AVENIO ctDNA Targeted Kit

Tumor Profiling: Guideline-driven biomarkers

The AVENIO ctDNA Targeted Kit is a next-generation sequencing (NGS) liquid biopsy tumor profiling assay for identifying genomic aberrations in solid tumors. This panel contains **17 genes, including those in the U.S. National Comprehensive Cancer Network (NCCN) Guidelines.**[1]

Benefits

- Confidently report **all four mutation classes**—SNVs, indels, fusions, and CNVs—from just 10 – 50 ng of cfDNA.
- Delivers exceptional analytical performance supported by **integrated digital error suppression (iDES) strategies**, combining **molecular barcodes** with *in silico* error suppression techniques.[2,3]
- Analyze plasma containing DNA from a variety of solid tumor types using a **single workflow** optimized for running up to 16 samples at a time.
- Rely on a single trusted supplier for **complete support** of your isolations, library prep, target enrichment panels, and post-hybridization reagents.
- Receive an **inclusive solution** with the required reagents, a robust bioinformatics pipeline, and software for analysis and reporting to keep your lab at the forefront of cancer research.[†]

Research focus

Lung, Colorectal, Breast, Gastric, Glioma, Melanoma, Ovarian, Thyroid, and Pancreatic

Applications

- Non-invasive tumor profiling
- Non-invasive detection of resistance biomarkers

Performance metrics[3]

Mutation Class	SNVs		Indels		Fusions		CNVs	
Mutant Allele Frequency/ Copy Number	0.5%*		1.0%*		1.0%		At LOD**	
Sensitivity and PPV	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV
	>99%	>99%	>99%	>99%	>99%	>99%	>99%	>99%

* Detects variants down to 0.1%
** Samples tested at limit of detection (LOD): MET 2.3 copies in cfDNA; EGFR 3.2 copies in cfDNA; ERBB2 4.5 copies in cfDNA.

Performance samples - cell line mixes, cfDNA 10 ng – 50 ng input

Sensitivity and Positive Predictive Value (PPV) metrics based on typical product performance. Sensitivity and PPV performance reported per variant. SNV performance data based on hotspot calls; CNV performance based on ERBB2, EGFR, and MET genes. Results above were tested at the stated mutant allele frequencies. The AVENIO ctDNA Analysis Kits also achieve >99.99% per base specificity across each of the panels. Stated performance requires at least 40 million reads per sample for Targeted Kit and 60 million reads per sample for Expanded and Surveillance Kits. Sequencing performed on an Illumina® NextSeq® 500 instrument.

Specifications

Panel size	81 kb
Sample size	4 mL of plasma
cfDNA input	10 – 50 ng

Reactions per kit	16
Turnaround time	5 days from extraction to results

Assay targets

Gene	Seq Target	SNV	Indel*	Fusion**	CNV**
ALK	Selected Regions	▪	▪	▪	
APC	Selected Regions	▪	▪		
BRAF	Selected Regions	▪	▪		
BRCA1	All Coding Regions	▪			
BRCA2	All Coding Regions	▪			
DPYD	Selected Regions	▪			
EGFR	All Coding Regions	▪	▪		▪
ERBB2	All Coding Regions	▪	▪		▪
KIT	Selected Regions	▪	▪		

Gene	Seq Target	SNV	Indel*	Fusion**	CNV**
KRAS	All Coding Regions	▪			
MET	All Coding Regions	▪	▪		▪
NRAS	Selected Regions	▪			
PDGFRA	Selected Regions	▪			
RET	Selected Regions	▪		▪	
ROS1	Selected Regions	▪		▪	
TP53	All Coding Regions	▪			
UGT1A1***	Selected Regions	▪			

All coding regions are based on the longest transcript from Ensembl build 82.

* Indels are limited to variants in a pre-specified list of positions, referred to as "Loci of Interest", except for EGFR exon 19 long deletions, EGFR exon 20 long insertions, and MET long insertions, which are not restricted to a pre-defined set of Indels.

** Detection of Fusions and CNVs are limited to variants in a pre-specified list of positions, referred to as "Loci of Interest" in the AVENIO analysis software.

*** UGT1A1*28 allele sequenced but not currently called by the AVENIO analysis software.

AVENIO family of NGS oncology assays

AVENIO ctDNA Targeted Kit is a part of the AVENIO family of NGS oncology assays that include three ctDNA assays and three corresponding tumor tissue assays. By using the wider family of AVENIO assays, labs can obtain detailed molecular findings across all four mutation classes from both plasma and tissue samples.

1. National Comprehensive Cancer Network. http://www.nccn.org. October 15, 2016.
2. Newman AM, Lovejoy AF, Klass DM, et al. Integrated digital error suppression for improved detection of circulating tumor DNA. *Nature Biotechnology*. 2016;34(5):547–555. doi:10.1038/nbt.3520.
3. Data on file.

†**Required hardware:** Illumina NextSeq 500/550 sequencer and Roche Oncology Analysis Server. NextSeq 500/550 instruments and associated sequencing reagents are manufactured and sold by Illumina and are not supplied by Roche.

For more information about the AVENIO ctDNA Analysis Kits, please contact your Roche Sequencing representative.

Published by:

Roche Sequencing and Life Science
9115 Hague Road
Indianapolis, IN 46256

go.roche.com/assays

MC-US-02757 SS801001 A427 12/18