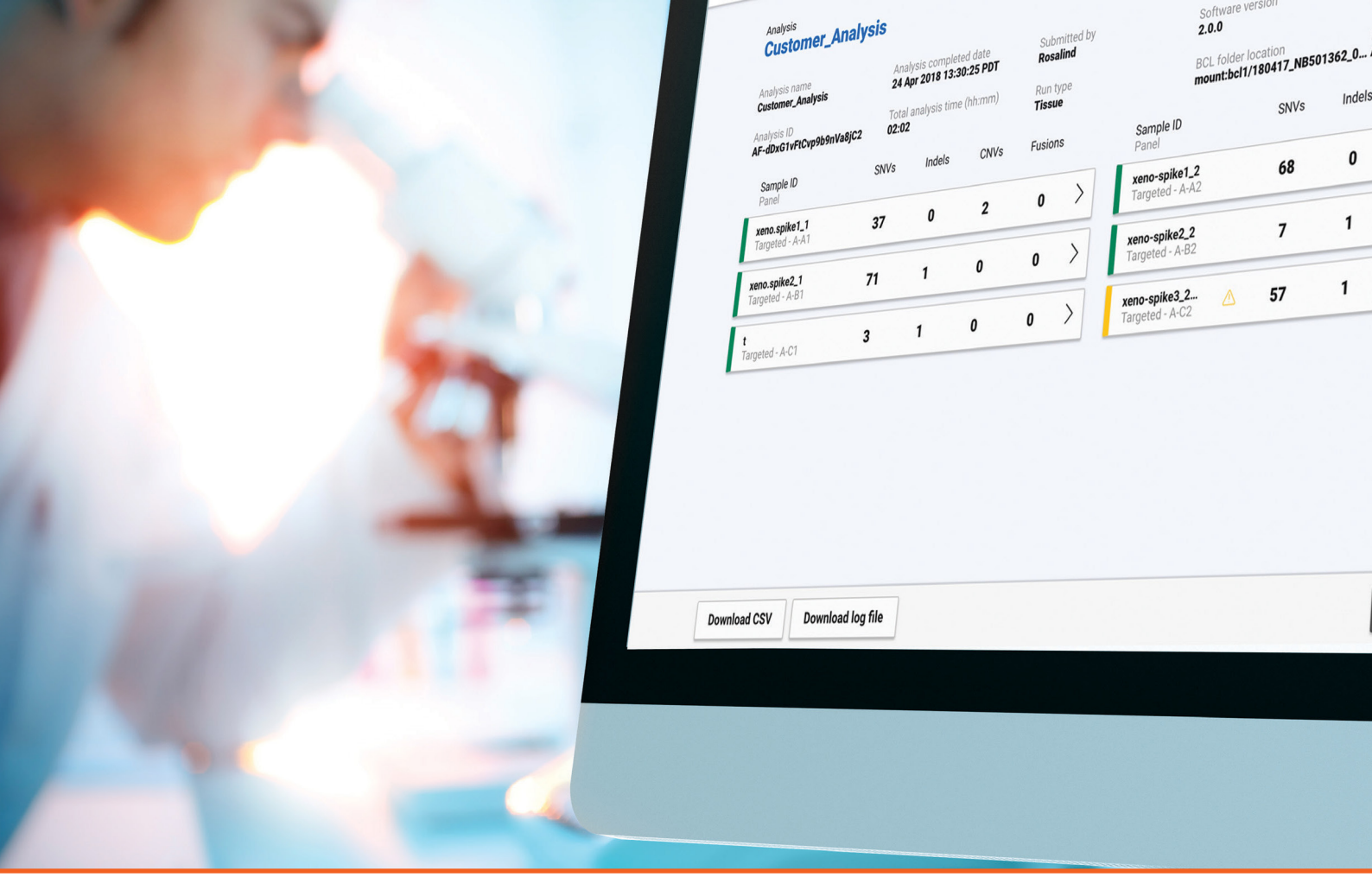
AVENIO Oncology Analysis Software

Exceptional performance, minimal effort

For Research Use Only. Not for use in diagnostic procedures.



AVENIO Oncology Analysis Software

The **AVENIO Oncology Analysis Software** processes sequencing data from plasma and tissue samples run using the AVENIO ctDNA Analysis Kits V2 and AVENIO Tumor Tissue Analysis Kits V2.

The interface guides users confidently through the post-sequencing workflow. Intelligent bioinformatics with advanced proprietary algorithms and error suppression strategies deliver comprehensive results with proven accuracy and reproducibility.[1,2]

Powerful and intuitive, the AVENIO Oncology Analysis Software offers simplicity, efficiency, and accuracy.

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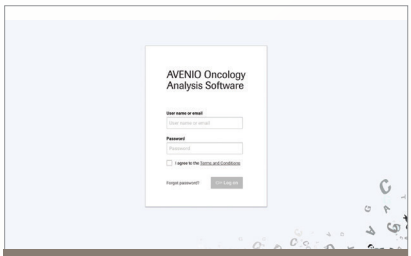
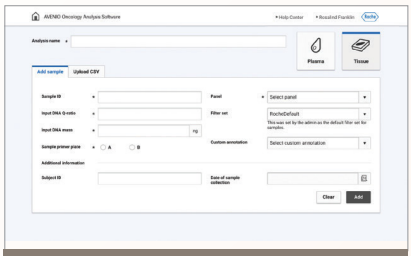
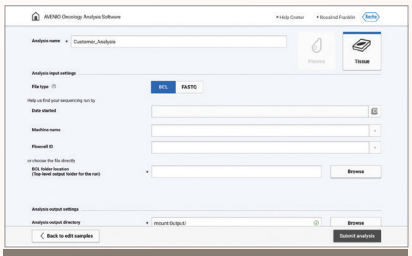


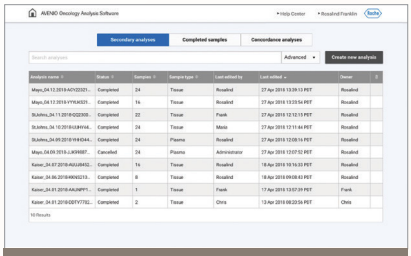
Log-in



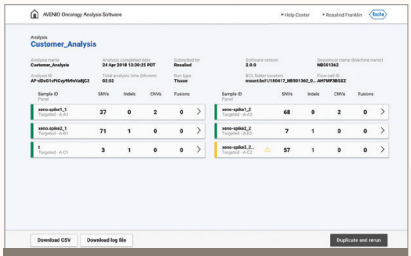
Select plasma or tissue



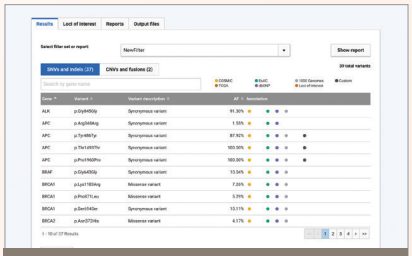
Run settings



Analysis



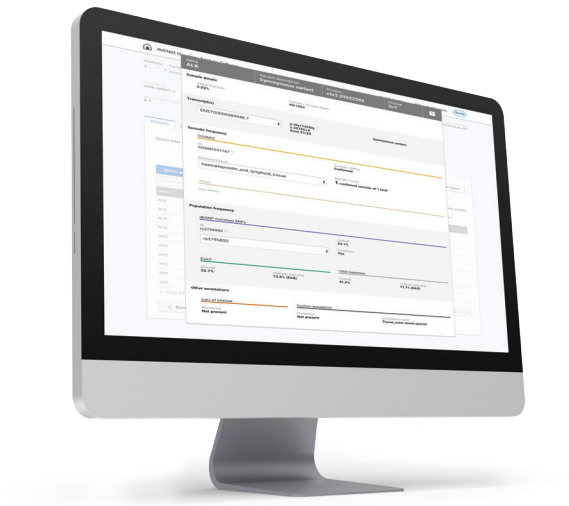
Results



Reporting

Set up and run the analysis with ease

The AVENIO Oncology Analysis Software requires minimal expertise to set up and run an analysis. This allows laboratory and bioinformatics professionals to focus more of their time on the findings and insights, and less on managing information systems.



Intuitive user interface:

- Select plasma or tissue
- Offers two user types (Admin, Lab User)
- Provides real-time tracking of analysis status
- Enables filtering, custom annotation, and analytical concordance reporting between tissue and plasma
- Provides reports in PDF format, as well as variant results in VCF and BAM file formats.

With its ability to process approximately 800 million reads in less than a day, the AVENIO Oncology Analysis Software can be set up to run in the evening, delivering results ready for review in the morning.

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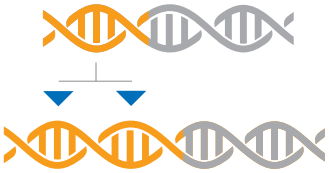
SNV
Single
Nucleotide
Variant

Indel
Insertion
or Deletion

Fusion



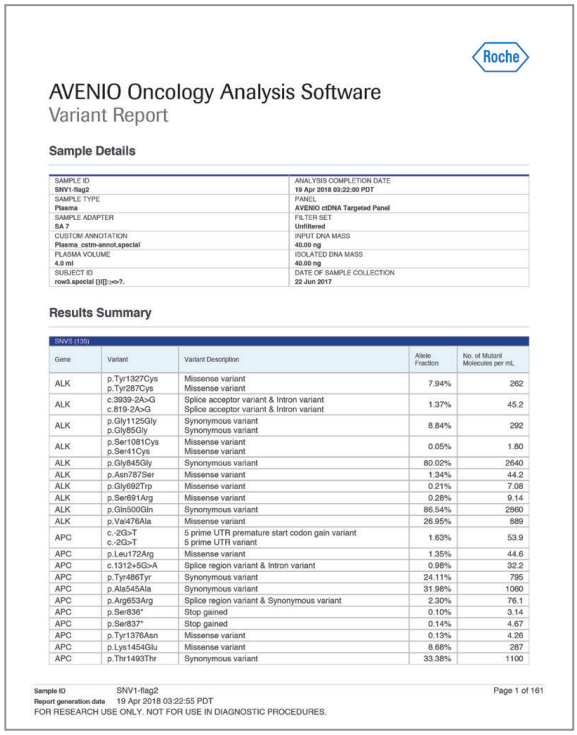
CNV
Copy Number
Variant

Detect all four mutation classes in a single DNA workflow

The software's bioinformatic algorithms and checkpoints have been optimized to enable accurate variant calls across all four mutation classes.[1]

Detect low frequency alleles with exceptional sensitivity and specificity

The AVENIO Oncology Analysis Software employs integrated digital error suppression (iDES) strategies in the ctDNA workflow, combining molecular barcodes with in silico error suppression techniques. This proprietary method enables detection of low frequency alleles down to 0.1% with exceptional sensitivity and specificity.[1,2] The tumor tissue workflow employs enzymatic error suppression and molecular barcodes for accurate detection of all four mutation classes from DNA only.



Roche

AVENIO Oncology Analysis Software
Variant Report

Sample Details

SAMPLE ID **SNV1-flag2**	ANALYSIS COMPLETION DATE **19 Apr 2018 03:22:00 PDT**
SAMPLE TYPE **Plasma**	PANEL **AVENIO ctDNA Targeted Panel**
SAMPLE ADAPTER **SA 7**	FILTER SET **Unfiltered**
CUSTOM ANNOTATION **Plasma_cstm-annot.special**	INPUT DNA MASS **40.00 ng**
PLASMA VOLUME **4.0 ml**	ISOLATED DNA MASS **40.00 ng**
SUBJECT ID **row5.special [i][]:=>7.**	DATE OF SAMPLE COLLECTION **22 Jun 2017**

Results Summary

SNV5 (135)

Gene	Variant	Variant Description	Allele Fraction	No. of Mutant Molecules per mL
ALK	p.Tyr1327Cys p.Tyr287Cys	Missense variant Missense variant	7.94%	262
ALK	c.3939-2A>G c.819-2A>G	Splice acceptor variant & Intron variant Splice acceptor variant & Intron variant	1.37%	45.2
ALK	p.Gly1125Gly p.Gly855Gly	Synonymous variant Synonymous variant	8.84%	292
ALK	p.Ser1081Cys p.Ser41Cys	Missense variant Missense variant	0.05%	1.80
ALK	p.Gly845Gly	Synonymous variant	80.02%	2640
ALK	p.Asn787Ser	Missense variant	1.34%	44.2
ALK	p.Gly592Trp	Missense variant	0.21%	7.08
ALK	p.Ser691Arg	Missense variant	0.28%	9.14
ALK	p.Gln500Gln	Synonymous variant	86.54%	2860
ALK	p.Val476Ala	Missense variant	26.95%	889
APC	c.-2G>T c.-2G>T	5 prime UTR premature start codon gain variant 5 prime UTR variant	1.63%	53.9
APC	p.Leu172Arg	Missense variant	1.35%	44.6
APC	c.1312+5G>A	Splice region variant & Intron variant	0.98%	32.2
APC	p.Tyr486Tyr	Synonymous variant	24.11%	795
APC	p.Ala545Ala	Synonymous variant	31.98%	1060
APC	p.Arg653Arg	Splice region variant & Synonymous variant	2.30%	76.1
APC	p.Ser836*	Stop gained	0.10%	3.14
APC	p.Ser837*	Stop gained	0.14%	4.67
APC	p.Tyr1376Asn	Missense variant	0.13%	4.26
APC	p.Lys1454Glu	Missense variant	8.68%	287
APC	p.Thr1493Thr	Synonymous variant	33.38%	1100

Sample ID SNV1-flag2 Page 1 of 161
Report generation date 19 Apr 2018 03:22:55 PDT
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Performance metrics[1]

AVENIO ctDNA Analysis Kits

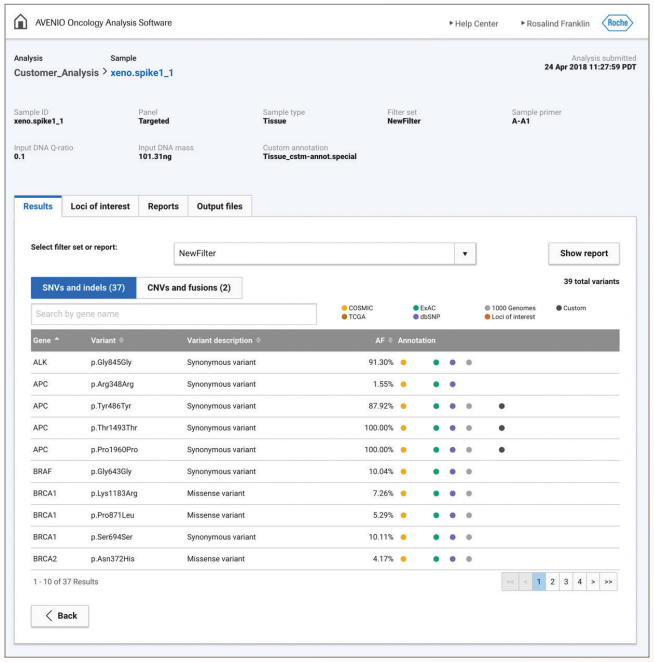
Mutant Allele Frequency/ Copy Number	SNVs		Indels		Fusions		CNVs**
	0.5%*		1.0%*		1.0%		Sample Dependent
AVENIO Tissue Kit	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV	
Targeted	> 99%	> 99%	> 99%	> 99%	> 99%	> 99%	
Expanded	> 99%	> 98%	> 99%	> 99%	> 99%	> 99%	
Surveillance	> 99%	> 99%	> 99%	> 99%	> 99%	> 99%	

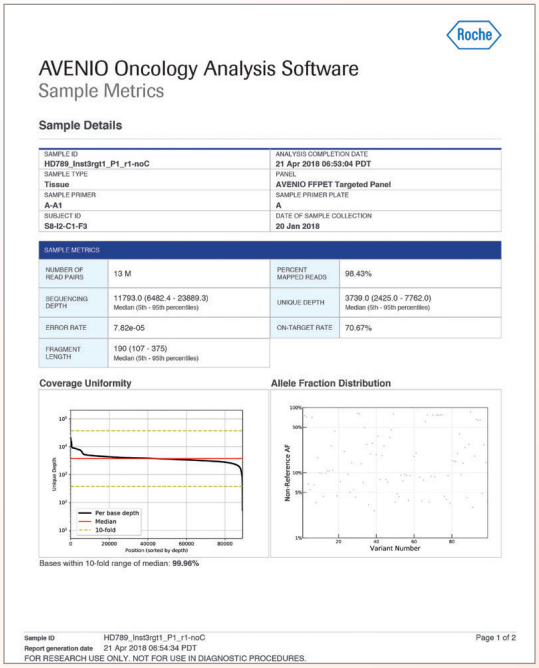
*The reported sensitivity and PPV is for 50ng DNA input at the stated AF%. The kit has the ability to report variants down to 0.1% AF (with lower sensitivity), and can make libraries with as low as 10 ng.
**The kit reports ERBB2, EGFR, and MET CNVs. Performance is dependent on various factors, including sample type, input DNA amount, percent tumor content, and the individual tumor's genomic copy number. Shown are examples of detected CNVs at ddPCR verified copy numbers, using a commercially available reference sample (50 ng). CNV specificity was high (PPV >99%). ERBB2 detected at 2.2 copies, MET detected at 2.6 copies.
Performance samples: Seraseq ctDNA Complete Mutation Mixes (SeraCare), healthy donor cfDNA.Sensitivity and Positive Predictive Value (PPV) metrics based on observed product performance. Sensitivity and PPV performance reported per variant. Sensitivity was determined using commercially available reference samples containing verified mutations at the stated allele frequencies. SNV performance data based on hotspot calls. The AVENIO ctDNA Analysis Kit V2 can achieve >99.99% per base specificity across each of the panels. Stated performance requires at least 40 million reads per sample for all AVENIO ctDNA Panels V2.
Sequencing performed on an Illumina NextSeq 500/550/550Dx (Research Use Only mode) instrument

AVENIO Tumor Tissue Analysis Kits

Mutant Allele Frequency/ Copy Number	SNVs		Indels		Fusions		CNVs
	5.0% *		5.0%		5.0%		Sample Dependent
AVENIO ctDNA Kit	Sensitivity	PPV	Sensitivity	PPV	Sensitivity	PPV	
Targeted	> 99%	> 99%	> 99%	> 99%	> 99%	> 99%	
Expanded	> 99%	> 98%	> 99%	> 99%	> 99%	> 99%	
Surveillance	> 99%	> 99%	> 99%	> 99%	> 99%	> 99%	

Samples: FFPE tissue curls/sections, DNA input: ≥20 ng of FFPET DNA, total DNA amount for each sample determined by input QC.
Sensitivity and Positive Predictive Value (PPV) metrics based on observed product performance. Sensitivity and PPV performance reported per variant. Sensitivity was determined using commercially available reference samples containing verified mutations at the stated allele frequencies. SNV performance is panel wide. Indel, Fusion based on whitelist variants. AVENIO Tumor Tissue Analysis Kits V2 achieve >99.99% per base specificity across each of the panels. Stated performance requires at least 20 million reads per sample for Targeted, Expanded and Surveillance Kits V2. Sequencing performed on an Illumina NextSeq 500/550/550Dx (Research Use Only mode) instrument. ERBB2 detected at 4.5 copies, MET detected at 4.5 copies.





Call mutations with confidence

Five leading oncology databases, a curated loci of interest list and a customizable annotation database are integrated into the AVENIO Oncology Analysis Software. This allows quick and easy access to trusted public resources for cross-referencing and verification of results:

- COSMIC
- TCGA
- ExAC
- dbSNP
- 1000 Genomes

These annotation databases can help users call mutations with increased confidence.

Control quality across the workflow

The AVENIO Oncology Analysis Software provides a sequencing quality report with key metrics such as sequencing depth, number of reads, on-target rate, coverage uniformity, and error rate to confirm quality at different stages in the workflow.

Published by:

Roche Sequencing Solutions, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588

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1. Data on file with Roche.
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.

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