GUARDANT360® Assay Specifications

Test. Take Action.

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

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GUARDANT™

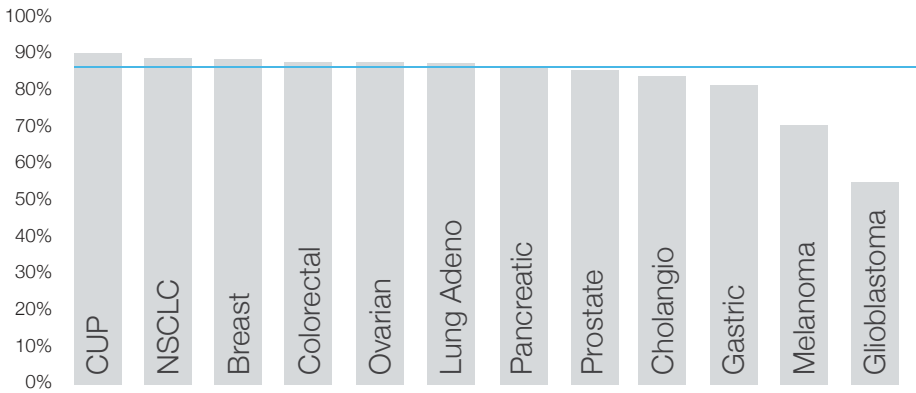
GUARDANT360 COVERS ALTERATIONS IN OVER 70 GENES RELEVANT TO MULTIPLE SOLID TUMORS INCLUDING MSI-HIGH

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 ASSAY[1]



Average across cancer types: **86%**

Tumors stabilized by therapy typically do not shed as much DNA into circulation, nor do tumors that are slow-growing.[2] In these clinical contexts, Guardant360 may not detect any tumor DNA in a patient sample.

Based on 24,000 consecutive clinical samples

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

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