NeXT Dx™ Test

Personalis NeXT Dx™ Test

Increasingly, oncologists and pathologists are utilizing information on genomic alterations in solid tumors, such as lung, colon, breast, melanoma, and prostate cancers, to help guide and optimize therapeutic options for patients including enrolling into cancer clinical trials. The Personalis NeXT Dx™ Test provides clinicians with a comprehensive and accurate next generation sequencing-based testing solution for solid tumors. This test is not validated for hematolymphoid malignancies.

Clinical Reports

The Personalis NeXT Dx Test is a comprehensive genomic testing solution that provides clinicians with a clinical report on the genetic alterations found in 247 cancer-related genes. The analysis includes single nucleotide variants, small insertions and deletions, copy number alterations, and gene fusions along with other relevant biomarkers such as exome-wide tumor mutational burden (TMB) and microsatellite instability (MSI) status. Based on the tumor's molecular profile, the report delivers relevant therapy recommendations and clinical trial matches. We use our leading Personalis® NeXT Platform™ to provide high accuracy, clinical grade next generation sequencing and analysis. Each case is reviewed by a team of board-certified molecular geneticists and genetic counselors. Test results are provided to clinicians by fax or electronic format.

Higher Levels of Gene Finishing

The NeXT Dx Technology provides additional targeted sequencing to fill in the gaps and address problematic regions not adequately addressed by standard panels.

Accurate Identification of SNVs, Indels, CNAs and Fusions

Personalis delivers high accuracy variant calls through advanced sequencing alignment tools, sophisticated algorithms, and correction for systematic biases inherent in sequencing technologies.

Comprehensive Analysis

Variant interpretation is based on a comprehensive assessment that takes into account information from multiple sources. Each variant is reviewed in detail by Personalis' clinical team, and assessed for clinical relevance in relation to the latest evidence-based therapy recommendations and available clinical trials.

Intuitive and Actionable Reports

Reports are easy to read and results are presented in a clear and intuitive manner so that healthcare providers can easily understand and quickly incorporate the results into clinical care. The report lists approved drugs and clinical trials within the US.

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What Makes Our Test Unique

The Personalis NeXT Dx Test goes beyond typical cancer genomics tests in a few key areas:

- Proprietary methods for improving sequencing coverage in traditionally difficult to sequence regions typically missed or excluded from other cancer panel tests.
- Analysis of DNA and RNA from the same sample to enable robust identification of gene fusions over a broad number of genes.
- Integration of multiple immunotherapy markers such as MSI and exome-wide TMB in a single test.
- Determination of exome-wide TMB by measuring the number of non-synonymous, somatic coding mutations.
- Mutations in 29 homologous recombination (HR) related genes (*ARID1A, ATM, ATR, ATRX, BAP1, BRCA1, BRCA2, BRIP1, CHEK1, CHEK2, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, FANCM, MRE11A, PALB2, RAD50, RAD51, RAD51B, RAD51C, RAD51D, SLX4, STK11*) are highlighted in the clinical report.

Test Performance Specifications

Sensitivity	
Single Nucleotide Variants (at mutant allele frequency ≥5%)	99.5%
Small Insertions and Deletions (at mutant allele frequency ≥10%)	98.7%
Copy Number Alterations (at ≥30% tumor content)	97.2%
Gene Fusions	94.9%
Positive Predictive Value*	
Single Nucleotide Variants (at mutant allele frequency ≥5%)	99.8%
Small Insertions and Deletions (at mutant allele frequency ≥10%)	97.4%
Copy Number Alterations (at ≥30% tumor content)	94.6%
Gene Fusions	94.9%
Additional Assay Specifications	
Microsatellite Instability (MSI)**	97.9% concordance rate
Tumor Mutation Burden (TMB)+	Whole exome
Typical Median Depth	>1000x
Sample Types++	FFPE or fresh frozen tumor samples ≥20% tumor purity
Regions Analyzed	Coding and relevant non-coding regions of 247 genes
Type of Sequencing	DNA and RNA using Illumina next generation sequencing
Turn Around Time	2–3 weeks from sample receipt
Test Requisition Form Required	Yes

*Positive predictive value is calculated by comparing variants detected by the NeXT Dx Test to those detected by a validated next generation sequencing-based test.

**MSI status is determined by measuring nucleotide repeats at the five canonical loci (BAT25, BAT26, NR-21, NR-24, and NR-27).

+TMB is reported as the number of mutations per megabase (muts/Mb). Please note that there is currently no standard cut-off to define a high TMB for different tumor types.

++Unacceptable specimens include hematolymphoid malignancies and decalcified bone. Additionally, specimens collected in New York State are not acceptable at this time.

NeXT Dx Gene List

Single nucleotide variants, small insertions and deletions, copy number alterations, and gene fusions involving the genes below may be reported in the test.

ABL1	CD40	ETV6	HSP90AA1	MSLN	PTCH1	STAT3
AKAP9	CDH1	EWSR1	IDH1	MTOR	PTEN	STAT5B
AKT1	CDH3	EZH2	IDH2	MUTYH	PTK2	STK11
AKT2	CDK4	FANCA	IGF1R	MYC	PTPN11	SULT1A1
AKT3	CDK6	FANCB	IKZF1	MYCN	PVRL4	SYK
ALK	CDK9	FANCC	IL2RA	MYD88	RAD21	TERT
APC	CDKN1A	FANCD2	JAK1	MYH11	RAD50	TET2
AR	CDKN1B	FANCE	JAK2	NF1	RAD51	TGFBR1
ARAF	CDKN2A	FANCF	JAK3	NF2	RAD51B	TGFBR2
AREG	CDKN2B	FANCG	KDM6A	NFE2L2	RAD51C	TMPRSS2
ARID1A	CEBPA	FANCI	KDR	NKX2-1	RAD51D	TNFRSF4
ASXL1	CHEK1	FANCL	KIT	NOTCH1	RAF1	TNFRSF8
ATM	CHEK2	FANCM	KLB	NOTCH2	RARA	TP53
ATR	CREBBP	FBXW7	KMT2A	NPM1	RB1	TSC1
ATRX	CRKL	FCER2	KRAS	NRAS	RBM15	TSC2
AURKA	CRLF2	FGF19	LAG3	NTRK1	RET	U2AF1
AXL	CRTC1	FGF2	MAGEA3	NTRK2	RICTOR	VEGFA
BAP1	CSF1R	FGFR1	MAGEA4	NTRK3	ROS1	VEGFB
BCL2	CSF3R	FGFR2	MAP2K1	NUP214	RPN1	VHL
BCL6	CTAG2	FGFR3	MAP2K2	PALB2	RUNX1	WEE1
BCOR	CTLA4	FGFR4	MAP2K4	PARP1	RUNX1T1	WT1
BCORL1	CTNNB1	FH	MAP3K1	PDCD1	SDHB	XPO1
BCR	CUX1	FLCN	MAPK1	PDCD1LG2	SDHC	XRCC1
BRAF	DDR2	FLT1	MCL1	PDGFRA	SDHD	YES1
BRCA1	DEK	FLT3	MDM2	PDGFRB	SETBP1	ZRSR2
BRCA2	DKK1	FLT4	MDM4	PGR	SF3B1	
BRIP1	DLL3	FOLR1	MECOM	PIK3CA	SHH	
BTK	DNMT3A	FOXL2	MEN1	PIK3CB	SLX4	
CALR	EGFR	FYN	MET	PIK3CD	SMAD4	
CBFB	EML4	GATA1	MKL1	PIK3CG	SMARCA4	
CBL	EP300	GATA2	MLH1	PIK3R1	SMARCB1	
CCND1	EPCAM	GNA11	MLLT3	PML	SMC1A	
CCND2	ERBB2	GNAQ	MPL	PMS2	SMC3	
CCND3	ERBB3	GNAS	MRE11A	POLE	SMO	
CCNE1	ERBB4	GPNMB	MS4A1	PRAME	SRC	
CD274	ESR1	HNF1A	MSH2	PRKACA	SRSF2	
CD276	ESR2	HRAS	MSH6	PSCA	STAG2	

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Personalis NeXT Dx Test: This laboratory developed test (LDT) will be performed in a CLIA/CAP accredited laboratory. The test was developed and its performance characteristics determined by the Personalis Clinical Laboratory. It has not been cleared or approved by the United States Food and Drug Administration (FDA). The Personalis Clinical Laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing.

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