GUARDANT360 TissueNext™

Assay **Specifications**

About Guardant360 TissueNext

Guardant360 TissueNext™ is an analytically validated tissue Comprehensive Genomic Profiling (CGP) panel that includes TMB, MSI status, and PD-L1 IHC, if ordered.

Test specifications

Sample input
FFPE tissue block or unstained slides.

Sample specifications
Tumor Area > 25 mm^2
Tumor Content > 10% tumor nuclei.

Test turnaround time
2-3 weeks from sample receipt to results.

2-3 WEEKS

Guardant360 TissueNext panel. All four major classes of alterations detected.

Point Mutations (SNVs) and Deletion Variants (Indels) *(84 Genes)*

AKT1	*ALK*	*APC*	*AR*	*ARAF*	*ARID1A*	*ATM*	***BRAF***
BRCA1	*BRCA2*	*CCND1*	*CCND2*	*CCNE1*	*CDH1*	*CDK4*	*CDK6*
CDK12	*CDKN2A*	*CHEK2*	*CTNNB1*	*DDR2*	***EGFR***	***ERBB2***	*ESR1*
EZH2	*FANCA*	*FBXW7*	*FGFR1*	*FGFR2*	*FGFR3*	*GATA3*	*GNA11*
GNAQ	*GNAS*	*HNF1A*	*HRAS*	*IDH1*	*IDH2*	*JAK2*	*JAK3*
KEAP1	*KIT*	***KRAS***	*MAP2K1*	*MAP2K2*	*MAPK1*	*MAPK3*	***MET***
MLH1	*MPL*	*MSH6*	*MSH2*	*MTOR*	*MYC*	*MYCN*	*NF1*
NFE2L2	*NOTCH1*	*NPM1*	*NRAS*	*NTRK1*	*NTRK2*	*NTRK3*	*PALB2*
PDGFRA	*PIK3CA*	*PMS2*	*PTEN*	*PTPN11*	*RAD51D*	*RAF1*	*RB1*
RET	*RHEB*	*RHOA*	*RIT1*	*ROS1*	*SMAD4*	*SMO*	*STK11*
TERT†	*TP53*	*TSC1*	*VHL*				

Amplifications *(20 Genes)*

AR	*BRAF*
CCND1	*CCND2*
CCNE1	*CDK4*
CDK6	*EGFR*
ERBB2	*ESR1*
FGFR1	*FGFR2*
KIT	*KRAS*
MET	*MYC*
MYCN	*PDGFRA*
PIK3CA	*RAF1*

Fusions *(12 Genes)*

ALK
BRAF
EGFR
FGFR1
FGFR2
FGFR3
MET
NTRK1
NTRK2
NTRK3
RET
ROS1

PD-L1 status (if ordered)

MSI status Qualitative result

TMB status Mutations per Megabase

NSCLC guideline-recommended genes shown in bold / † Includes *TERT* promoter region

Analytical performance

Alteration Type	Reportable Range	Analytical Sensitivity#	Allelic Fraction/ Copy Number##	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 defined as the Detection Rate, that is, limit of detection (LoD)

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

###Analytical Specificity defined as 100% minus the per-sample false positive rate

####Percent Tumor Fraction

Client Services: 1.855.698.8887 • **clientservices@guardanthealth.com**

REC-MKT-000118 R2

GUARDANT™