RANDOX
BIOSCIENCES

# CDx DEVELOPMENT

# Your Ideal Companion for CDx DEVELOPMENT

Personalized medicine is the result of our ongoing understanding of disease complexity and variability. It is now accepted that the future of the Pharmaceutical Industry is dependent on the development of therapeutic agents that are more closely tailored to targeted patient groups or sub-groups resulting in safer drugs with enhanced therapeutic efficacy and specificity, developed in a more cost-effective manner. A key element to realizing the potential for personalized medicine is companion diagnostic (CDx) development.

Randox are committed to revolutionizing healthcare by providing class-leading diagnostic, prognostic and predictive assays. This is evidenced by our 30 year track record as an innovative global clinical diagnostic manufacturer with operations and partners in over 145 countries.

## Why Partner with Randox?

- We offer a fully flexible partnership through our custom assay development to meet your specific CDx needs.
- Our in-house production of materials enables our service to meet the pressing deadlines associated with the Pharma industry.
- Cost effective solutions utilizing our innovative Biochip Array Technology for rapid, accurate testing.
- Full in-house regulatory affairs, engineering, chemistry & biotechnology divisions ensuring an accelerated speed to market.
- Expertise to support your project from antibody development through to commercialization.
- Over 30 years' experience in raw material manufacture and assay development from our ISO 13485 accredited UK manufacturing plant.
- Global distribution and operations in over 145 countries ensuring no block to commercial adoption of the CDx.

## Our CDx Capabilities

- Over 120 FDA/CE marked kits & over 400 RUO biomarker assays.
- Innovative Biochip Array Technology providing tailored protein & molecular multiplex testing.
- Extensive Life Sciences catalogue of over 900 products for a multitude of R&D applications including more than 500 monoclonal and polyclonal antibodies, 140 human recombinant proteins, as well as antibody fragments (sdAbs, scFvs, fAbs).
- Full in-house custom antibody development service available for novel markers including monoclonal, polyclonal, recombinant proteins and antibody fragments (sdAbs, scFvs, fAbs).
- Randox Clinical Laboratory Services available for safety & clinical testing.

## Randox Companion Diagnostic Development Plan

### Feasibility

- Customer requirements
- Design specifications
- Regulatory strategy

### Develop Prototype

- Randox Life Sciences – custom Antibodies, Proteins, ScFv development
- Immunoassay development & optimization – single analyte & multiplex
- Clinical Chemistry assays
- Multiplex nucleic acid arrays

### Analytical Validation

- Verify assay performance
- Perform internal validations
- Manufacture three GMP lots

## Pharmaceutical Development Phases

Pre-Clinical

Clinical

Phase I

Phase II

## Randox CDx Assay formats:

With over 120 FDA cleared assays, Randox offers the full package of Diagnostic and CDx assay development and optimization that can be utilized on 3rd party platforms as well as our own proprietary technology which includes:

### Immunoassay

Single or multiplex assays and analyzers

ELISA

Evidence Investigator


Evidence Evolution

### Clinical chemistry

Immunoturbidimetric, enzymatic and colorimetric assays and analyzers

RX imola

RX daytona+


RX modena

### Nucleic acid

SNP genotyping, mutation and pathogen detection assay formats and analyzers

Evidence Investigator

Building on these unrivalled capabilities, Randox is engaged in companion diagnostic programs with a number of global Biopharma companies. These include not only single analyte clinical chemistry based assays but multiplex pathogen detection, mutation, SNP and gene expression.

**Clinical Validation**

- Supply of kits
- Conduct clinical trials
- Perform external validations

**Regulatory Submission**

- Prepare submission
- Regulatory co-filing
- Full regulatory support including FDA/CE
- Global registrations
- Reimbursement

**Post Launch Support**

- Production lots in inventory
- Training & education
- Distribution

Phase III → Regulatory Submission → Post Launch Support

Advancing scientific discovery,
drug development and diagnostics globally

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