

Oncomine Precision Assay on the Genexus System

Leading-Edge Pan-Cancer NGS Testing

Genomic profiling of a tumor to characterize clinically relevant variants has become critically important for cancer diagnosis and prognosis, as well as in driving therapeutic decision making. There is a growing need for rapid assessment of somatic variants in genes of key interest in oncology. The Oncomine™ Precision Assay on the Ion Torrent™ Genexus™ Sequencer (OPAGX) is an amplicon-based automated next generation sequencing (NGS) assay that enables quick turnaround genomic profiling of biomarkers across 50 genes from solid tumor and liquid biopsy samples.



FOCUSED MULTI-GENE PANEL

The Oncomine[™] Precision Assay panel contains 50 genes and 2,769 unique variants, applicable to a wide range of tumor types for detection of SNV, Insertion-Deletion, Copy Number Alterations, and Fusions. FusionSync[™] technology enables detection of novel fusions.

FFPE AND PLASMA

Minimal input of 10 ng required for FFPE and 20 ng for cfTNA*

ION AMPLISEQ™ HD

Amplicon-based library preparation utilizing unique molecular tags allows for high sensitivity while requiring minimal sample input.

GENEXUS NGS SYSTEM

The Genexus System is a seamless NGS solution requiring minimal user touchpoints, resulting in consistent performance and straightforward implementation to scale quickly across our global sites.

DNA HOTSPOTS					CNV		INTER-GENETIC FUSIONS**		INTRA-GENETIC FUSIONS
AKT1	CHEK2	FGFR3	KIT	NTRK3	ALK	FGFR1	ALK	NTRK1	AR
AKT2	CTNNB1	FGFR4	KRAS	PDGFRA	AR	FGFR2	BRAF	NTRK2	EGFR
AKT3	EGFR	FLT3	MAP2K1	PIK3CA	CD274	FGFR3	ESR1	NTRK3	MET
ALK	ERBB2	GNA11	MAP2K2	PTEN	CDKN2A	KRAS	FGFR1	NUTM1	
AR	ERBB3	GNAQ	MET	RAF1	EGFR	MET	FGFR2	RET	
ARAF	ERBB4	GNAS	MTOR	RET	ERBB2	PIK3CA	FGFR3	ROS1	
BRAF	ESR1	HRAS	NRAS	ROS1	ERBB3	PTEN	MET	RSPO2	
CDK4	FGFR1	IDH1	NTRK1	SMO			NRG1	RSPO3	
CDKN2A	FGFR2	IDH2	NTRK2	TP53					

^{*}Oncomine Precision Assay detects fusions in cell-free RNA

^{**} Novel fusions detected for select gene targets through FusionSync Ion Torrent, Oncomine, FusionSync and AmpliSeq are trademarks of Thermo Fisher Scientific.

Sample input requirements

NUCLEIC ACID	DNA/RNA • FFPE: 35 ng at concentration of >1 ng/ μ L in a volume of 35 μ L • cfDNA: \geq 30 ng in 20 μ L volume
FFPE	 Cumulative tissue area of ≥ 200 mm² using 5 μm sections (or ≥ 100 mm² using 10 μm sections). Tumor cell content recommendation is ≥ 30% with a minimum of 20% 4-16 5 μm sections or 2-8 10 μm sections (< 80 μm total thickness per sample)
PLASMA	5 mL (a minimum of \geq 2 mL) of double spun plasma collected from either EDTA (processed within 4 hours of collection) or Streck cfDNA Blood Collection Tubes (BCT)
WHOLE BLOOD	10 mL whole blood samples collected in Streck cfDNA BCT

IQVIA Laboratories global testing footprint



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