GUARDANT360 Liquid CDx

Assay **Specifications**

About Guardant360® Liquid CDx

Guardant360 Liquid CDx is a fast, FDA-approved comprehensive liquid biopsy for advanced solid tumors that provides results in 7 days*.

Test specifications

Sample input
Two 10mL Streck tubes of whole blood†

Storage and shipping
Do not freeze or refrigerate. Ship same or next day at room temperature

Turnaround time
7 calendar days from sample receipt to results*

7 DAYS

*Median tunraround time from sample receipt to first results
†Minimum 5 mL in one tube required to process

Gene panel

All four major classes of alterations detected

SNVs and indels *(741 genes)*

ABCB1	*ATRX*	*CARD11*	*CDKN2B*	*DDR1**	*ELAVL2**	*FAAP100*	*FH*	*GPATCH8**	*IKBKE**	*KRAS*	*MGA*	*NOTCH3*	*PDCD1*	*PPM1D*
ABL1	*AURKA*	*CASP8**	*CDKN2C*	*DDR2*	*ELF3**	*FAAP20*	*FLCN*	*GPC3**	*IKZF1**	*LATS1*	*MITF‡*	*NOTCH4**	*PDCD1LG2*	*PPP2CA**
*ABL2**	*AURKB*	*CASR*	*CEBPA*	*DDX17**	*ELOC**	*FAAP24**	*FLT1*	*GREM1*	*IL1R1*	*LGR4*	*MKNK1**	*NOVA1**	*PDE7A*	*PPP2R1A*
ABRAXAS1	*AURKC*	*CAV1*	*CELF4**	*DDX18**	*EML4*	*FANCA‡*	*FLT3*	*GRIN2A**	*IL2RA*	*LGR5*	*MLH1‡*	*NPM1**	*PDGFRA*	*PPP2R2A*
ACVR1	*AXIN1*	*CBFB**	*CEP295**	*DDX27**	*EMSY*	*FANCB**	*FLT4**	*GSK3B*	*IL2RB*	*LGR6*	*MLH3**	*NPRL2*	*PDGFRB*	*PPP3CA*
*ACVR1B**	*AXIN2*	*CBL*	*CFAP20**	*DDX3X**	*EP300*	*FANCC**	*FOXA1**	*GSTM1*	*IL2RG*	*LIG1**	*MLST8*	*NPRL3*	*PDK1**	*PPP6C**
*ACVR2A**	*AXL*	*CBLB**	*CHD4*	*DDX41**	*EPAS1**	*FANCD2**	*FOXL2*	*GSTP1*	*IL7R*	*LIG4*	*MPL*	*NRAS*	*PDPK1*	*PRDM1*
ADARB2	*B2M**	*CCAR1**	*CHEK1*	*DEPDC5*	*EPCAM*	*FANCE**	*FOXO1**	*H3-4*	*INHBA*	*LMO1**	*MRAS**	*NRG1*	*PHF6**	*PREX1*
*ADGRA2**	*BABAM1*	*CCN6**	*CHEK2*‡*	*DEPTOR*	*EPHA3*	*FANCF*	*FOXP1**	*H3F3A**	*INPP4B*	*LRP1B*	*MRE11*	*NSD1**	*PHLPP1*	*PREX2*
*ADGRG4**	*BABAM2*	*CCNA2*	*CIC*	*DHX15*	*EPHA5*	*FANCG**	*FRS2*	*HACD4**	*INTS6L**	*LRP2**	*MSH2‡*	*NSD2*	*PHLPP2*	*PRKAR1A*
*AFDN**	*BAP1*	*CCNB1*	*CLDN18*	*DHX16**	*EPHA7**	*FANCI*	*FUBP1**	*HDAC2*	*IRF1*	*LRP5*	*MSH3**	*NSD3*	*PHOX2B*	*PRKCI**
*AGGF1**	*BARD1‡*	*CCND1*	*CMTM4*	*DHX36**	*EPHB1**	*FANCL*	*FUBP3**	*HDAC6*	*IRF2*	*LRP6*	*MSH6‡*	*NSRP1**	*PIAS4*	*PRKDC**
AIP	*BCL2*	*CCND2*	*CMTM6*	*DHX9**	*ERBB2*	*FANCM**	*FUS**	*HELQ*	*IRF4**	*LTK*	*MTAP*	*NTHL1*	*PIK3C2B**	*PRKN*
AKT1	*BCL2L1*	*CCND3*	*CNOT3**	*DICER1*	*ERBB3*	*FAS**	*FYN*	*HES1*	*IRS2**	*LYN*	*MTHFR*	*NTRK1*	*PIK3CA*	*PRMT5*
AKT1S1	*BCL2L2**	*CCNE1*	*CREBBP**	*DIS3L2*	*ERBB4*	*FAT1**	*FZD1*	*HEY1*	*JAK1*	*LZTR1*	*MTOR*	*NTRK2**	*PIK3CB*	*PRPF40B**
AKT2	*BCL6**	*CCNE2*	*CRKL**	*DLL4*	*ERCC1**	*FBXW7*	*FZD10*	*HEYL*	*JAK2*	*MAD2L2*	*MUTYH‡*	*NTRK3**	*PIK3CD**	*PRPF4B**
AKT3	*BCOR*	*CD274*	*CRTC1**	*DNAJB1*	*ERCC2*	*FCGR2A*	*FZD2*	*HGF*	*JAK3*	*MALT1*	*MYB**	*NUMA1*	*PIK3CG*	*PSENEN*
ALB	*BCORL1**	*CD276*	*CSF1R*	*DNMT1**	*ERCC3**	*FCGR3A*	*FZD3*	*HNF1A*	*JUN*	*MAP2K1*	*MYC*	*NUMB*	*PIK3R1*	*PSMB10*
ALK	*BCR**	*CD74**	*CSF3R*	*DNMT3A*	*ERCC4**	*FEN1*	*FZD4*	*HNRNPDL**	*KAT6A**	*MAP2K2*	*MYCL*	*NUP93**	*PIK3R2**	*PSMB8*
ALOX12B	*BIRC5**	*CD79A*	*CTC1*	*DNMT3B*	*ERCC5*	*FGF1*	*FZD5*	*HOXB 13*	*KAT6B*	*MAP2K4*	*MYCN*	*NUTM1**	*PIK3R3*	*PSMB9*
ALOX15B	*BLM*	*CD79B*	*CTCF*	*DOT1L**	*ERCC6*	*FGF10**	*FZD6*	*HRAS*	*KDM4A*	*MAP3K1*	*MYD88*	*P2RY8**	*PIM1*	*PTCH1*
ALOX5	*BMPR1A‡*	*CDC27*	*CTLA4*	*DPYD*	*ERCC6L2*	*FGF12*	*FZD7*	*HSD3B1**	*KDM5A**	*MAP3K13*	*MYOD1*	*PABPC1**	*PIN1*	*PTDSS1*
AMER1	*BRAF*	*CDC5L**	*CTNNA1*	*DUSP4*	*ERCC8*	*FGF14**	*FZD8*	*HSP90AA1**	*KDM5B**	*MAP4K3**	*NAB2*	*PAK1*	*PKM**	*PTEN‡*
APC‡	*BRCA1‡*	*CDC7*	*CTNNB1*	*DYNLL1**	*EREG*	*FGF19*	*FZD9*	*ICOSLG*	*KDM5C*	*MAPK1*	*NBN*	*PAK3**	*PLCG2*	*PTPN11*
APEX1	*BRCA2‡*	*CDC73*	*CUL3*	*DYRK2*	*ERF*	*FGF2*	*GAS6*	*ID3*	*KDM6A*	*MAPK3*	*NCOR1**	*PALB2‡*	*PLEKHS1*	*PTPN2*
APLNR	*BRCC3*	*CDH1‡*	*CUL4A*	*E2F3**	*ERG*	*FGF23**	*GATA1*	*IDH1*	*KDR*	*MAPKAP1*	*NCR1*	*PARG*	*PLRG1**	*PTPRD**
AR	*BRD2**	*CDH6*	*CUX1**	*ECT2L**	*ERRFI1**	*FGF3*	*GATA2*	*IDH2*	*KEAP1*	*MARK2*	*NCR3*	*PARP1**	*PMS1**	*PTPRS*
ARAF	*BRD3**	*CDK11A**	*CWC22**	*EFTUD2**	*ESR1*	*FGF4**	*GATA3*	*IDO1*	*KIN**	*MAX‡*	*NEGR1*	*PARP2**	*PMS2*‡*	*PTPRT*
*ARFRP1**	*BRD4**	*CDK12*	*CXCR4*	*EGFR‡*	*ETS1*	*FGF5*	*GATA4*	*IFNG*	*KIT*	*MCL1*	*NELFE**	*PAX3*	*POLA1*	*QKI**
ARHGAP35	*BRIP1‡*	*CDK4*	*CYLD**	*EIF1AX**	*ETV1*	*FGF6**	*GATA6*	*IFNGR1*	*KLF4*	*MDC1**	*NF1*	*PAX5*	*POLD1*	*RAB35*
ARID1A	*BSG*	*CDK6*	*CYP17A1*	*EIF4A1*	*ETV4*	*FGF7**	*GEN1*	*IFNGR2*	*KLHL6**	*MDM2*	*NF2‡*	*PAX7*	*POLE*	*RAC1**
ARID1B	*BTG1**	*CDK7*	*CYP19A1*	*EIF4A2*	*ETV5**	*FGF8*	*GID4**	*IFNW1*	*KLHL9*	*MDM4*	*NFE2L2*	*PAX8*	*POLH*	*RAD18**
ARID2	*BTG2**	*CDK8**	*CYP2C19*	*EIF4A3*	*ETV6*	*FGF9*	*GLI1*	*IGF1*	*KMT2A*	*MED12*	*NFKBIA**	*PAXIP1*	*POLQ**	*RAD21**
ASXL1	*BTK*	*CDKN1A*	*CYP3A4**	*EIF4B*	*EWSR1**	*FGFR1*	*GNA11*	*IGF1R*	*KMT2B*	*MEF2B**	*NHEJ1**	*PBRM1**	*POT1*	*RAD50*
ATM‡	*BUB1B**	*CDKN1B*	*DAXX*	*EIF4E*	*EXO1**	*FGFR2*	*GNA13**	*IGF2*	*KMT2C*	*MEN1‡*	*NKX2-1*	*PCBP1*	*POU2F2*	*RAD51*
ATMIN	*C9orf78**	*CDKN1C*	*DCUN1D1*	*EIF4E2*	*EZH1*	*FGFR3*	*GNAQ*	*IGF2BP3**	*KMT2D*	*MERTK*	*NOTCH1*	*PCBP2**	*PPARG*	*RAD51B*
ATR	*CALR*	*CDKN2A‡*	*DDIT3**	*ELAVL1**	*EZH2*	*FGFR4*	*GNAS*	*IGF2R*	*KNSTRN**	*MET*	*NOTCH2*	*PCDH15**	*PPIG**	*RAD51C‡*

*Regions of interest covered by the panel; some exons are not included.
†Reporting is enabled for pathogenic germline alterations only. Somatic alterations are not reported.
‡Reporting is enabled for both pathogenic germline and somatic alterations.

GUARDANT360 Liquid CDx

Assay Specifications

Gene panel (Continued)

All four major classes of alterations detected

SNVs and indels *(741 genes)*

RAD51D‡	*ROS1*	*SF3B1*	*SOX9*	*TEK*	*TPMT*	*WEE1*
*RAD52**	*RPA1**	*SF3B3**	*SPEN*	*TEN1*	*TRAF2*	*WRN*
RAD54L	*RPS27A**	*SH2D1A*	*SPOP*	*TENT5C*	*TRAF3*	*WT1*‡
RAET1E	*RPS6KA3*	*SHLD1*	*SRC*	*TERT*	*TRAF7*	*WWP1*
RAF1	*RPS6KB1*	*SHLD2**	*SRSF2*	*TET1*	*TRIM24**	*XBP1**
RARA	*RPS6KB2*	*SLC34A2*	*SRY*	*TET2*	*TRIP13*	*XPA*
*RASA1**	*RPTOR*	*SLFN11*	*SS18*	*TFE3*	*TSC1*‡	*XPC**
RB1†‡	*RRAGC*	*SLIT2**	*STAG2*	*TFRC*	*TSC2*‡	*XPO1*
*RBBP6**	*RSPO1*	*SMAD2*	*STAT1*	*TGFBR1*	*TSHR**	*XRCC1**
RBM10	*RSPO2*	*SMAD3**	*STAT3**	*TGFBR2*	*TSHZ2**	*XRCC2*
*RBMX**	*RSPO4*	*SMAD4*‡	*STAT4**	*THRAP3**	*TYMP*	*XRCC3*
RECQL	*RUNX1*	*SMARCA2*	*STK11*‡	*TIA1**	*TYMS*	*XRCC4**
RECQL4	*RUNX1T1**	*SMARCA4*	*STK19**	*TIPARP*	*TYRO3**	*XRCC5**
RET‡	*RXRA*	*SMARCAL1*	*STK40*	*TMEM127*	*U2AF1*	*XRCC6**
REV3L	*RYBP*	*SMARCB1*	*STN1*	*TMPRSS2*	*UBE2T**	*YAP1**
RGS1	*SAMHD1*	*SMARCD1*	*SUFU*	*TNFAIP3*	*UGT1A1**	*YES1*
RHEB	*SDC4*	*SMARCE1**	*SYK**	*TNFRSF14**	*UIMC1*	*ZC3H13**
RHOA	*SDHA*†	*SMC1A*	*SYNCRIP**	*TNFRSF1A*	*ULBP1*	*ZC3H18**
RHOB	*SDHAF2*	*SMC3*	*TACSTD2*	*TNK2**	*ULBP3*	*ZC3H4**
RICTOR	*SDHB*†	*SMO*	*TAF1L*	*TNPO1**	*USP28*	*ZMYM3**
RIF1	*SDHC*†	*SNCAIP*	*TAP1*	*TOP1*	*USP7*	*ZNF217*
*RILPL1**	*SDHD*†	*SOCS1*	*TAP2*	*TOP2A*	*USP9X**	*ZNF703**
RIT1	*SEM1**	*SOCS3*	*TAPBP*	*TOPAZ1**	*VEGFA**	*ZNRF3*
RNASEH2B	*SERPINB3*	*SOS1*	*TBC1D7*	*TP53*‡	*VEGFB*	*ZRSR2**
RNF43	*SERPINB4*	*SOX10**	*TBX3**	*TP53BP1*	*VHL*‡	
ROBO1	*SESN2*	*SOX17*	*TCERG1**	*TP63**	*VIRMA**	
ROBO2	*SETD2*	*SOX2*	*TCF7L2*	*TP73**	*WBP11**	

CNAs *(2 Genes)*

ERBB2
MET

CNL *(1 Gene)*

BRCA1

Fusions/Rearrangements *(9 Genes)*

ALK
RET
ROS1
NRG1
NTRK1
NTRK2
NTRK3
FGFR2
FGFR3

*Regions of interest covered by the panel; some exons are not included.
†Reporting is enabled for pathogenic germline alterations only. Somatic alterations are not reported.
‡Reporting is enabled for both pathogenic germline and somatic alterations.

Performance specifications

Alterations	Analytical Sensitivity*	Allelic Fraction/ Copy Number†		Analytical Specificity‡	Threshold for Positivity
		Low Input	High Input		
SNVs	≥ 94.9%	≥ 1%	≥ 0.2%	≥ 99.8%	≥ 0.001% MAF
Indels	≥ 95.0%	≥ 0.9%	≥ 0.2%	≥ 99.9%	≥ 0.01% MAF
CNAs	≥ 91.6%	≥ 2.3-2.4 copies	≥ 2.3-2.4 copies	≥ 99.9%	≥ 2.18-2.2 copies
CNL	≥ 95.0%	22.7%‖	-	≥ 97.5%	Tumor fraction ≥ 20%
Fusions/Rearrangements	≥ 94.6%	≥ 0.6-1.6%	≥ 0.2-0.4%§	≥ 99.7%	≥ 2 unique molecules

Low input is defined as 400-500 NSC. High input is defined as 30ng.

*Analytical Sensitivity defined as analytical concordance with an orthogonal NGS device for clinically significant variants

†Demonstrated Allelic Fraction/Copy Number at 95% detection rate, limit of detection (LoD), at low and high input

‡Analytical Specificity defined as per-variant NPA against an orthogonal NGS comparator

§LoD established and/or verified using clinical samples for all variant categories

‖Reported as TF

GUARDANT360 Liquid CDx

Assay **Specifications**

Guardant360® Liquid CDx Intended Use

Guardant360® Liquid CDx is a qualitative next generation sequencing-based *in vitro* diagnostic device that uses targeted high throughput hybridization-based capture technology for detection of single nucleotide variants (SNVs) and insertions and deletions (indels) in 741 genes, copy number amplifications (CNAs) in two genes, copy number loss (CNL) in one gene, rearrangements in nine genes. Guardant360 Liquid CDx utilizes circulating cell-free DNA (cfDNA) from plasma of peripheral whole blood collected in Streck Cell-Free DNA Blood Collection Tubes (BCTs). The test is intended to be used as a companion diagnostic to identify patients who may benefit from treatment with the therapies listed in Table 1-1 in accordance with the approved therapeutic product labeling. Additionally, the test is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for cancer patients with solid malignant neoplasm. The test is for use with patients previously diagnosed with cancer and in conjunction with other laboratory and clinical findings.

Table 1-1 Companion Diagnostic Indications:

Indication	Biomarker	Therapy
Breast cancer	*ESR1 missense mutations between codons 310-547*	ORSERDU™ (elacestrant)
	ESR1, E380, V422del, S463, L469, L536, Y537, and D538 mutations	INLURIYO™ (imlunestrant)
Colorectal cancer	*BRAF* V600E	BRAFTOVI® (encorafenib) in combination with ERBITUX® (cetuximab)
Non-small cell lung cancer (NSCLC)	*EGFR* exon 19 deletions, L858R, and T790M*	TAGRISSO® (osimertinib)
	EGFR exon 20 insertions	RYBREVANT® (amivantamab-vmjw)
	ERBB2/HER2 activating mutations (SNVs and exon 20 insertions)	ENHERTU® (fam-trastuzumab deruxtecan-nxki)
	KRAS G12C	LUMAKRAS™ (sotorasib)

A negative result from a plasma specimen does not assure that the patient's tumor is negative for genomic findings. Patients who are negative for the biomarkers listed in **Table 1-1** should be reflexed to tissue biopsy testing for **Table 1-1** biomarkers using an FDA-approved tumor tissue test, if feasible. *The efficacy of TAGRISSO (osimertinib) has not been established in the *EGFR T790M* plasma-positive, tissue-negative or unknown population and clinical data for T790M plasma-positive patients are limited; therefore, testing using plasma specimens is most appropriate for consideration in patients from whom a tumor biopsy cannot be obtained. Genomic findings other than those listed in **Table 1-1** are not prescriptive or conclusive for labeled use of any specific therapeutic product. Guardant360 Liquid CDx is a single-site assay performed at Guardant Health, Inc.

Contraindications

There are no known contraindications.

Warnings and Precautions

- Alterations reported may include somatic (not inherited) or germline (inherited) alterations. The assay filters germline variants from reporting except for pathogenic alterations in 38 genes. However, if a reported alteration is suspected to be germline, confirmatory testing should be performed using a validated germline test, as this assay is not intended to replace comprehensive germline testing or to provide definitive information about cancer predisposition.
- Genomic findings from cfDNA may originate from circulating tumor DNA (ctDNA) fragments, germline alterations, or non-tumor somatic alterations, such as clonal hematopoiesis of indeterminate potential (CHIP).
- Allow the Streck blood collection tube to fill completely until blood stops flowing into the tube. Underfilling of tubes with less than 5 mL of blood (bottom of the label indicates 5 mL fill when tube is held vertically) may lead to incorrect analytical results or poor product performance. This tube has been designed to fill with 10 mL of blood.

Limitations

- For *in vitro* diagnostic use.
- For prescription use only. This test must be ordered by a qualified medical professional in accordance with clinical laboratory regulations.
- The test is not intended to be used for standalone diagnostic purposes.
- The test is intended to be performed on specific serial number-controlled instruments by Guardant Health, Inc.
- A negative result for any given variant does not preclude the presence of this variant in tumor tissue.
- The efficacy of TAGRISSO (osimertinib) has not been established in the EGFR T790M plasma- positive, tissue-negative or unknown population and clinical data for T790M plasma-positive patients are limited; therefore, testing using plasma specimens is most appropriate for consideration in patients from whom a tumor biopsy cannot be obtained.
- ORSERDU efficacy has not been established in patients with ESR1 missense mutations < 0.03% MAF.
- INLURIYO efficacy has not been established in patients with ESR1 V422 deletion < 0.19% MAF and in patients with ESR1 SNVs < 0.03% MAF.
- BRAFTOVI + ERBITUX efficacy has not been established in patients with BRAF V600E mutation < 0.06% MAF.
- TAGRISSO efficacy has not been established in patients with EGFR exon 19 deletions < 0.07% MAF, in patients with EGFR L858R < 0.12% MAF, and in patients with EGFR T790M < 0.05% MAF.
- RYBREVANT efficacy has not been established in patients with EGFR exon 20 insertions < 0.05% MAF.
- LUMAKRAS efficacy has not been established in patients with KRAS G12C biomarkers < 0.05% MAF.
- ENHERTU efficacy has not been established in patients with ERBB2 exon 20 insertions < 0.03% MAF and in patients with ERBB2 SNVs < 0.18% MAF.

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ONC-US-00552 05/2026

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Limitations (Continued)

- Decisions on patient care and treatment must be based on the independent medical judgment of the treating physician, taking into consideration all applicable information concerning the patient's condition, such as patient and family history, physical examinations, information from other diagnostic tests, and patient preferences, in accordance with the standard of care.
- ctDNA shedding rate may be lower in patients with primary central nervous system (CNS) tumors.

As a professional service, Guardant360 Liquid CDx assesses 746 genes and generates a professional services report that includes MSI-High status, bTMB, Viral (HBV/EBV) detection, pharmacogenomics, HLA genotyping, and additional features powered by InfinityAI.^

^These additional features are reported by Guardant360 Liquid CDx as a professional service and have not been cleared or approved by the US FDA.