

About Guardant360 TissueNext™

Guardant360 TissueNext is a comprehensive tissue profiling test that interrogates 498 genes, and includes TMB, MSI status, and PD-L1 assessment.*

Test specifications

Sample input	Sample specifications	Turnaround time
1 or more FFPE tissue block(s) or 11-13 unstained slides	Surface area $\geq 25 \text{ mm}^2$ (optimal) Tumor content $\geq 5\%$ tumor nuclei (required)	<2 weeks from sample receipt to results†

Performance specifications

	Alterations	Reportable Range	Analytical Sensitivity‡	Allelic Fraction/ Copy Number§	Analytical Specificity
Enhanced sensitivity regions	SNVs	$\geq 1.60\%$ MAF	$\geq 95\%$	1.60%	98.9%
	Indels	$\geq 1.10\%$ MAF	$\geq 95\%$	1.10%	100%
	CNAs	≥ 2.60 copies	$\geq 95\%$	4.07 copies	100%
	Fusions	$\geq 0.16\%$ MAF	$\geq 95\%$	0.80%	100%
Panel-wide	SNVs	$\geq 2.50\%$ MAF	$\geq 95\%$	3.80%	$\geq 99.9\%$
	Indels	$\geq 1.10\%$ MAF	$\geq 95\%$	3.30%	$\geq 99.9\%$
MSI status		MSI-High	$\geq 95\%$	2.50%¶	100%

*This test can be ordered at the same time as Guardant360 TissueNext. PD-L1 assessment from Guardant Galaxy uses AI-powered image analysis developed by Lunit®.

†Average turnaround time from sample receipt to results.

‡Analytical Sensitivity defined as the Detection Rate, that is, limit of detection (LoD).

§Demonstrated Allelic Fraction / Copy Number at 95% Analytical Sensitivity with 50 ng DNA input.

¶Percent Tumor Fraction.

CNA: Copy Number Amplification; FFPE: Formalin-Fixed Paraffin-Embedded; MAF: Mutant Allele Frequency; MSI: Microsatellite Instability; PD-L1: Programmed death-ligand 1; SNV: Single Nucleotide Variant; TMB: Tumor Mutation Burden.

Important Note: The Guardant360 TissueNext and Guardant Galaxy PD-L1 tests were developed and their performance characteristics determined by the Guardant Health Clinical Laboratory in Redwood City, CA, USA, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity testing. These tests have not been cleared or approved by the US FDA.

Gene Panel

MSI status - Qualitative result

TMB - Mutations per megabase

PD-L1 status - (if ordered) AI-powered

ABL1	BRD3	DEPDC5	FANCB	GNA11	KNSTRN	NFKBIA	PPARG	RUNX1	TRAF3
ABL2	BRD4	DEPTOR	FANCC	GNA13	KRAS[†]	NHEJ1	PPM1D	RUNX1T1	TSC1
ACVR1B	BRIP1	DICER1	FANCD2	GNAQ	LGR4	NKX2-1	PPP2CA	SDHB	TSC2
ACVR2A	BTG1	DLL4	FANCE	GNAS	LGR5	NOTCH1	PPP2R1A	SDHC	TSHR
ADARB2	BTG2	DNMT3A	FANCF	GRIN2A	LGR6	NOTCH2	PPP2R2A	SDHD	TSHZ2
ADGRA2	BTK	DOT1L	FANCG	GSK3B	LIG1	NOTCH3	PPP3CA	SESN2	TYRO3
ADGRG4	BUB1B	DYRK2	FANCI	H3F3A	LIG4	NOTCH4	PPP6C	SETD2	U2AF1
AFDN	CARD11	E2F3	FANCL	HDAC2	LMO1	NPM1	PRDM1	SF3B1	UBE2T
AKT1	CASP8	ECT2L	FANCM	HELQ	LRP1B	NPRL2	PREX1	SHFM1	USP9X
AKT1S1	CBFB	EGFR^{***}	FAS	HES1	LRP2	NPRL3	PREX2	SLFN11	VEGFA
AKT2	CBL	EIF1AX	FAT1	HEY1	LRP5	NRAS	PRKAR1A	SLIT2	VHL
AKT3	CBLB	EIF4A1	FBXW7	HEYL	LRP6	NSD1	PRKCI	SMAD2	WEE1
ALB	CCND1[†]	EIF4A2	FEN1	HGF	MAD2L2	NTRK1^{***}	PRKDC	SMAD3	WISP3
ALK^{***}	CCND2[†]	EIF4A3	FGF3	HIST3H3	MAP2K1	NTRK2^{***}	PTCH1	SMAD4	WRN
ALOX5	CCND3	EIF4B	FGF4	HNF1A	MAP2K2	NTRK3^{***}	PTEN	SMARCA2	WT1
ALOX12B	CCNE1[†]	EIF4E	FGF6	HRAS	MAP2K4	NUMB	PTPN11	SMARCA4	XBP1
ALOX15B	CD79A	EIF4E2	FGF10	HSP90AA1	MAP3K1	NUP93	PTPRD	SMARCB1	XPA
AMER1	CD79B	ELF3	FGF14	IDH1	MAP4K3	NUTM1	RAC1	SMO	XPC
APC	CD274	EML4	FGF19	IDH2	MAPK1	PAK3	RAD18	SOC1	XPO1
APCX1	CDC7	EMSY	FGF23	IDO1	MAPK3	PALB2	RAD21	SOC3	XRCC1
AR[†]	CDC73	EP300	FGFR1^{***}	IFNG	MAPKAP1	PARG	RAD50	SOS1	XRCC2
ARAF	CDH1	EPCAM	FGFR2^{***}	IFNGR1	MAX	PARP1	RAD51	SOX2	XRCC3
ARFRP1	CDK4[†]	EPHA3	FGFR3^{***}	IFNGR2	MCL1	PARP2	RAD51B	SOX9	XRCC4
ARHGAP35	CDK6[†]	EPHA5	FGFR4	IGF1	MDC1	PAX5	RAD51C	SOX10	XRCC5
ARID1A	CDK8	EPHA7	FH	IGF1R	MDM2	PBRM1	RAD51D	SPEN	XRCC6
ARID1B	CDK12	EPHB1	FLCN	IGF2	MDM4	PCDH15	RAD52	SPOP	YAP1
ARID2	CDKN1A	ERBB2[†]	FLT1	IGF2R	MED12	PDCD1	RAD54L	SRC	ZNF217
ASXL1	CDKN1B	ERBB3	FLT3	IKBKE	MEF2B	PDCD1LG2	RAF1[†]	SRSF2	ZNF703
ATM	CDKN2A	ERBB4	FLT4	IKZF1	MEN1	PDGFRA[†]	RARA	STAG2	ZNRF3
ATR	CDKN2B	ERCC1	FOXA1	IL2RG	MERTK	PDGFRB	RASA1	STAT3	ZRSR2
ATRX	CDKN2C	ERCC2	FOXL2	IL7R	MET^{***}	PDK1	RB1	STAT4	
AURKA	CEBPA	ERCC3	FOXO1	INHBA	MITF	PHF6	RBM10	STK11	
AURKB	CEP295	ERCC4	FOXP1	INPP4B	MLH1	PIAS4	RET^{***}	STK19	
AXIN1	CHEK1	ERCC5	FRS2	IRF1	MLH3	PIK3C2B	REV3L	SUFU	
AXIN2	CHEK2	ERCC6	FUBP1	IRF4	MLST8	PIK3CA[†]	RGS1	SYK	
AXL	CIC	ERCC8	FZD1	IRS2	MPL	PIK3CB	RHEB	TBC1D7	
B2M	CNOT3	ERG	FZD2	JAK1	MRAS	PIK3CD	RHOA	TBX3	
BAP1	CREBBP	ERRF1	FZD3	JAK2	MRE11	PIK3CG	RHOB	TEK	
BARD1	CRKL	ESR1[†]	FZD4	JAK3	MSH2	PIK3R1	RICTOR	TERT[#]	
BCL2	CRTC1	ETV1	FZD5	JUN	MSH3	PIK3R2	RIT1	TET2	
BCL2L1	CSF1R	ETV4	FZD6	KAT6A	MSH6	PIK3R3	RNF43	TGFB2	
BCL2L2	CTCF	ETV5	FZD7	KDM4A	MTOR	PIM1	ROBO1	TMPSR2	
BCL6	CTLA4	ETV6	FZD8	KDM5A	MUTYH	PIN1	ROBO2	TNFAIP3	
BCOR	CTNNA1	EWSR1	FZD9	KDM5B	MYB	PKM	ROS1^{***}	TNFRSF1A	
BCORL1	CTNNB1	EXO1	FZD10	KDM5C	MYC[†]	PLEKHS1	RPA1	TNFRSF14	
BCR	CUL3	EZH2	GAS6	KDM6A	MYCL	PMS1	RPS6KA3	TNK2	
BIRC5	CUX1	FAAP20	GATA1	KDR	MYCN[†]	PMS2	RPS6KB1	TOP1	
BLM	CYLD	FAAP24	GATA2	KEAP1	MYD88	POLD1	RPS27A	TOPAZ1	
BRAF^{***}	DAXX	FAAP100	GATA3	KIT[†]	NBN	POLE	RPTOR	TP53	
BRCA1	DDIT3	FAM46C	GATA6	KLHL6	NF1	POLH	RRAGC	TP53BP1	
BRCA2	DDR1	FAM175A	GEN1	KMT2A	NF2	POLQ	RSO1	TP63	
BRD2	DDR2	FANCA	GID4	KMT2D	NFE2L2	POU2F2	RSPO4	TP73	

[†]Includes TERT promoter region.

[†]Includes CNAs.

^{***}Includes Fusions.

Bold denotes enhanced sensitivity regions.