

ABOUT GUARDANT360®

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

USING GUARDANT360® IN CLINICAL PRACTICE

Indicated for:

- > Advanced solid tumors
- > 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.



ANALYTICAL PERFORMANCE

Alteration Type	Analytical Sensitivity#	Limit of Detection (LoD)		Analytical Specificity##	Threshold for Positivity
		5ng cfDNA input	30ng cfDNA input		
SNVs	≥ 95%	≥ 1.8%	≥ 0.2%	98.33%	MAF ≥ 0.001%
Indels	≥ 95%	≥ 2.65%	≥ 0.2%	99.17%	MAF ≥ 0.01%
CNAs	≥ 95%	≥ 2.3-2.4 copies	≥ 2.3-2.4 copies	99.58%	≥ 2.16-2.18 copies
Fusions	≥ 95%	≥ 0.72-1.5%†	≥ 0.1-0.2%	100%	≥ 2 unique molecules

#Analytical Sensitivity defined as the Detection Rate for variants present at or above the limit of detection (LoD).

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

†Data based on cell line samples. See Technical Information document for further information†

Actual CNA and Fusion 95% Limit of Detection (5ng/30ng): CNAs - *ERBB2* (2.3/2.3 copies), *MET* (2.4/2.4 copies); Fusions - *NTRK1* (0.9/0.2% MAF), *RET* (0.72/0.1% MAF), *ROS1* (1.2/0.2% MAF), *ALK* (1.4/0.2% MAF)

MAF—mutant allele fraction

This is the analytical performance for Guardant360® CDx¹

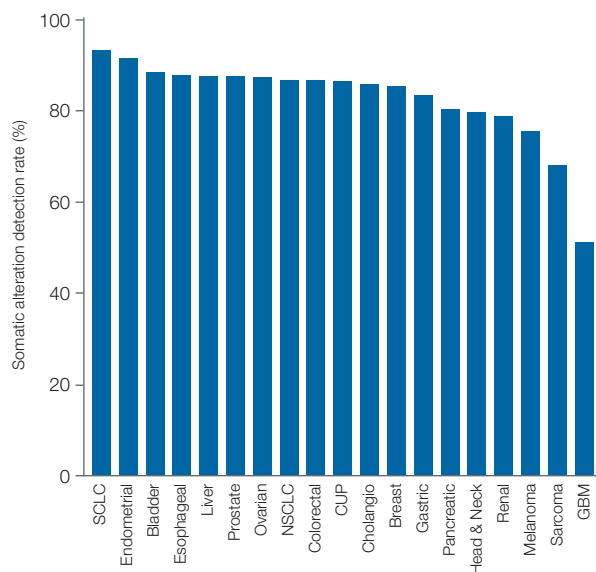
GUARDANT360® COVERS ALTERATIONS, INCLUDING MSI-HIGH, IN OVER 70 GENES RELEVANT TO MULTIPLE SOLID TUMORS

Point Mutations (SNVs), Insertion 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

† Includes TERT promoter region
SNV=single nucleotide variants

ctDNA DETECTION RATE BY CANCER TYPE WITH THE GUARDANT360® ASSAY²



Average across cancer types: **85%**

Tumors stabilized by therapy typically do not shed as much DNA into circulation, nor do tumors that are slowly growing³. In these clinical contexts, Guardant360® may not detect any tumor DNA.

Based on 25,578 consecutive sample numbers

SCLC : Small Cell Lung Cancer
NSCLC : Non-Small Cell Lung Cancer
CUP : Carcinoma of Unknown Primary
Cholangio : Cholangiocarcinoma
GBM : Glioblastoma

REFERENCES: 1. Blood Draw and Instructions G360 CDx_0625-V9 https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200010C.pdf accessed on 18 June 2021 2. Zill et al (2018) Clin Cancer Res 24(15); 3528–38 3. Holdenrieder et al (2004) Clin Cancer res 10.1158/1078-0432

 www.guardanthealthamea.com

 clientservices@guardantamea.com

 WhatsApp Hotline: +65 8940 0360

