PGDx elio™ plasma complete

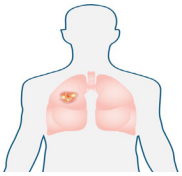
About PGDx elio™ plasma complete

PGDx elio™ plasma complete is an end-to-end kitted liquid biopsy solution that analyzes circulating tumor DNA for genetic alterations in cancer, eliminating the need for an invasive biopsy or tumor tissue. Designed to be used across the globe on the PGDx elio™ testing platform, PGDx elio plasma complete also includes automated bioinformatics ensuring consistent, high-quality results.

What does PGDx elio™ mean?

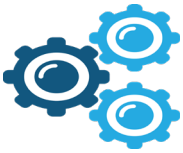
Empowering Local Insight for Oncology

End-to-end Kitted Solution



521 Genes From a Single Sample

Turn-key Bioinformatics Pipeline



Developed Under Design Control

Assay Specifications

PARAMETER	DETAILS
Panel Size	2.1MB
Panel Content and Variant Type	521 SNV & Indels 38 genes for amplifications 21 genes for translocations bMSI bTMB (Muts/Mb) LOH status
Sample requirement	plasma ctDNA
DNA input requirement	25ng recommended, 10ng minimum
Sample Pass Rate	97.4% overall pass rate (227/233)
Sequencing platform/flowcell	NovaSeq 6000/S2 flow cell
Sequence run	2 x 150 bp
Cases per sequencing run	16 (no external control required)
Workflow	Manual and Automated Available
Average total coverage	~20,000x

Performance Specifications

Variant	Reportable Range	Analytical Sensitivity (LOD95)	Analytical Specificity
Actionable SNVs/Indels	≥ 0.1% VAF	0.40% VAF	100%
Non-actionable SNVs/Indels	≥ 0.5% VAF	1.16% VAF	99.9%
All Translocations	≥ 3 fusion reads	0.33% VAF	100%
All Amplifications	≥ 1.15-fold	1.32-fold	100%

PRODUCT FEATURES

- Plasma analysis for pan-cancer solid tumor biomarker testing and discovery
- 500+ gene kitted assay developed under Design Control
- Comprehensive coverage of biomarkers, clinically relevant targets, cancer signaling pathways and DNA damage repair pathways
- Large panel size supports TMB and LOH

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PGDx elio™ plasma complete RUO gene panel
Proprietary Methods for Microsatellite Instability (bMSI), Tumor Mutation Burden (bTMB) and Loss of Heterozygosity (bLOH)
Full coding and specific exon analysis for SNVs and Indels in 521 well-characterized cancer genes

ABL1	BCORL1	CHEK1	EPCAM	FGF19	GRIN2A	KDM6A	MSH2	PAX5	PTPN11	SGK1	TLR9
ABL2	BCR	CHEK2	EPHA2	FGF23	GSK3B	KDR	MSH3	PAX8	PTPRD	SH2D1A	TMPRSS2
ACVR1	BIRC3	CIC	EPHA3	FGF3	H3F3A	KEAP1	MSH6	PAXIP1	PTPRT	SHLD1	TNFAIP3
ACVR1B	BIRC5	CREBBP	EPHA5	FGF4	H3F3C	KEL	MST1R	PBRM1	RAC1	SLFN11	TNFRSF14
ACVR2A	BLM	CRKL	EPHB1	FGF6	HDAC1	KIT	MTAP	PDCD1	RAD21	SLX4	TOP1
ADORA2A	BMP1	CRLF2	EPHB4	FGFR1	HDAC2	KLF4	MTOR	PDCD1LG2	RAD50	SMAD2	TOP2A
AHCTF1	BMPR1A	CRTC1	ERBB2	FGFR2	HDAC6	KMT2A	MUTYH	PDGFRA	RAD51	SMAD3	TP53
AKT1	BRAF	CSF1	ERBB3	FGFR3	HGF	KMT2B	MYB	PDGFRB	RAD51B	SMAD4	TP53BP1
AKT2	BRCA1	CSF1R	ERBB4	FGFR4	HIST1H1C	KMT2C	MYC	PDK1	RAD51C	SMARCA4	TP63
AKT3	BRCA2	CSF2	ERCC1	FH	HIST1H3B	KMT2D	MYCL	PDPK1	RAD51D	SMARCB1	TRAF3
ALB	BRD4	CSF3R	ERCC2	FLCN	HLA-A	KRAS	MYCN	PGR	RAD52	SMC3	TSC1
ALK	BRD7	CTC1	ERCC3	FLI1	HLA-B	LATS1	MYD88	PHF6	RAD54L	SMO	TSC2
ALMS1	BRIP1	CTCF	ERCC4	FLT1	HLA-C	LATS2	MYOD1	PHOX2B	RAF1	SOCS1	TSHR
ALOX12B	BTG1	CTLA4	ERCC5	FLT3	HNF1A	LRP1B	NBEA	PIK3C2B	RARA	SOX10	TYRO3
AMER1	BTG2	CTNNA1	ERCC6	FLT4	HOXB13	LTK	NBN	PIK3C2G	RASA1	SOX17	U2AF1
APC	BTK	CTNNB1	ERCC8	FOXA1	HRAS	LYN	NCOA3	PIK3C3	RB1	SOX2	UBE2T
AR	CALR	CUL3	ERG	FOXL2	HSP90AA1	LZTR1	NCOR1	PIK3CA	RBM10	SOX9	VEGFA
ARAF	CARD11	CUL4A	ERRFI1	FOXO1	HUWE1	MAD2L2	NF1	PIK3CB	RECQL4	SPOP	VHL
ARID1A	CASP8	CXCR2	ESR1	FOXP1	ID3	MAF	NF2	PIK3CD	REL	SPTA1	VTCN1
ARID1B	CBFB	CXCR4	ETV1	FUBP1	IDH1	MALT1	NFE2L2	PIK3CG	RET	SRC	WAS
ARID2	CBL	CYLD	ETV4	FZD1	IDH2	MAML1	NFKBIA	PIK3R1	REV3L	SRCAP	WEE1
ARID5B	CCND1	CYP17A1	ETV5	FZD10	IGF1	MAP2K1	NKX2-1	PIK3R2	RFC1	SRSF2	WRN
ASXL1	CCND2	DAXX	ETV6	FZD2	IGF1R	MAP2K2	NKX3-1	PIK3R3	RHEB	STAG2	WT1
ASXL2	CCND3	DDIT3	EWSR1	FZD3	IGF2	MAP2K4	NOTCH1	PIM1	RHOA	STAT3	XIAP
ATM	CCNE1	DDR1	EXO1	FZD4	IGF2R	MAP3K1	NOTCH2	PLCG2	RICTOR	STK11	XPA
ATR	CD22	DDR2	EZH2	FZD5	IKBKE	MAP3K13	NOTCH3	PMAIP1	RIF1	STN1	XPC
ATRX	CD274	DICER1	FAM175A	FZD6	IKZF1	MAPK1	NOTCH4	PMS1	RIT1	SUFU	XPO1
AURKA	CD276	DIS3	FAM35A	FZD7	IL10	MAPK3	NPM1	PMS2	RNF43	SUZ12	XRCC1
AURKB	CD70	DNMT1	FAM46C	FZD8	IL6ST	MAX	NRAS	POLD1	ROS1	SYK	XRCC2
AXIN1	CD79A	DNMT3A	FANCA	FZD9	IL7R	MCL1	NSD1	POLE	RPA1	TAF1	XRCC3
AXIN2	CD79B	DNMT3B	FANCC	GABRA6	INHBA	MDC1	NSD2	POLG	RPS6KA3	TBX3	XRCC4
AXL	CDC73	DOT1L	FANCD2	GATA1	INPP4B	MDM2	NSD3	POLQ	RPS6KA4	TCF3	XRCC5
B2M	CDH1	E2F3	FANCE	GATA2	INSR	MDM4	NTRK1	PPARG	RPS6KB2	TCF7L2	XRCC6
BAP1	CDK12	EED	FANCF	GATA3	IRF2	MED12	NTRK2	PPM1D	RPTOR	TEK	YAP1
BARD1	CDK2	EEF1A1	FANCG	GATA4	IRF4	MEF2B	NTRK3	PPP2R1A	RUNX1	TEN1	YES1
BAX	CDK4	EGFR	FANCI	GATA6	IRS1	MEN1	NUP93	PPP2R2A	RUNX1T1	TERC	ZNF217
BBC3	CDK6	EIF1AX	FANCL	GLI1	IRS2	MERTK	NUTM1	PPP6C	SDHA	TERT	ZRSR2
BCL10	CDK8	EIF4E	FANCM	GNA11	JAK1	MET	PAK1	PRDM1	SDHAF2	TET1	
BCL2	CDKN1A	ELF3	FAS	GNA13	JAK2	MITF	PAK7	PREX2	SDHB	TET2	
BCL2L1	CDKN1B	EML4	FAT1	GNAQ	JAK3	MLC1	PALB2	PRKAR1A	SDHC	TGFBR1	
BCL2L11	CDKN2A	EMSY	FBXW7	GNAS	JUN	MLH1	PARG	PRKDC	SDHD	TGFBR2	
BCL2L2	CDKN2B	EP300	FGF10	GPC3	KAT6A	MLH3	PARK2	PTCH1	SETBP1	TLR4	
BCL6	CDKN2C	EP400	FGF12	GPR124	KDM5A	MPL	PARP1	PTEN	SETD2	TLR7	
BCOR	CEBPA	EPAS1	FGF14	GREM1	KDM5C	MRE11A	PARP2	PTK2	SF3B1	TLR8	

Amplifications (38 Genes)

AXL	CCND2	CDK4	ERBB2	FGF4	FGFR4	MET	MYC	PIK3CA	RB1		
BRCA1	CCND3	CDKN2A	ERRFI1	FGFR1	KDR	MLC1	MYCN	PIK3CB	VEGFA		
BRCA2	CCNE1	CDKN2B	FGF19	FGFR2	KIT	MLH1	PALB2	PIK3R1			
CCND1	CD274	EGFR	FGF3	FGFR3	MDM2	MSH2	PDGFRA	PTEN			

Translocations (21 Genes)

ALK	BRAF	BRCA2	ETV4	EWSR1	FGFR2	NTRK1	NTRK3	PDGFRB	RET	TMPRSS2	
AXL	BRCA1	EGFR	ETV6	FGFR1	FGFR3	NTRK2	PDGFRA	RAF1	ROS1		

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