ERCC1	FGF4	FGF10	FGFR3	MDM2	NRAS	PTEN	
Fusions and Splice Variants (from RNA) * Splice Variants - RUO Assay Only									
ABL1	BRAF	EML4	ETV4	FGFR4	KIF5B	MYC	NTRK2	PIK3CA	TMPRSS2
AKT3	BRCA1	ERBB2	ETV5	FLI1	KIT	NOTCH1	NTRK3	PPARG	
ALK	BRCA2	ERG	EWSR1	FLT1	KMT2A(MLL)	NOTCH2	PAX3	RAF1	
AR	CDK4	ESR1	FGFR1	FLT3	MET	NOTCH3	PAX7	RET	
AXL	CSF1R	ETS1	FGFR2	JAK2	MLLT3	NRG1	PDGFRA	ROS1	
BCL2	EGFR	ETV1	FGFR3	KDR	MSH2	NTRK1	PDGFRB	RPS6KB1	

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