LABCORP ONCOLOGY

PGDx elio® plasma focus™ Dx

The first FDA-authorized pan solid tumor liquid biopsy kitted solution

Our in vitro diagnostic device is specifically designed to enable your in-house liquid biopsy profiling, serving as a reliable alternative to tissue genomic profiling for advanced cancers. It delivers actionable insights with a clinical success rate of over 96%.

PGDx elio plasma focus Dx

PGDx elio plasma focus Dx is a qualitative next-generation sequencing-based in vitro diagnostic device that uses targeted high throughput hybridization-based capture technology for the detection of single nucleotide variants (SNVs), insertions and deletions (indels) in 33 genes, copy number amplifications (CNAs) in five genes, and translocations in three genes.

PGDx elio plasma focus Dx gene list

PGDx elio plasma focus Dx					
AKT1	BRCA1	CSF1R	HRAS	NTRK1	RET
ALK	BRCA2	EGFR	KIT	PDGFRA	ROS1
APC	BRIP1	ERBB2	KRAS	PIK3CA	TP53
ARID1A	CCND1	EZH2	MET	POLD1	
ATM	CD274	FGFR1	MYC	POLE	
BRAF	CDH1	FGFR2	NRAS	RAF1	

Sequence Mutations (SNVs and Indels)				
33 genes				
Amplifications (five genes)				
CCND1	CD274	ERBB2	FGFR2	MET
Translocations (three genes)				
ALK	NTRK1	RET		

Amplifications

Translocations

- Developed under design control and FDA-authorized
- High clinical utility – covers clinically actionable variants in pan-solid tumors
- For In vitro diagnostic use (IVD)

labcorp | Oncology

Why choose PGDx elio plasma focus Dx

Eliminate the burden of full validation and go-live in as few as six weeks

- FDA-authorized assays eliminate the burden of full validation requiring only on-site verification steps
- Implementation support and dedicated project management accelerates path to go-live

Fast turnaround time

Experience rapid and scalable liquid biopsy genomic testing. Report actionable findings with confidence, all with 4 – 5 day turnaround time from isolated nucleic acid to variant report.

Sample and data ownership open avenues for both research and clinical studies

- Ensure sample chain of custody for accurate reporting
- Retain access to archival samples and data to drive novel insights

Workflow efficiency

Lower DNA inputs and robust workflows reduce sample drop out, and automated bioinformatics reduces the burden of manual variant curation.

PGDx elio plasma focus Dx offers 100% specificity for clinically significant sequence variants, amplifications, and translocations, while maintaining high sensitivity across all variant types. It can detect select actionable mutations at variant allele frequencies as low as 0.1%

Product Specifications:

Specification	PGDx elio plasma focus Dx
Intended Use	IVD
Genes Evaluated	33
Panel Size	0.24 Mb
Sample Matrix and Collection Tube	Plasma; Streck cell-free BCT® tubes
Sample Type and Input Quantity	cfDNA, 25 ng
System Compatibility	Illumina NextSeq 550Dx
Case per Sequencing Run	8 samples (7 cases + 1 external control)
Read Length	2x150bp
Average Total/De-duplicated Error-corrected Coverage	30,000x/2,600x
Assay Time to Results	4 – 5 days*
Bioinformatics workflow	Single automated pipeline
SNVs. Indels, Translocations, Amplifications	Yes
Variant Allele Frequency (VAF) to Report	0.1% (select actionable), 0.5% (all bases)
Sample Pass Rate	96%

* Full workflow

We want to hear how we can support your lab diagnostic needs. For more information, please contact your local Labcorp sales representative or email **pgdxinfo@labcorp.com**.

labcorp | Oncology