

ABOUT GUARDANT360 CDx

Guardant360 CDx provides guideline-recommended genomic results for advanced cancer patients in 5 days from a routine blood draw. With demonstrated concordance to tissue in multiple prospective studies, Guardant360 CDx ensures fast and reliable results.

USING GUARDANT360 CDx IN CLINICAL PRACTICE

BEFORE FIRST-LINE THERAPY

Get ahead of the challenges of tissue testing in advanced NSCLC by utilizing Guardant360 CDx 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

5 calendar days from sample receipt to results.



PERFORMANCE SPECIFICATIONS

Alteration Type	Analytical Specificity [#]	Allelic Fraction/ Copy Number ^{##}		Analytical Sensitivity ^{###}	Threshold for Positivity
		5ng	30ng		
SNVs	≥ 95%	≥ 1.8%	≥ 0.2%	100%	≥ 0.001% MAF
Indels	≥ 95%	≥ 2.7%	≥ 0.2%	95.2%	≥ 0.01% MAF
CNAs ^{**}	≥ 95%	≥ 2.3-2.4% copies	≥ 2.3-2.4% copies	100%	≥ 2.16-2.18% copies
Fusions [*]	≥ 95%	≥ 0.7-1.5%	≥ 0.1-0.2% ¹	100%	≥ 2 unique molecules

^{*}Analytical Sensitivity defined as the Detection Rate, that is, limit of detection (LoD)

^{**}Demonstrated Allelic Fraction/Copy Number at 95% Analytical Sensitivity with 5ng and 30ng cfDNA input

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

¹Data based on cell-line samples. See Technical Information document for further information

Actual CNA and Fusion 95% Limit of Detection for (5ng/30ng): CNAs-ERBB2 (2.3/2.3 copies), MET (2.4/2.4 copies) Fusions -NTRK1 (0.9/0.2% MAF), RET (0.7/0.1% MAF), ROS1 (1.2/0.2% MAF), ALK (1.5/0.2% MAF)
^{*}Based on ERBB2 and MET. ^{**}Based on ALK, NTRK1, RET and ROS1.

Guardant360 CDx 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)						Amplifications (18 Genes)		Fusions (6 Genes)
AKT1	CDH1	FGFR2	KRAS	NPM1	RIT1	AR	FGFR1	ALK
ALK	CDK4	FGFR3	MAP2K1	NRAS	ROS1	BRAF	FGFR2	FGFR2
APC	CDK6	GATA3	MAP2K2	NTRK1	SMAD4	CCND1	KIT	FGFR3
AR	CDK12	GNA11	MAPK1	NTRK3	SMO	CCND2	KRAS	NTRK1
ARAF	CDKN2A	GNAQ	MAPK3	PDSFRA	STK11	CCNE1	MET	RET
ARID1A	CTNNB1	GNAS	MET	PIK3CA	TERT	CDK4	MYC	ROS1
ATM	DDR2	HNFA1	MLH1	PTEN	TP53	CDK6	PDGFRA	
BRAF	EGFR	HRAS	MPL	PTPN11	TSC1	EGFR	PIK3CA	
BRCA1	ERBB2	IDH1	MTOR	RAF1	VHL	ERBB2	RAF1	
BRCA2	ESR1	IDH2	MYC	RB1				
CCND1	EZH2	JAK2	NF1	RET				
CCND2	FBXW7	JAK3	NFE2L2	RHEB				
CCNE1	FGFR1	KIT	NOTCH1	RHOA				

Microsatellite Instability (MSI)

Guardant360 CDx was highly concordant with tissue and improved alteration detection amongst patients with advanced NSCLC¹



90% Concordance with tissue for targetable alterations before first-line therapy



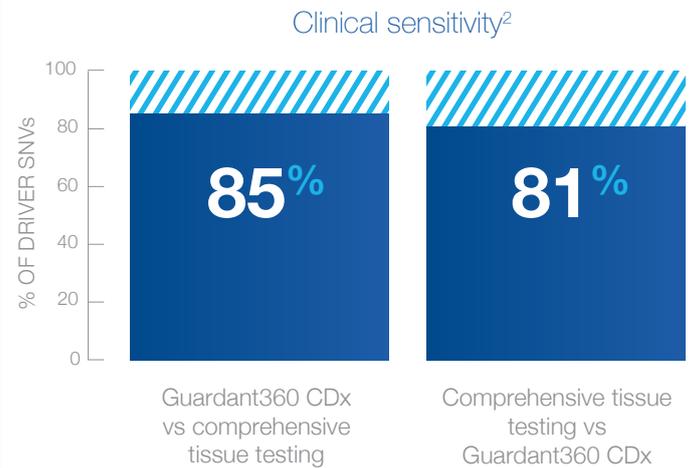
86% Patients who received a targeted therapy based on Guardant360 results had a response or stable disease according to RECIST criteria



2x More patients had targetable alterations detected by Guardant360 CDx and tissue testing (n=82) versus tissue testing alone (n=47)

Disclaimer: Data shown is for the performance of Guardant360 Laboratory Developed Test (LDT).

Guardant360 CDx Demonstrates Consistent Concordance With Tissue Across Solid Tumors



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



ISO15189



References:

1. Aggarwal et al. 2018 JAMA Oncol
2. Lanman et al. 2015 PLoS One