

# About Guardant360

Guardant360 is a comprehensive liquid profiling test that evaluates 740 genes and includes TMB, MSI status, CHIP filtering, and methylation-based features.

## Test Specifications

Sample input	Sample specifications	Turnaround time
Two 10 mL tubes of whole blood	Ship same or next day at room temperature - do not freeze or refrigerate	7 days from sample receipt to results*

## Performance Specifications

Alterations	Limit of Detection at 95% Sensitivity <sup>†</sup>	Specificity	Threshold for Positivity <sup>‡</sup>
SNVs	0.20%	≥99.9%	≥0.001%
Indels	0.26%	≥99.9%	≥0.01%
CNAs	2.46 copies	≥99.9%	≥2.16 copies
Fusions/Rearrangements	0.15%	≥99.9%	≥2 unique molecules
MSI-High	0.05%	≥99.9%	—
Tumor Fraction	0.05%	—	—
TMB	≥0.3% <sup>§</sup>	—	—
Promoter Methylation	1.6%	—	≥5 methylated molecules

\*Median turnaround time from sample receipt to results.

<sup>†</sup>Limit of detection (LoD) defined as the allele fraction/copy number at which the test has a 95% probability of detection for oncogenic variants and genes with relevance in guidelines, drug labels, and clinical trials.

<sup>‡</sup>Indicates mutant allele fraction for detected SNVs and Indels.

<sup>§</sup>Tumor mutation burden (TMB) evaluable at or above a sample allele fraction of 0.3%.

CHIP: Clonal Hematopoiesis of Indeterminate Potential; CNA: Copy Number Amplification; MSI: Microsatellite Instability; SNV: Single Nucleotide Variant.

**Important Note:** The Guardant360 test was developed as a Laboratory Developed Test (LDT), and its performance characteristics determined, by the Guardant Health Clinical Laboratory in Redwood City, CA, USA, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity testing. This test has not been cleared or approved by the US FDA.

## Gene Panel

MSI status - Qualitative result

TMB - Mutations per megabase

CHIP - Potential variants noted

Tumor fraction - Percent

ABCB1	BTG1	CUX1	ERCC6L2	FZD10	INTS6L	MKNK1	PBRM1 <sup>††</sup>	PTPRT	SHLD2	TNK2
ABL1	BTG2	CWC22	ERCC8	FZD2	IRF1	MLH1 <sup>††</sup>	PCBP1	QKI	SLC34A2	TNPO1
ABL2	BTK	CXCR4	EREG	FZD3	IRF2	MLH3	PCBP2	RAB35	SLFN11	TOP1
ABRAXAS1	BUB1B	CYLD	ERF	FZD4	IRF4	MLST8	PCDH15	RAC1	SLIT2	TOP2A
ACVR1	C9orf78	CYP17A1	ERG	FZD5	IRS2	MPL	PDCD1	RAD18	SMAD2	TOPAZ1
ACVR1B	CALR	CYP19A1	ERRF1	FZD6	JAK1	MRAS	PDCD1LG2	RAD21	SMAD3	TP53 <sup>††</sup>
ACVR2A	CARD11	CYP2C19	ESR1 <sup>#</sup>	FZD7	JAK2	MRE11	PDE7A	RAD50 <sup>††</sup>	SMAD4 <sup>††</sup>	TP53BP1
ADARB2	CASP8	CYP3A4	ETS1	FZD8	JAK3	MSH2 <sup>††</sup>	PDGFRA <sup>#</sup>	RAD51 <sup>††</sup>	SMARCA2	TP63
ADGRA2	CASR	DAXX	ETV1	FZD9	JUN	MSH3	PDGFRB	RAD51B	SMARCA4	TP73
ADGRG4	CAV1	DCUN1D1	ETV4	GAS6	KAT6A	MSH6 <sup>††</sup>	PDK1	RAD51C <sup>††††</sup>	SMARCAL1	TPMT
AFDN	CBFB	DDIT3	ETV5	GATA1	KAT6B	MTAP <sup>††††</sup>	PDPK1	RAD51D <sup>††††</sup>	SMARCB1	TRAF2
AGGF1	CBL	DDR1	ETV6	GATA2	KDM4A	MTHFR	PHF6	RAD52	SMARCD1	TRAF3
AIP	CBLB	DDR2	EWSR1	GATA3	KDM5A	MTOR	PHLPP1	RAD54L	SMARCE1	TRAF7
AKT1	CCAR1	DDX17	EXO1	GATA4	KDM5B	MUTYH <sup>††</sup>	PHLPP2	RAE1E	SMC1A	TRIM24
AKT1S1	CCN6	DDX18	EZH1	GATA6	KDM5C	MYB	PHOX2B	RAF1 <sup>#</sup>	SMC3	TRIP13
AKT2	CCNA2	DDX27	EZH2	GATA3	KDM6A	MYC <sup>#</sup>	PIAS4	RARA	SMO	TSC1
AKT3	CCNB1	DDX3X	FAAP100	GID4	KDR	MYCL	PIK3C2B	RASA1	SNCAIP	TSC2 <sup>††</sup>
ALB	CCND1 <sup>#</sup>	DDX41	FAAP20	GLI1	KEAP1 <sup>††††</sup>	MYCN	PIK3CA <sup>#</sup>	RB1 <sup>††††</sup>	SOC1	TSHR
ALK <sup>#</sup>	CCND2 <sup>#</sup>	DEPDC5	FAAP24	GNA11	KIN	MYD88	PIK3CB	RBBP6	SOC5	TSZ2
ALOX12B	CCND3	DEPTOR	FANCA <sup>††</sup>	GNA13	KIT <sup>#</sup>	MYOD1	PIK3CD	RBM10	SOS1	TYMP
ALOX15B	CCNE1 <sup>#</sup>	DHX15	FANCB	GNAQ	KLF4	NAB2	PIK3CG	RBMX	SOX10	TYMS
ALOX5	CCNE2	DHX16	FANCC	GNAS	KLHL6	NBN	PIK3R1	RECQL	SOX17	TYRO3
AMER1	CD274	DHX36	FANCD2	GPATCH8	KLHL9	NCOR1	PIK3R2	RECQL4	SOX2	U2AF1
APC <sup>††</sup>	CD276	DHX9	FANCE <sup>††</sup>	GPC3	KMT2D	NCR1	PIK3R3	RET <sup>1</sup>	SOX9	UBE2T
APEX1	CD74	DICER1	FANCF <sup>††</sup>	GREM1	KMT2B	NCR3	PIM1	REV3L	SPEN	UGT1A1
APLN	CD79A	DIS3L2	FANCG <sup>††</sup>	GRIN2A	KMT2C	NEGR1	PIN1	RGS1	SPOP	UIMC1
AR <sup>#</sup>	CD79B	DLL4	FANCI	GSK3B	KMT2D	NELFE	PKM	RHEB	SRC	ULBP1
ARAF	CDC27	DNAJB1	FANCL <sup>††</sup>	GSTM1	KNSTRN	NF1 <sup>††</sup>	PLCG2	RHOA	SRSF2	ULBP3
ARFRP1	CDC5L	DNMT1	FANCM	GSTP1	KRAS <sup>#</sup>	NF2 <sup>††</sup>	PLEKHS1	RHOB	SRY	USP28
ARHGAP35	CDC7	DNMT3A	FAS	H3-4	LATS1	NFE2L2	PLRG1	RICTOR	SS18	USP7
ARID1A <sup>††</sup>	CDC73	DNMT3B	FAT1	H3F3A	LGR4	NFKBIA	PMS1	RIF1	STAG2	USP9X
ARID1B <sup>††</sup>	CDH1 <sup>††</sup>	DOT1L	FBXW7	HACD4	LGR5	NHEJ1	PMS2 <sup>††</sup>	RILPL1	STAT1	VEGFA
ARID2	CDH6	DPYD	FCGR2A	HDAC2	LGR6	NKX2-1	POLA1	RIT1	STAT3	VEGFB
ASXL1	CDK11A	DUSP4	FCGR3A	HDAC6	LIG1	NOTCH1	POLD1	RNASEH2B	STAT4	VHL
ATM <sup>††††</sup>	CDK12 <sup>††††</sup>	DYNLL1	FEN1	HELO	LIG4	NOTCH2	POLE <sup>††</sup>	RNF43	STK11 <sup>††††</sup>	VIRMA
ATMIN	CDK4 <sup>#</sup>	DYRK2	FGF1	HES1	LMO1	NOTCH3	POLH	ROBO1	STK19	WBP11
ATR <sup>††</sup>	CDK6 <sup>#</sup>	E2F3	FGF10	HEY1	LRP1B	NOTCH4	POLQ	ROBO2	STK40	WEE1
ATRX	CDK7	ECT2L	FGF12	HEYL	LRP2	NOVA1	POT1	ROS1 <sup>†</sup>	STN1	WRN
AURKA	CDK8	EFTUD2	FGF14	HGF	LRP5	NPM1	POU2F2	RPA1	SUFU	WT1
AURKB	CDKN1A	EGFR <sup>#</sup>	FGF19	HNF1A	LRP6	NPRL2	PPARG	RPS27A	SYK	WWP1
AURKC	CDKN1B <sup>††</sup>	EIF1AX	FGF2	HNRNPDL	LTK	NPRL3	PIIG	RPS6KA3	SYNCRIP	XBP1
AXIN1	CDKN1C	EIF4A1	FGF23	HOXB13	LYN	NRAS	PPM1D	RPS6KB1	TACSTD2 (TRP2)	XPA
AXIN2	CDKN2A <sup>††††</sup>	EIF4A2	FGF3	HRAS	LZTR1	NRG1 <sup>†</sup>	PPP2CA	RPS6KB2	TAF1L	XPC
AXL	CDKN2B	EIF4A3	FGF4	HSD3B1	MAD2L2	NSD1	PPP2R1A	RPTOR	TAP1	XPO1
B2M <sup>††</sup>	CDKN2C	EIF4B	FGF5	HSP90AA1	MALT1	NSD2	PPP2R2A	RRAGC	TAP2	XRCC1
BABAM1	CEBPA	EIF4E	FGF6	ICOSLG	MAP2K1	NSD3	PPP3CA	RSPO1	TABBP	XRCC2
BABAM2	CELF4	EIF4E2	FGF7	ID3	MAP2K2	NSRP1	PPP6C	RSPO2	TBC1D7	XRCC3
BAP1	CEP295	ELAVL1	FGF8	IDH1	MAP2K4	NTHL1	PRDM1	RSPO4	TBX3	XRCC4
BARD1	CFAP20	ELAVL2	FGF9	IDH2	MAP3K1	NTRK1 <sup>†</sup>	PREX1	RUNX1	TCERG1	XRCC5
BCL2	CHD4	ELF3	FGFR1 <sup>#</sup>	IDO1	MAP3K13	NTRK2 <sup>†</sup>	PREX2	RUNX1T1	TCF7L2	XRCC6
BCL2L1	CHEK1 <sup>††</sup>	ELOC	FGFR2 <sup>#</sup>	IFNG	MAP4K3	NTRK3 <sup>†</sup>	PRKAR1A	RXRA	TEK	YAP1
BCL2L2	CHEK2 <sup>††††</sup>	EML4	FGFR3 <sup>†</sup>	IFNGR1	MAPK1	NUMA1	PRKCI	RYBP	TEN1	YES1
BCL6	CIC	EMSY	FGFR4	IFNGR2	MAPK3	NUMB	PRKDC	SAMHD1	TENT5C	ZC3H13
BCOR	CMTM4	EP300	FH	IFNW1	MAPKAP1	NUP93	PRKN	SDC4	TERT <sup>†</sup>	ZC3H18
BCORL1	CMTM6	EPCAM	FLCN	IGF1	MARK2	NUTM1	PRMT5	SDHA <sup>††</sup>	TET1	ZC3H4
BCR	CNOT3	EPHA3	FLT1	IGF1R	MAX	P2RY8	PRPF40B	SDHAF2	TET2	ZMYM3
BIRC5	CREBBP	EPHA5	FLT3	IGF2	MCL1	PABPC1	PRPF4B	SDHB <sup>††</sup>	TFE3	ZNF217
BLM	CRKL	EPHA7	FLT4	IGF2BP3	MDC1	PAK1	PSENEN	SDHC <sup>††</sup>	TFRC	ZNF703
BMPR1A	CRTC1	EPHB1	FOXA1	IGF2R	MDM2	PAK3	PSMB10	SDHD <sup>††</sup>	TGFBF1	ZNF3
BRAF <sup>#</sup>	CSF1R	ERBB2 <sup>#</sup> (HER2)	FOXL2	IKBKE	MDM4	PALB2 <sup>††††</sup>	PSMB8	SEM1	TGFBF2	ZRSR2
BRCA1 <sup>††††</sup>	CSF3R	ERBB3	FOXO1	IKZF1	MED12	PARG	PSMB9	SERPINB3	THRAP3	
BRCA2 <sup>††††</sup>	CTC1	ERBB4	FOXP1	IL1R1	MEF2B	PARP1	PTCH1	SERPINB4	TIA1	
BRCC3	CTCF	ERCC1	FRS2	IL2RA	MEN1	PARP2	PTDSS1	SESN2	TIPARP	
BRD2	CTLA4	ERCC2	FUBP1	IL2RB	MERTK	PAX3	PTEN <sup>††††</sup>	SETD2	TMEM127	
BRD3	CTNNA1	ERCC3	FUBP3	IL2RG	MET <sup>#</sup>	PAX5	PTPN11	SF3B1	TMPRSS2	
BRD4	CTNNA1	ERCC4	FUS	IL7R	MGA	PAX7	PTPN2	SF3B3	TNFAIP3	
BRIP1 <sup>††</sup>	CUL3	ERCC5	FYN	INHBA	MGMT <sup>††</sup>	PAX8	PTPRD	SH2D1A	TNFRSF14	
BSG	CUL4A	ERCC6	FZD1	INPP4B	MITF	PAXIP1	PTPRS	SHLD1	TNFRSF1A	

<sup>†</sup>Includes TERT promoter region. <sup>#</sup>Includes CNAs. <sup>†</sup>Includes Fusions/Rearrangements. <sup>††</sup>Includes Copy Number Losses. <sup>†††</sup>Includes Promoter Methylation. <sup>††††</sup>Promoter Methylation only. CHIP filter is based on a proprietary algorithm that identifies variants that are potentially derived from clonal hematopoiesis.