

Biopharma Partnering and Laboratory Services

From biomarker discovery to diagnosis

PGDx partners with researchers and biopharmaceutical companies worldwide to help identify new biomarker targets and accelerate biomarker-driven drug development. Our portfolio of end-to-end tissue and liquid biopsy precision oncology solutions was designed to meet global study needs and is available for in-house testing or through our CRO network.



End-to-end Services

- Research and discovery support: Define complex and emerging biomarkers of response with highly sensitive and accurate assays
- Clinical trial assay support: Leverage our CAP/CLIA lab or our global network of CRO partners for your clinical trial needs
- Global patient access: Distributed kit model enables access to larger patient cohorts via labs around the world
- CDx codevelopment: Draw on our international regulatory expertise and deep commercialization experience and reduce risk with our established elio platform

Partner with confidence

- NGS biomarker solutions developed under design control to comply with US FDA, EU IVDR, and ISO standards
- ISO 15189:2012 and ISO 13485:2016 certified
- Rigorous approach to product development supports a broad range of intended uses to help meet regulatory requirements worldwide
- PGDx elio[™] tissue complete is FDA-cleared and CE-IVD-marked
- Experience with multiple precision medicine trials and IDE approval
- Breakthrough device designation for PGDx elio[™] plasma resolve
- CAP-accredited, CLIA-certified laboratory

elio kitted solutions: Pan solid tumor profiling and biomarker solutions



PGDx elio tissue complete:
An FDA-cleared and CE-IVD-marked tumor tissue CGP test



PGDx elio plasma complete:
A liquid biopsy CGP
research assay



PGDx elio plasma resolve: A focused liquid biopsy research assay

Don't see an existing solution that meets your needs? Contact Sales@PGDx.com to access additional innovative solutions in our pipeline.



Pharma partnering solutions:

Agile development across the CDx continuum

We bring a track record of innovation and years of experience to cutting-edge diagnostics development, equipping us to support your oncology breakthrough to market.



Demonstrated performance: Leading tissue and liquid biopsy solutions accurately highlight current and emerging biomarkers and genomic signatures, supported by industry-respected publications and global recognition of key opinion leaders



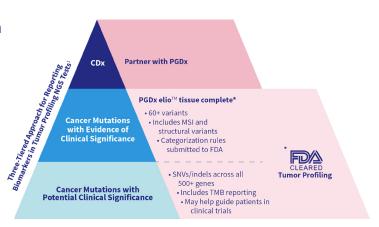
Regulatory and commercial expertise: PGDx offers deep expertise in companion diagnostic development and experience in global biopharma partnerships, with a proven track record of navigating complicated technical and legal frameworks internationally



Consultative partnership model: Partnering with PGDx means our joint project team and dedicated service coordinators will support you every step of the way as you navigate the regulatory landscape to approval

Fast-track to CDx with our established platform

- Build on our established platform: De-risk operational setup and avoid lengthy validation timelines with our FDA-cleared and CE-IVD-marked comprehensive genomic profiling (CGP) kit, elio tissue complete
- Seamlessly bridge to our global solution: Our expertise in trial transfers and distributed kit model ease the transition from single-site LDTs and enable global patient access



Laboratory services:

Driving innovation from hypothesis to breakthrough solution

Gain unparalleled access to expertise and proprietary novel technologies that have yet to hit the market.



Biomarker discovery:

Identify new biomarker targets using retrospective testing services and gain early access to new technological innovations to fuel your research



Expert assay and algorithm development:

Benefit from customized solutions powered by computational algorithms to enable accurate and sensitive biomarker detection



Clinical trials:

Support your research needs with inhouse capabilities and advance your prospective clinical trial testing

1. US Food and Drug Administration: FDA fact sheet: CDRH's approach to tumor profiling next generation sequencing tests



