

About Guardant360 TissueNext™

- Guardant360 TissueNext™ is an analytically validated comprehensive next-generation sequencing panel that includes clinically actionable biomarkers to enable informed treatment decisions for patients with advanced solid tumors.
- Includes TMB, MSI status, HRR genes and selected fusions.
- Optional PD-L1 IHC, if ordered.
- Performed at a CLIA-certified, CAP-accredited laboratory in Redwood City, California.



Test specifications

<p>Sample input 10 FFPE unstained slides.</p> <p><small>(Additional 3 FFPE unstained slides if PD-L1 is ordered)</small></p>	<p>Sample requirements Tumor Area > 25 mm². Tumor Content > 10% tumor nuclei.</p>	<p>Test turnaround time Approximately 2–3 weeks from sample receipt to results.</p>	<div style="border: 2px solid blue; border-radius: 50%; padding: 10px; width: 60px; margin: 0 auto;"> <p style="margin: 0;">2–3 weeks</p> </div>
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Guardant360 TissueNext™ panel. All four major classes of alterations reported.

Point Mutations (SNVs) and Deletion Variants (Indels) (84 Genes)								Amplifications (20 Genes)		Fusions (12 Genes)	PD-L1 status (if ordered)
AKT1	ALK	APC	AR	ARAF	ARID1A	ATM	BRAF	AR	BRAF	ALK	
BRCA1	BRCA2	CCND1	CCND2	CCNE1	CDH1	CDK4	CDK6	CCND1	CCND2	BRAF	MSI status Qualitative result
CDK12	CDKN2A	CHEK2	CTNNB1	DDR2	EGFR	ERBB2	ESR1	CCNE1	CDK4	EGFR	
EZH2	FANCA	FBXW7	FGFR1	FGFR2	FGFR3	GATA3	GNA11	CDK6	EGFR	FGFR1	TMB status Mutations per Megabase
GNAQ	GNAS	HNF1A	HRAS	IDH1	IDH2	JAK2	JAK3	ERBB2	ESR1	FGFR2	
KEAP1	KIT	KRAS	MAP2K1	MAP2K2	MAPK1	MAPK3	MET	FGFR1	FGFR2	FGFR3	
MLH1	MPL	MSH6	MSH2	MTOR	MYC	MYCN	NF1	KIT	KRAS	MET	
NFE2L2	NOTCH1	NPM1	NRAS	NTRK1	NTRK2	NTRK3	PALB2	MET	MYC	NTRK1	
PDGFRA	PIK3CA	PMS2	PTEN	PTPN11	RAD51D	RAF1	RB1	MYCN	PDGFRA	NTRK2	
RET	RHEB	RHOA	RIT1	ROS1	SMAD4	SMO	STK11	PIK3CA	RAF1	NTRK3	
TERT†	TP53	TSC1	VHL							RET	
										ROS1	

Analytical performance

Alteration Type	Threshold for Positivity	Analytical Sensitivity#	Limit of Detection (LoD)##	Analytical Specificity###
SNVs	≥1.60% MAF	≥95%	1.60%	98.9%
Indels	≥1.10% MAF	≥95%	1.10%	100%
CNAs	≥2.60 copies	≥95%	4.07 copies	100%
Fusions	≥0.16% MAF	≥95%	0.80%	100%
MSI	MSI-High	≥95%	2.5%####	100%

#Analytical Sensitivity is defined as the Detection Rate for variants present at or above the Limit of Detection (LoD)

##Demonstrated Limit of Detection (LoD) at 95% Analytical Sensitivity with 50ng DNA input

###Analytical Specificity is defined as 1 minus the per-sample false positive rate

####Percent Tumor Fraction

TMB: Tumor mutational burden | FFPE: Formalin-fixed paraffin-embedded | SNVs: Single-nucleotide variants | CNAs: Copy number alterations

