

ABOUT GUARDANT360®

Guardant360 provides guideline-recommended genomic results in 7 days from a routine blood draw, eliminating the need to solely rely on tissue testing. Guardant360 also enables informed treatment decisions for patients with advanced solid tumors and identifies treatment options or clinical trials for patients progressing on treatment. With demonstrated concordance to tissue in multiple prospective studies, Guardant360 ensures fast, reliable and informed treatment decisions.

USING GUARDANT360 IN CLINICAL PRACTICE

Before first-line therapy

- > Get ahead of the challenges of tissue testing in advanced cancer by utilizing Guardant360 at diagnosis before 1st-line therapy to guide treatment decisions

At progression

- > Identify potential treatment options relevant across multiple solid tumors including high microsatellite instability (MSI-High) to help find options (such as targeted therapies and clinical trials) for patients progressing on treatment

Not indicated for:

- > Hematologic malignancies
- > Early stage (stage I/II) 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

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

Test turnaround time

7 calendar days from sample receipt to results.



PERFORMANCE SPECIFICATIONS

Alteration Type	Reportable Range	Allelic Fraction/ Copy Number	Analytical Sensitivity	Analytical Specificity*
SNVs	≥0.04%	>0.5%	100%	100%
		0.1 - 0.5%	88.3%	98.9%
Indels	≥0.04%	>0.5%	99.8%	100%
		0.1 - 0.5%	73.9%	100%
Fusions**	≥0.04%	≥0.3%	100%	100%
		0.05 - 0.3%	90.8%	100%
CNAs***	≥2.18 copies	2.3 copies****	100%	100%
MSI	MSI-H 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.

*Per sample, 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

****Equivalent to 5% tumor fraction and 8 ERBB2 (HER2) gene copies in tumor

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

Point Mutations and InDels (Complete or Critical Exon Coverage in 74 Genes)

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

Amplifications

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

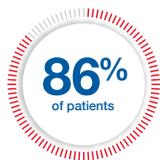
Fusions

ALK	FGFR2	FGFR3	RET	ROS1	NTRK1
-----	-------	-------	-----	------	-------

2018 PROSPECTIVE STUDY FOUND
Guardant360 was concordant with tissue and improved alteration detection amongst patients with advanced cancer.¹



Concordance with tissue for targetable alterations before first-line therapy

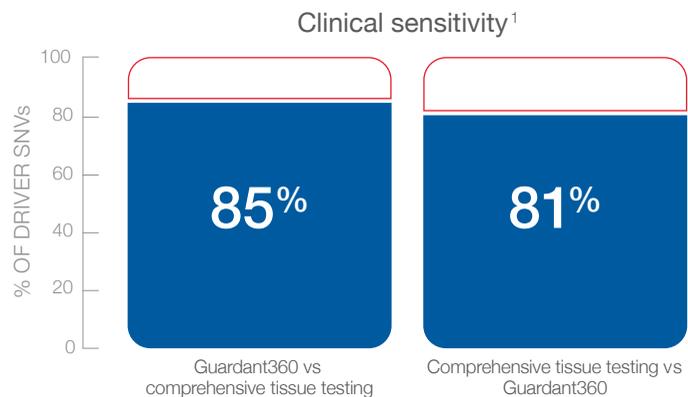


Patients who received a targeted therapy based on Guardant360 results had a response or stable disease according to RECIST criteria



More patients had targetable alterations detected by Guardant360 and tissue testing (n=82) versus tissue testing alone (n=47)

GUARDANT360 DEMONSTRATES CONSISTENT CONCORDANCE WITH TISSUE ACROSS SOLID TUMORS



15%-20% of the time tissue misses what liquid finds and vice versa

- Results for single nucleotide variants (SNVs) from 165 patient samples across multiple solid tumors
- Clinical specificity of nearly 100%



References:
1. Lanman et al. 2015 PLoS One