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 Formalin-Fixed Paraffin-Embedded (FFPE) solid tumour and lymph node samples from patients with pan-cancer diseases, and fresh-frozen (FF), bone marrow aspirate (BMA) and peripheral blood (PB) samples from patients with haematological malignancies.

Assay	
Assay intended use	For prospective use in clinical trials
Quality & regulatory	CLIA and CLEP compliant
Technology & platform	NGS Technology - Illumina MiSeq
Assay type	Central laboratory-based test
Disease indication	
Disease indication	Pan-cancer and haematological disorders
Gene targets	*TP53*
Variants	Single nucleotide variant (SNVs), small indels
Sample requirements	
Tissue/Sample type	Formalin-Fixed Paraffin-Embedded (FFPE) solid tumour and lymph node. Fresh-frozen (FF) bone marrow aspirate (BMA) and peripheral blood (PB).
Recommended tissue requirements	Recommended 1mm^3 of tissue
Recommended BMA/PB requirements	A minimum of 400 µL collected in K2 EDTA tube
Minimum viable tumour cells	10%
Input material	DNA
Recommended input requirements	FFPE tissue: 250 ng* BMA/PB: 100 ng *Validated input for Mutation Not Detected reporting, however Mutation Detection reporting could be achieved with as low as 40 ng DNA input.
Detection rate	
Performance	High levels of accuracy, sensitivity and precision, suitable for clinical trial use. (See assay validation performance specification for detailed information).
Turnaround time	
TAT	10 days from sample receipt 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 per client request.
Bioinformatics applications	Almac bioinformatics analysis pipeline and integrated quality control (QC) software. Bespoke data filtering and reporting software per client request.
Added value	
Added value to client	Almac Diagnostic Service's experience in interventional clinical trials under a CLIA compliant testing environment. Clear locked results and RUO data provision for other use.

Key benefits:

- Analytically validated clinical trial assay (CTA) for prospective testing of FFPE tissue and FF BMA/PB samples
- Full coding coverage of all *TP53* isoforms
- Detection of single nucleotide variants and small indels
- Watson & Crick DNA strand coverage and incorporation of unique molecular identifiers (UMIs) and stringent coverage QC resulting in high-confidence *Mutation Detected & Mutation Not Detected* status
- Rapid turnaround time
- Access to raw data
- Comprehensive reporting and interpretation services

Find out more:

Visit our website almacgroup.com/diagnostics