

# Your lab, Our tests

Labcorp's FDA-authorized tissue and liquid biopsy kitted assays eliminate the burden of full validation, requiring only verification steps.



## **PGDx elio™ tissue complete**

**The first FDA-cleared**

pan-solid tumor tissue kitted assay

## **PGDx elio™ plasma focus Dx**

**The first and only FDA-authorized**

pan-solid tumor liquid biopsy kitted assay

### **Key benefits of Labcorp's FDA-authorized kitted assays**

#### **Eliminate the burden of full validation, enabling a go-live in as few as six weeks**

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

#### **Enable seamless tissue-to-liquid reflexing when tissue results fail or tissue insufficient**

- The same validated chemistry, bioinformatics servers, and DNA sequencers enable efficient, streamlined workflows

#### **High clinical success rates and guideline-driven targets ensure robust, reliable and actionable results for pan solid tumors**

- Target guideline-driven biomarkers for pan-solid tumors
  - 500+ genes, TMB and MSI for tissue-based profiling
  - 33 clinically actionable genes for ctDNA-based testing
- High clinical success rates:
  - PGDx elio tissue complete: 92%
  - PGDx elio plasma focus Dx: 96%

#### **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

## PGDx elio™ tissue complete

The first FDA-cleared solid tumor tissue kitted assay for pan-cancer tumors



### Assay features:

- SNVs: 505 genes
- Indels: 505 genes
- Amplification: 1 gene
- Translocations: 4 genes
- Genomic Signatures: TMB and MSI

### Assay specifications:

- Assay time to results: 4-5 days
- Bioinformatics: Single automated pipeline
- Sequencer: NextSeq550 Dx
- Variant allele frequency (VAF): Down to 2%
- Clinical success rate: 92%
- Specificity: 99.9% specificity across all variant classes
- Rigorously validated: Our accuracy study assessed more than 30 different solid tumor types



Learn more about  
**PGDx elio tissue complete**

## PGDx elio™ plasma focus Dx

The first and only FDA-authorized liquid biopsy kitted assay for pan-cancer tumors



### Assay features:

- SNVs: 33 genes
- Indels: 33 genes
- Amplifications: 5 genes
- Translocations: 3 genes

### Assay specifications:

- Assay time to results: 4-5 days
- Bioinformatics: Single automated pipeline
- Sequencer: NextSeq550 Dx
- Variant allele frequency (VAF): Down to 0.1%
- Clinical success rate: 96%
- Specificity: 100% specificity for clinically significant sequence variants, amplifications and translocations
- Rigorously validated: Our accuracy study assessed more than 30 different solid tumor types



Learn more about  
**PGDx elio plasma focus Dx**

For more information, contact your local Labcorp sales representative or email [pgdxinfo@labcorp.com](mailto:pgdxinfo@labcorp.com).