PROTAVIO
Proteomics for Better Health

In-vitro Diagnostics
Development & Manufacturing

We turn your Biomarker Research into an In Vitro Diagnostic (IVD) product

- ✓ **Support in every step of the IVD process**
- ✓ **ISO 9001-certified quality system**
- ✓ **ISO13485 & GMP compliant service**

Which Platforms are supported?

Luminex™

For multi-protein diagnostic solutions.

ELISA

For single-protein diagnostic solutions.

Lateral Flow

For point-of-care, self-testing diagnostics

Design & Development Pipeline

FEASIBILITY STUDY

This step demonstrates whether the assay can be developed in a selected platform

- Material identification, sourcing & preparation
- Material testing (antibody pairwise testing etc)
- Detection of analyte in sample of interest

DEVELOPMENT & OPTIMIZATION

Assay is developed & optimized to meet design input requirements. Assay is verified & validated according to IVDR & ISO13485 guidelines

- Design Initiation Plan
- Material preparation & optimization
- Analytical Performance verification
- Clinical Performance validation
- Design freeze

TRANSFER TO MANUFACTURING

Manufacturing documentation & manufacturing lots prepared for regulatory purposes

- Preparation of technical specification documents
- Integration into company's QMS
- Three lots produced for customer's verification & validation purposes (for CE marking or FDA clearance)

CONSULTATION & SUPPORT

Support at all stages from feasibility to commercialization

- Platform selection
- IP search
- Market research
- KOL support
- Regulatory guidelines

TRUSTED EXCELLENCE

- **20 +** years of innovation
- **> 100** global customers
- **> 300** developed assays
- **Quality** ISO 9001 ISO 13485

Luminex® A DiaSorin Company

Olink

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learn more

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You will find us in three Bio-Science parks in UK, USA, & Greece

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