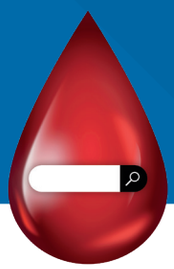


GUARDANT360® Assay Specifications

Test. Take Action.

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[1]

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® CDx[1]

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

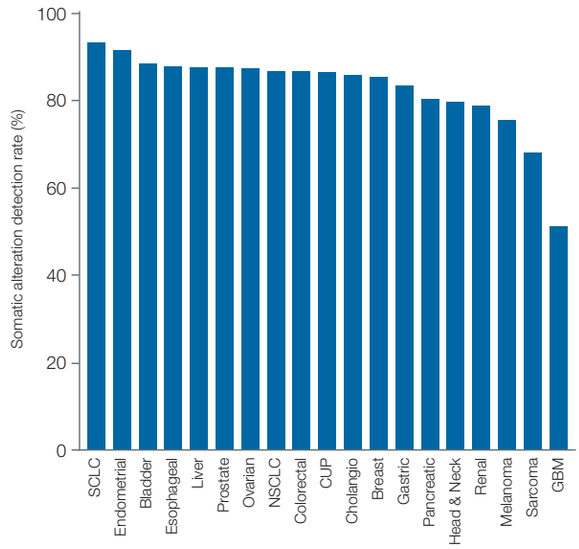
Point Mutations (SNVs), Insertion and Deletion Variants (Indels) *(74 Genes)*							Amplifications *(18 Genes)*		Fusions *(6 Genes)*
AKT1	*ALK*	*APC*	*AR*	*ARAF*	*ARID1A*	*ATM*	*AR*	*BRAF*	*ALK*
BRAF	*BRCA1*	*BRCA2*	*CCND1*	*CCND2*	*CCNE1*	*CDH1*	*CCND1*	*CCND2*	*FGFR2*
CDK4	*CDK6*	*CDK12*	*CDKN2A*	*CTNNB1*	*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® ASSAY[2]



Average across cancer types: 85%

Tumors stabilized by therapy typically do not shed as much DNA into circulation, nor do tumors that are slowly growing[3]. 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.** Holdenrierder et al (2004) Clin Cancer res 10.1158/1078-0432

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