



ABOUT GUARDANT360[®]

Guardant360 provides guideline-recommended genomic results including high microsatellite instability (MSI-High) in 7 days from sample receipt at the laboratory using a routine blood draw, eliminating the need to solely rely on tissue testing. Guardant360 enables informed treatment decisions for advanced solid-tumor cancer patients and identifies treatment options or clinical trials for patients before first-line therapy or at progression.

USING GUARDANT360 IN CLINICAL PRACTICE

Indicated for:

- > Advanced solid-tumor cancers
- > Before first-line therapy or at progression

Not indicated for:

- > Hematologic malignancies
- > Early stage cancers
- > When disease is stable or responding to therapy

TEST SPECIFICATIONS

Sample type and volume

Two 10 mL tubes of whole blood.

Storage and shipping conditions

Ship same or next day at room temperature. Do not freeze or refrigerate.

Test turnaround time

7 calendar days from sample receipt at the laboratory to results.



PERFORMANCE SPECIFICATIONS

Alteration Type	Reportable Range	Allelic Fraction/ Copy Number	Analytical Sensitivity	Analytical Specificity*
SNVs	≥0.04%	>0.25%	100%	100%
		0.05 - 0.25%	77%	98%
Indels	≥0.04%	>0.5%	100%	100%
		0.1 - 0.5%	74%	
Fusions**	≥0.04%	≥0.3%	100%	100%
		<0.3%	91%	
CNAs***	≥2.18 copies	2.3 copies	100%	100%
MSI	Detected/ Not Detected	≥0.1%	95%	100%

Based on cell-free DNA input of 30 ng in patient samples. Analytical sensitivity cited above are for targeted, clinically important regions. Sensitivity outside these regions or in highly repetitive sequence contexts may vary.

*Over entire genomic reportable range of Guardant360 panel.

**Based on fusion detection in ALK, NTRK1, RET, ROS1

***Based on ERBB2 (HER2) and MET analytical sensitivity. Copy number sensitivity may vary with other genes

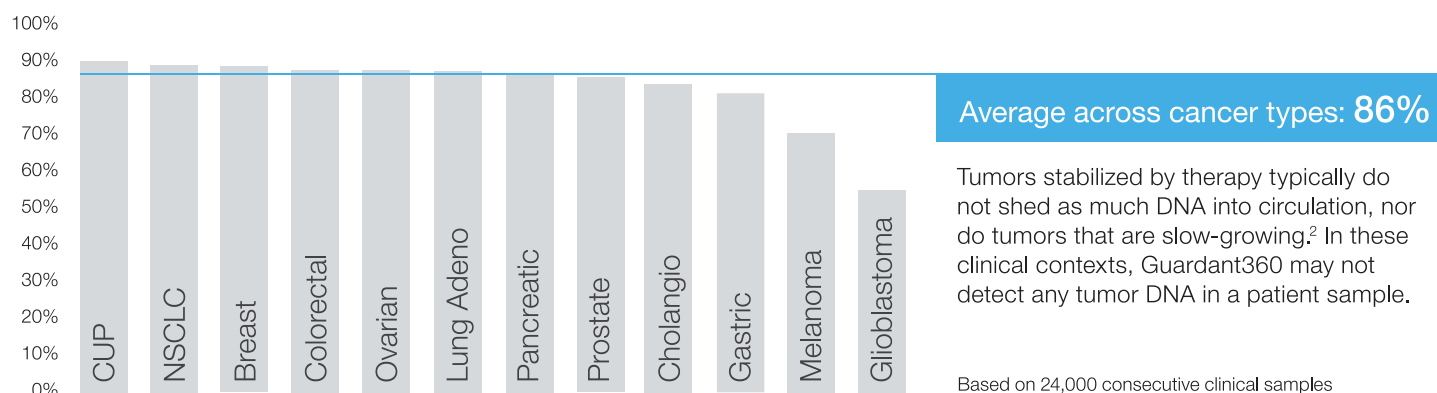
GUARDANT360 COVERS ALTERATIONS IN OVER 70 GENES RELEVANT TO MULTIPLE SOLID TUMORS INCLUDING MSI-HIGH

Point Mutations (SNVs) and Deletion Variants (Indels) (74 Genes)							Amplifications (18 Genes)		Fusions (6 Genes)
AKT1	ALK	APC	AR	ARAF	ARID1A	ATM	AR	BRAF	ALK
BRAF	BRCA1	BRCA2	CCND1	CCND2	CCNE1	CDH1	CCND1	CCND2	FGFR2
CDK4	CDK6	CDK12	CDKN2A	CTNNB1	DDR2	EGFR	CCNE1	CDK4	FGFR3
ERBB2	ESR1	EZH2	FBXW7	FGFR1	FGFR2	FGFR3	CDK6	EGFR	NTRK1
GATA3	GNA11	GNAQ	GNAS	HNF1A	HRAS	IDH1	ERBB2	FGFR1	RET
IDH2	JAK2	JAK3	KIT	KRAS	MAP2K1	MAP2K2	FGFR2	KIT	ROS1
MAPK1	MAPK3	MET	MLH1	MPL	MTOR	MYC	KRAS	MET	
NF1	NFE2L2	NOTCH1	NPM1	NRAS	NTRK1	NTRK3	MYC	PDGFRA	
PDGFRA	PIK3CA	PTEN	PTPN11	RAF1	RB1	RET	PIK3CA	RAF1	
RHEB	RHOA	RIT1	ROS1	SMAD4	SMO	STK11			
TERT [†]	TP53	TSC1	VHL						

Critical or all exons* completely sequenced and all four major classes of alterations

NSCLC guideline-recommended genes shown in **bold** / *Exons selected to maximize detection of known somatic mutations / [†] Includes TERT promoter region

ctDNA DETECTION RATE BY CANCER TYPE WITH THE GUARDANT360 ASSAY¹



CUP : Carcinoma of Unknown Primary
 NSCLC : Non-small Cell Lung Cancer
 Lung Adeno : Lung Adenocarcinoma
 Cholangio : Cholangiocarcinoma

REFERENCES: 1. Zill et al. 2018 Clin Cancer Res / 2. Holdenrieder et al. Clin Cancer Res 2004; Bettgeowda, et al. Sci Transl Med 2014

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