ALMAC

Partnering to Advance Human Health

Almac Diagnostic Services

Clinical Trial Assay

TP53 Assay

A Next Generation Sequencing (NGS) assay that targets *TP53* variants within genomic DNA derived from solid tumour, lymph node & bone marrow Formalin Fixed Paraffin Embedded (FFPE) samples.

Assay	
Assay intended use	For prospective use in clinical trials
Quality & regulatory	CLIA Compliant and CE Marked
Technology & platform	NGS Technology - Illumina MiSeq
Assay type	Central laboratory based test
Disease indication	
Disease indication	Solid tumour, lymph node & bone marrow
Gene targets	*TP53*
Variants	Single nucleotide variant (SNV), small insertion and deletion events
Sample requirements	
Tissue type	Formalin Fixed Paraffin Embedded (FFPE) tissue
Recommended tissue requirements	Recommended 1mm^3 of tissue
Minimum viable tumour cells	10%
Input material	DNA
Recommended input requirements	DNA input is determined through assessment of amplifiability assessment and comparison to a high quality DNA control. A delta Cq value of ≤4 must be achieved to proceed
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	7 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	Almac software for run QC Bespoke data filtering and reporting software as per project basis
Added value	
Added value to client	Almac Diagnostics experience in prospective clinical trials under a CLIA compliant testing environment. Clear locked results and RUO data provision for other use

Key benefits:

- Full coding sequence coverage of Isoform A (NM_000546.5; CCDS11118.1)
- Detection of SNVs, small insertion and deletion events
- Dual amplicon workflow and individual base coverage QC ensure *high-confidence Mutation Detected and Mutation Not Detected calls from FFPE samples*
- Optimised for FFPE tissue
- Rapid turnaround time
- Access to raw data
- Powerful reporting and interpretation services

Find out more:

Visit our website almacgroup.com/diagnostics