Provider's FAQs for NeXT Dx™ Test

1. What is the NeXT Dx Test?

The NeXT Dx Test is a laboratory developed test performed at Personalis' CAP-accredited and CLIA'88-certified laboratory. It is intended for profiling a solid tumor's genomic and molecular characteristics using clinical-grade, next-generation sequencing (NGS) technology to report small nucleotide variants (SNVs), small insertions and deletions (indels), copy number alterations (CNAs), and fusions in up to 247 cancer related genes. Additionally, MSI and exome-wide "true" TMB is reported by leveraging the exome-wide analysis of non-synonymous small variants (SNVs and indels both).

2. What does the NeXT Dx Test do?

The NeXT Dx Test helps identify potential therapies (targeted and immuno-therapies) and clinical trial options for cancer patients based on the tumor molecular profile.

3. Which genes are tested?

A list of genes tested is located on page 2 of this document.

4. Who is eligible for the NeXT Dx Test?

Any patient with a solid tumor including sarcoma is eligible for the NeXT Dx Test.

5. What sample types are appropriate for the NeXT Dx Test?

The NeXT Dx Test is validated for solid tumor FFPE samples. Unacceptable specimens include hematolymphoid malignancies or decalcified bone. Additionally, samples from patients living in New York State are not acceptable at this time.

6. What is the required tumor content for the NeXT Dx Test?

The required tumor content for the NeXT Dx Test is 20% or greater. Please note that CNAs can only be reported for samples with 30% or greater tumor content.

7. How is the NeXT Dx Test performed?

The NeXT Dx Test utilizes DNA and RNA isolated from patient's tumor tissue to perform whole exome and transcriptome analysis respectively. The clinical report includes SNVs, indels, CNAs, MSI and TMB results derived from DNA analysis and fusion results derived from RNA analysis.

8. How do I obtain the results?

A PDF report will be emailed to the authorized healthcare provider.

9. How do I order the NeXT Dx Test?

For ordering inquiry please contact Personalis at clinical@personalis.com

For additional questions, you can contact us at clinical@personalis.com.

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Cancer Genes of Clinical Importance

Single nucleotide variants, small insertions and deletions, copy number alterations, and gene fusions involving the genes below may be reported in the test. Genes for which copy number alteration is assessed are indicated by an asterisk ("*"). Genes in **BOLD** are those for which FDA approved drugs are available to treat solid tumors as of August 2020 (FDA, oncoKB data).

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

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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