PGDx elio™ plasma resolve

A pan solid tumor focused liquid biopsy assay

Biomarker Analysis and Discovery for Cancer Research

The PGDx elio™ plasma resolve kit evaluates a targeted panel of 33 well-characterized cancer genes using circulating tumor DNA (ctDNA). Get rapid, accurate results from low yielding plasma specimens from patients with solid tumors.

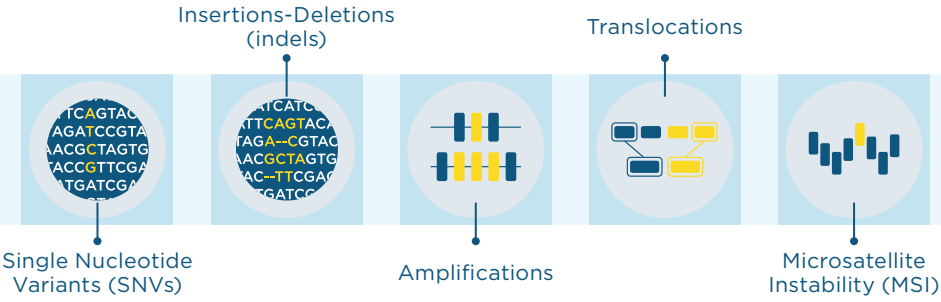
Product Features

- **Reliable:** highly accurate somatic mutation identification
- **Curated:** identifies variants in 33 full coding genes that have approved therapies or are in professional guidelines for oncology
- **Fast:** results generated in 4—5 days via streamlined workflow and automated bioinformatics that enable high-throughput runs
- **Accessible:** in-house testing with complete data ownership
- **Global:** available to clinical research labs around the world

Development

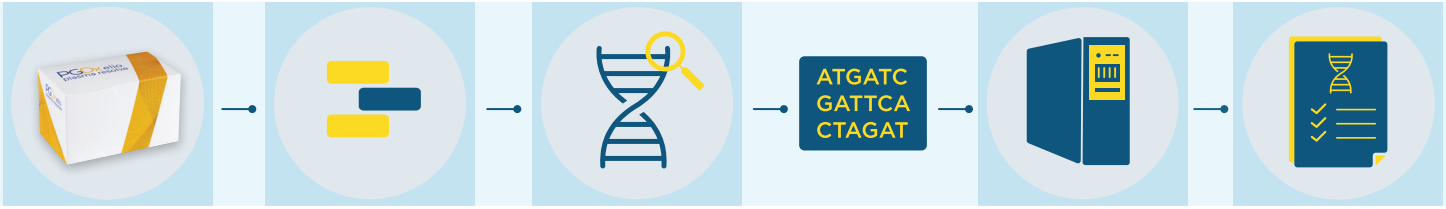
- **Pan solid tumor:** plasma analysis for in-house solid tumor biomarker analysis and discovery
- **Proven:** results concordant to tissue-based tests across variants of clinical significance
- **Reliable:** robustly tested in clinical trials to ensure highly accurate results
- **Trustworthy:** 30,000x sequencing coverage
- **Leading:** FDA breakthrough device designation based on ability to detect MSI status in plasma to aid in the selection of certain therapies for patients

PGDx elio plasma resolve identifies somatic mutations with high accuracy and sensitivity



Simplify Your Workflow

From extracted circulating free DNA (cfDNA) to curated analytical reports, PGDx has developed methods to optimize your workflow and results. PGDx elio bioinformatics rapidly and accurately identifies cancer mutations, empowering every lab with timely and trustworthy results. High-quality training data, expert curation, and machine learning algorithms combine to provide best-in-class identification of cancer mutations.



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A Sample-to-Answer Liquid Biopsy Solution

PGDx elio™ plasma resolve is an in-house pan solid tumor NGS liquid biopsy assay that identifies key genomic alterations and guideline-supported biomarkers with high accuracy and sensitivity down to 0.1% variant allele frequency (VAF). It features proprietary methods for detecting microsatellite instability (MSI) as well as complex structural alterations and amplifications.

- **Simplify** sampling with low specimen input for high-impact genes
- **Streamline** genomic analysis with robust, automated bioinformatics
- **Access** rapid liquid biopsy-based tumor insights
- **Facilitate** large-scale studies with liquid biopsy format

Gene Panel

Proprietary method for MSI.

SNVs and Indels (33)										
AKT1	ARID1A	BRCA1	CCND1	CSF1R	EZH2	HRAS	MET	NTRK1	POLD1	RET
ALK	ATM	BRCA2	CD274	EGFR	FGFR1	KIT	MYC	PDGFRA	POLE	ROS1
APC	BRAF	BRIP1	CDH1	ERBB2	FGFR2	KRAS	NRAS	PIK3CA	RAF1	TP53
Amplifications (8)										
CCND1	CD274	EGFR	ERBB2	FGFR2	KIT	MET	MYC			
Translocations (5)										
ALK	FGFR2	NTRK1	RET	ROS1						

Assay Specifications

Sample type	Plasma cfDNA (Streck or EDTA)
cfDNA input amount	40 ng required
Sequencing platform	NextSeq 500/550/550Dx
Read Length	2 x 150 bp
Cases per sequencing run	8 samples on high output flow cell (7 cases + 1 control)

Analytical Performance

Variant	Reportable Range	Analytical Sensitivity (LOD95)	Analytical Specificity
Actionable SNVs/indels	>0.1% VAF	0.25 - 0.50%	100%
Non-actionable SNVs/indels	≥0.5% VAF	0.50 - 1.0%	99.99%
All Translocations	≥2 fusion reads	0.74 - 1.12%	99.50%
All Amplifications	≥1.2-fold	1.2 - 1.5-fold	99.70%

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