GUARDANT360 CDx

ASSAY SPECIFICATIONS

ABOUT GUARDANT360 CDx

Guardant360 CDx provides guideline-recommended genomic results for advanced cancer patients in 7 days from a routine blood draw. With demonstrated concordance to tissue in multiple prospective studies, Guardant360 CDx ensures fast and reliable results.[1,2]

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 to help select 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 blood sample.
Ship same or next day at room temperature.

Test turnaround time

7 calendar days from sample receipt to results.

7 DAYS

PERFORMANCE SPECIFICATIONS

Alteration Type	Analytical Sensitivity[#]	Allelic Fraction/ Copy Number[##]		Analytical Specificity[###]	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

[1]Data 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***.

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GUARDANT

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)*

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

Amplifications
(18 Genes)

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

Fusions
(6 Genes)

ALK
FGFR2
FGFR3
NTRK1
RET
ROS1

Microsatellite Instability (MSI-High)

Guardant360 CDx was highly concordant with tissue and improved alteration detection amongst patients with advanced NSCLC[1]

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

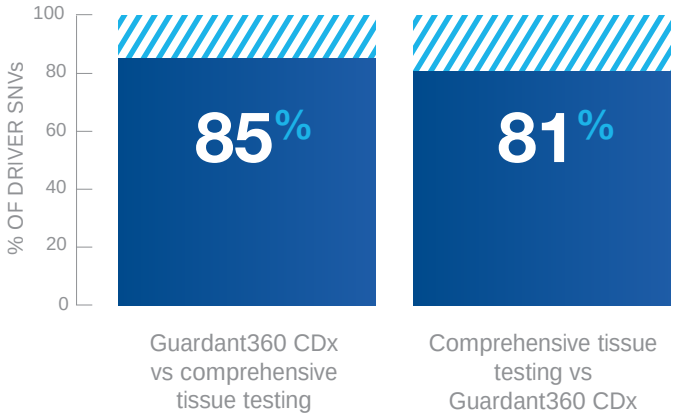
86% Patients who received a targeted therapy based on Guardant360 results had a response or stable disease according to RECIST criteria

2x More patients had targetable alterations detected by Guardant360 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 Demonstrated Consistent Concordance With Tissue Across Solid Tumors

Clinical sensitivity[2]



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

CE ISO15189 CAP ACCREDITED CLIA Clinical Laboratory Improvement Amendments

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