PGDx elio™ tissue complete

A pan solid tumor CGP test

Actionable Insights | Personalized Care

PGDx elio™ tissue complete enables rapid and actionable genomic insights for all patients with advanced cancer. Our FDA cleared and CE-IVD marked comprehensive tumor profiling kit is available for labs to ensure every patient has access to personalized treatment options.

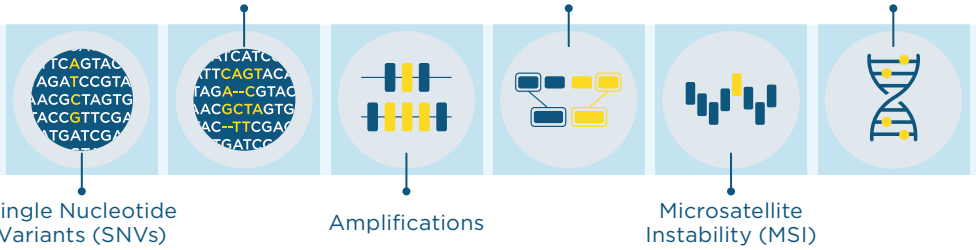
Product Features

- **Trustworthy:** FDA cleared and CE-IVD marked with overall clinical pass rate of 92.9%
- **Fast:** results generated in 4-5 days via streamlined 6-hour hands-on workflow and automated bioinformatics that enable quick high-throughput runs
- **Actionable:** 500+ solid tumor-related genes, including all FDA approved and professional guidelines biomarkers, with easy-to-interpret results
- **Accessible:** on-site testing within your institution's molecular laboratory
- **Flexible:** complete data ownership, easy access to raw data and intermediate files, and customizable reporting in RUO mode

Development and Validation

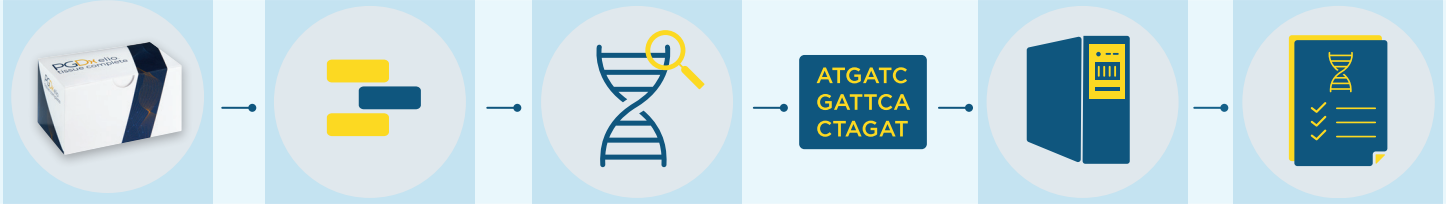
- **Pan solid tumor:** 35 solid tumor types across 9 organ systems
- **Robust:** >7,300 analytical samples tested
- **Rigorous:** 15,000 hours of sequencing time
- **Accurate:** 13 orthogonal methods used for comparison, including PCR, IHC, FISH, RNA and DNA-based NGS approaches

PGDx elio tissue complete identifies somatic mutations with high accuracy and sensitivity



Simplify Your Clinical Workflow

From extracted DNA to automatically generated clinical reports, PGDx has developed methods to optimize your clinical workflow and results. The PGDx elio tissue complete test is FDA cleared and CE-IVD marked, eliminating the need for time-consuming and costly validation. Deployment only requires verification under the direction of a laboratory director. This streamlines your lab with faster, more cost-effective access to reliable, high-quality comprehensive genomic profiling (CGP) insights.



PGDx elio™ tissue complete Kit → Library Preparation → Targeted Hybrid Capture → Next-Generation Sequencing → Automated Bioinformatics → Clinical Report

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In-House CGP with Full Data Ownership

Offer rapid genomic insights without specimens or data ever leaving your institution. Our IVD test automatically generates intuitive clinical reports that guide personalized treatment decisions. When using elio tissue complete for research purposes, you can also access customizable reporting through our professional services.

- **Eliminate** delayed results from sending out specimens
- **Access** rapid comprehensive tumor genomic insights
- **Personalize** treatment decisions with confidence
- **Explore** new reimbursement and research opportunities

Overview of Performance across Genomic Alterations

Alteration	Positive Predictive Value	Negative Predictive Value
EGFR Exon 19 Deletion	100.0%	100.0%
EGFR L858R	100.0%	100.0%
BRAF V600	100.0%	95.7%
Hotspot Sequence Mutations	93.4%	100.0%
Amplification	93.0%	92.9%
Translocation	95.0%	98.0%
Microsatellite Instability	98.8%	99.3%
Tumor Mutation Burden	Spearman Correlation	Tested Range (Muts/Mb)
	0.903	0.2 - 89.7

Accuracy of sequence mutations, comprising single nucleotide variants and insertion-deletions, were compared to two distinct orthogonal NGS panels to assess concordance. Amplifications and translocations were compared to biomarker specific FISH assays and detection of microsatellite instability was compared to PCR for concordance. Tumor mutation burden was correlated to whole-exome sequencing derived mutation burden to assess accuracy.

Assay Specifications

Sample requirements	Tumor only, FFPE tissue
Tumor purity minimum	20%
Sample pass rate	92.9%
DNA input required	50 ng minimum; 100 ng recommended
Library prep hands-on time	6 hours (2-day workflow)
Cases per sequencing run	15 samples and 1 control (included in kit)
Regions analyzed	Coding regions of 505 genes; non-coding regions for translocations
Panel size	2.23 Mb total
Read length	2x150bp
Average total coverage	2,300x
Bioinformatics	Patented PARE, Digital Karyotyping, and VariantDx
Turnaround time	4-5 days

PGDx elio tissue complete is an FDA cleared and CE-IVD marked device for use in tumor profiling applications.

Learn more about PGDx at PersonalGenome.com
For more details about our products, contact Sales@PGDx.com
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Market-leading Sensitivity Across Variant Types

SNVs & Indels

Variant	MAF Range
Hotspot SNVs	3.1% - 5.4%
Non-hotspot SNVs	6.3% - 17.8%
Indels at homopolymer context	13.7% - 17.5%
Indels at non-homopolymer context	6.1% - 10.9%

Amplifications, Translocations, & MSI

Variant	LoD Tumor Purity
MSI-H	18.1%
ERBB2 amplifications	4.4%
ALK translocations	5.6%
NTRK2 translocations	30%
NTRK3 translocations	11.5%
RET translocations	12.8%

Reportable Variants with Evidence of Clinical Significance

Central Nervous System (CNS)	
BRAF	V600E
H3F3A	K28M G34R, G34V
IDH1	R132
IDH2	R140Q, R172

Thyroid	
BRAF	V600E
RET	A883F, C634, M918T

Breast	
ERBB2	Amplification
PIK3CA	C420R, E542K, E545A, Q546, H1047

Gastric	
ERBB2	Amplification

Ovarian	
BRCA1/2	Deleterious Mutations

Prostate	
BRCA1/2	Deleterious Mutations

Rectal	
BRAF	V600E
KRAS	Exon 2, 3, and 4 Mutations
NRAS	Exon 2, 3, and 4 Mutations

Melanoma	
BRAF	V600
KIT	D816H, D816Y, V825A

Non-Small Cell Lung Cancer (NSCLC)	
ALK	Translocations
BRAF	V600E
EGFR	G719, S768I, T790M, L858R, L861Q, Exon 19 Deletions, Exon 19 Insertions, Exon 20 Insertions
ERBB2	V659E, Exon 20 Deletions, Exon 20 Insertions
KRAS	G12, G13
MET	Exon 14, Splice Site Events
RET	Translocations

Gastro-Intestinal Stromal Tumors (GISTs)	
BRAF	V600E
KIT	V825A, Exon 9 Mutations, Exon 11 Mutations
PDGFRA	V561D, D842V

Pancreatic	
BRCA1/2	Deleterious Mutations

Colon	
BRAF	V600E
KRAS	Exon 2, 3, and 4 Mutations
NRAS	Exon 2, 3, and 4 Mutations

Solid Tumor	
MSI	MSI-H/MSS
TMB	Muts/Mb
NTRK2	Translocations
NTRK3	Translocations

Intended Use

The PGDx elio™ tissue complete assay is a qualitative in vitro diagnostic device that uses targeted next generation sequencing of DNA isolated from formalin-fixed, paraffin-embedded tumor tissue from patients with solid malignant neoplasms to detect tumor gene alterations in a broad multi-gene panel. PGDx elio tissue complete is intended to provide tumor mutation profiling information on somatic alterations (SNVs, small insertions and deletions, one amplification and four translocations), microsatellite instability (MSI) and tumor mutation burden (TMB) for use by qualified healthcare professionals in accordance with professional guidelines in oncology for previously diagnosed cancer patients and is not conclusive or prescriptive for labeled use of any specific therapeutic product.

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Gene Panel

Proprietary method for MSI and TMB. Full coding and specific intron analyses in 505 well-characterized cancer genes.

SNVs and Indels (505)

ABL1	BMPR1A	CIC	ERBB2	FGF6	HNF1A	KRAS	MYCN	PIK3C2B	RAD51	SMAD3	TOP2A
ABL2	BRAF	CREBBP	ERBB3	FGFR1	HRAS	LATS1	MYD88	PIK3C2G	RAD51B	SMAD4	TP53
ACVR1	BRCA1	CRKL	ERBB4	FGFR2	HSD3B1	LATS2	MYOD1	PIK3C3	RAD51C	SMARCA4	TP53BP1
ACVR1B	BRCA2	CSF1	ERCC1	FGFR3	HSP90AA1	LMO1	NBN	PIK3CA	RAD51D	SMARCB1	TP63
ADORA2A	BRD4	CSF1R	ERCC2	FGFR4	HSP90AB1	LRP1B	NCOA3	PIK3CB	RAD52	SMARCD1	TRAF7
AKT1	BRIP1	CSF2	ERCC3	FH	ICOSLG	LTK	NCOR1	PIK3CD	RAD54B	SMO	TSC1
AKT2	BTG1	CSF3	ERCC4	FLCN	ID3	LYN	NF1	PIK3CG	RAD54L	SNCAIP	TSC2
AKT3	BTG2	CSF3R	ERCC5	FLT1	IDH1	LZTR1	NF2	PIK3R1	RAF1	SOCS1	TSHR
ALK	BTK	CTCF	ERCC6	FLT3	IDH2	MAF	NFE2L2	PIK3R2	RANBP2	SOX10	TYRO3
ALOX12B	BUB1B	CTLA4	ERCC8	FLT4	IFNGR1	MAGI2	NFKBIA	PIK3R3	RARA	SOX17	U2AF1
AMER1	C11ORF30	CTNNA1	ERG	FOXA1	IGF1	MAML1	NKX2-1	PIM1	RASA1	SOX2	VEGFA
APC	CALR	CTNNB1	ERRFI1	FOXL2	IGF1R	MAP2K1	NKX3-1	PLCG2	RB1	SOX9	VHL
AR	CARD11	CUL3	ESR1	FOXP1	IGF2	MAP2K2	NOTCH1	PLK2	RBM10	SPEN	VTCN1
ARAF	CASP8	CUL4A	ETV1	FRS2	IGF2R	MAP2K4	NOTCH2	PMAIP1	RECQL4	SPOP	WAS
ARFRP1	CBFB	CXCR2	ETV4	FUBP1	IKBKE	MAP3K1	NOTCH3	PMS1	REL	SPTA1	WEE1
ARID1A	CBL	CXCR4	ETV5	GABRA6	IKZF1	MAP3K13	NOTCH4	PMS2	RET	SRC	WHSC1
ARID1B	CCND1	CYLD	ETV6	GATA1	IL10	MAPK1	NPM1	PNRC1	RFWD2	STAG2	WHSC1L1
ARID2	CCND2	CYP17A1	EWSR1	GATA2	IL7R	MAX	NRAS	POLD1	RHOA	STAT3	WISP3
ARID5B	CCND3	DAXX	EXT1	GATA3	INHBA	MCL1	NSD1	POLE	RICTOR	STAT4	WRN
ASXL1	CCNE1	DCUN1D1	EXT2	GATA4	INPP4A	MDC1	NT5C2	POLH	RIT1	STK11	WT1
ASXL2	CD22	DDB2	EZH2	GATA6	INPP4B	MDM2	NTRK1	POT1	RNF43	STK40	XIAP
ATM	CD274	DDR1	FAM175A	GID4	INSR	MDM4	NTRK2	PPARG	ROS1	SUFU	XPA
ATR	CD276	DDR2	FAM46C	GLI1	IRF2	MED12	NTRK3	PPP2R1A	RPA1	SUZ12	XPC
ATRX	CD70	DICER1	FANCA	GNA11	IRF4	MEF2B	NUP93	PPP2R2A	RPS6KA4	SYK	XPO1
AURKA	CD79A	DIS3	FANCB	GNA13	IRS1	MEN1	NUTM1	PRDM1	RPS6KB2	TAF1	XRCC1
AURKB	CD79B	DNMT1	FANCC	GNAQ	IRS2	MERTK	PAK1	PREX2	RPTOR	TBX3	XRCC2
AXIN1	CDC73	DNMT3A	FANCD2	GNAS	JAK1	MET	PAK3	PRKAR1A	RUNX1	TEK	XRCC3
AXIN2	CDH1	DNMT3B	FANCE	GPC3	JAK2	MITF	PAK7	PRKCI	RUNX1T1	TERC	YAP1
AXL	CDK12	DOT1L	FANCF	GPR124	JAK3	MKNK1	PALB2	PRKDC	RYBP	TERT	YES1
B2M	CDK4	E2F3	FANCG	GREM1	JUN	MLH1	PARK2	PRSS1	SBDS	TET1	ZBTB2
BAP1	CDK6	EED	FANCI	GRIN2A	KAT6A	MLH3	PARP1	PRSS8	SDHA	TET2	ZNF217
BARD1	CDK8	EGFL7	FANCL	GRM3	KDM5A	MPL	PARP2	PTCH1	SDHAF2	TGFBR1	ZNF703
BBC3	CDKN1A	EGFR	FANCM	GSK3B	KDM5C	MRE11A	PARP3	PTEN	SDHB	TGFBR2	
BCL2	CDKN1B	EIF1AX	FAS	H3F3A	KDM6A	MSH2	PAX5	PTK2	SDHC	TIPARP	
BCL2L1	CDKN1C	EP300	FAT1	H3F3B	KDR	MSH3	PAX8	PTPN11	SDHD	TLR4	
BCL2L11	CDKN2A	EPAS1	FBXW7	H3F3C	KEAP1	MSH6	PBRM1	PTPRD	SETD2	TLR7	
BCL2L2	CDKN2B	EPCAM	FGF10	HDAC1	KEL	MST1R	PDCD1	PTPRO	SF3B1	TLR8	
BCL6	CDKN2C	EPHA2	FGF12	HDAC2	KIT	MTAP	PDCD1LG2	PTPRS	SGK1	TLR9	
BCOR	CEBPA	EPHA3	FGF14	HDAC6	KLF4	MTOR	PDGFRA	PTPRT	SH2D1A	TMEM127	
BCORL1	CHD2	EPHA5	FGF19	HGF	KLHL6	MUTYH	PDGFRB	QKI	SHQ1	TMPRSS2	
BCR	CHD4	EPHA7	FGF23	HIST1H1C	KMT2A	MYB	PDK1	RAC1	SLIT2	TNFAIP3	
BIRC2	CHEK1	EPHB1	FGF3	HIST1H2BD	KMT2C	MYC	PDPK1	RAD21	SLX4	TNFRSF14	
BLM	CHEK2	EPHB4	FGF4	HIST1H3B	KMT2D	MYCL	PHOX2B	RAD50	SMAD2	TOP1	

Amplifications - in IVD Mode (1)

ERBB2

Amplifications - in RUO Mode (27)

AXL	CCND1	CCNE1	EGFR	FGFR3	KIT	MLH1	MYCN	PIK3CA
BRCA1	CCND2	CD274	FGFR1	FGFR4	MDM2	MSH2	PALB2	PIK3CB
BRCA2	CCND3	CDK4	FGFR2	KDR	MET	MYC	PDGFRA	PIK3R1

Translocations - in IVD Mode (4)

ALK	NTRK2
RET	NTRK3

Translocations - in RUO Mode (16)

AXL	EGFR	ETV6	FGFR1	FGFR3	NTRK1	PDGFRB	ROS1
BRAF	ETV4	EWSR1	FGFR2	MYC	PDGFRA	RAF1	TMPRSS2

Learn more about PGDx at PersonalGenome.com

For more details about our products, contact Sales@PGDx.com

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The PGDx elio tissue complete test is for In Vitro Diagnostic Use. Refer to product documentation for complete intended use statement. MKPR-002-101421 – For US & EU Marketing Use.

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