Stratech

AmoyDx

AmoyDx® HANDLE Classic NGS Panel

High Satisfaction NGS Solution for Clinical Oncology

AmoyDx® HANDLE Classic NGS Panel is a next-generation sequencing (NGS) based in vitro diagnostic assay intended for qualitative detection of single nucleotide variants (SNVs), insertions and deletions (InDels), gene fusions, copy number amplifications(CNAs) and microsatellite instability (MSI) in 40 key solid tumor genes, using DNA and RNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The assay is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms.

Benefits and Advantages

Featuring the most prevalent and potentially actionable driver variants

- Analyze 40 key solid tumor genes in one tube
- Pan-cancer: lung cancer, colorectal cancer, breast cancer, gastric cancer, thyroid cancer, urothelial cancer, etc.
- Therapy indications for more than 70 related drugs

All in one

Low input, high accuracy

- LoD: SNV/InDel (AF≥1%), Fusion (100 copies), CNA (4 copy number)
- MSI: High concordance with Sanger method
- Less sample: Minimum 50ng DNA input

Simple workflow

- DNA&RNA co-detection in one workflow
- one-tube, one PCR step, one purification step
- 6 hours TAT for library preparation, including 1 hour hands-on time
- Automatic data analysis (ANDAS analyzer)

Detect SNV, InDel, Fusion, CNA and MSI Simultaneously

AKT1	△	FGFR1	△#	MAP2K1	△	PDGFRA	△
ALK	△#	FGFR2	△#	MET	△#&	PIK3CA	△
BRAF	△	FGFR3	△#	MYC	&	POLE	△
CDK4	&	FGFR4	△	NFE2L2	△	PTEN	△
CTNNB1	△	HRAS	△	NKX2-1	&	RB1	△
DDR2	△	IDH1	△	NRAS	△	RET	△#
DPYD	△	IDH2	△	NRG1	#	ROS1	△#
EGFR	△	KEAP1	△	NTRK1	△#	STK11	△
ERBB2	△&	KIT	△	NTRK2	△#	TP53	△
ESR1	△	KRAS	△	NTRK3	△#	UGT1A1	△

△ SNV/InDel # Fusion & CNA

Performance

Parameter	Specifications
Technology	HANDLE
Target Regions	40 genes and MSI
Alterations Detected	SNV, InDel, Fusion, CNA, MSI
Panel Size	43kb
Depth	EffectiveDepth ⩾400X
Sample Type	FFPE tumor tissue
NA Requirement	DNA: minimum 50 ng (Optimal 70 ng) RNA: minimum 30 ng (Optimal 400 ng)
Limit of Detection (LoD)	1% allele frequency; 5% allele frequency in non-core regions; minimum 20% tumor content
Data Output per Sample	MiSeq/MiniSeq: 375 Mb/sample NextSeq: 1 Gb/sample
Sequencer	Illumina MiSeqDx, NextSeq 550Dx
TAT for Library Preparation	5 h (hands-on time 1 h)
TAT from Sample to Report	3 days

Order Information

Product	Tests/kit	Cat. No.
AmoyDx® HANDLE Classic NGS Panel	24	8.06.0020
AmoyDx® HANDLE Classic NGS Panel	24	8.06.0027 (RUO)