

A vertical rectangular image with a blue tint, showing a close-up of a microscope and a test tube. The microscope is in the foreground, and the test tube is in the background. The image is partially obscured by the Randox Biosciences logo.

RANDOX
BIOSCIENCES

CDx PHARMA SERVICES

FAST, SAFE AND EFFECTIVE DEVELOPMENT



Biopharma



Clinical Laboratory



BioReagents

PHARMA SERVICES AND CDx

Why Partner with Randox?

Randox Biosciences is dedicated to the improvement of personalised diagnostic, prognostic, and predictive assays. We aim to help Pharma Biotechs and CROs move away from a "one treatment fits all" approach and help get a better understanding of the complexity and variability of diseases and increase efficacy of treatment.

Randox have key expertise in all elements of CDx and diagnostic development and offer a fully flexible partnership to accommodate your needs. We can be your CDx and biomarker assay development partner from early phase trials right through to drug launch, addressing all assay requirements in between.



Patient sample testing at Randox Clinical Laboratory
Services and/or 3rd party labs if required

Accreditations

- ISO 13485 accredited UK manufacturing facilities
- Fully validated Quality Management and LIMS systems
- IVDD 98/79/EC, currently transitioning towards IVDR
- ISO17043 – Randox International Quality Assessment scheme (RIQAS)
- ISO15189, ISO17025 accredited labs.
- FDA MDSAP CFR T21 part 820 compliant
- GCP Certified

DEVELOPMENT OF RAW MATERIALS

Randox biosciences presents an extensive portfolio of over 900 products for a multitude of R&D applications manufactured under ISO13485 accreditation, including more than 500 monoclonal and polyclonal antibodies, 140 human recombinant proteins, as well as antibody fragments such as sdAbs and scFvs.

In addition to our range of off the shelf raw materials, Randox can custom develop antibodies and proteins for use in new assays.

By using Randox antibodies, the raw material supply chain is controlled in house which is highly beneficial for CDx development.

ASSAY DEVELOPMENT

Randox offers a range of technologies and platforms for use in clinical trials, including our proprietary multiplex biochip technology that can be used in early exploratory biomarker stages and can be brought through to IVD/CDx grade. Biochip from high throughput to point of care technologies.

With comprehensive Original Equipment Manufacturing (OEM) capabilities, Randox can develop assays on any platform to ensure global reach.

All assays intended for IVD or CDx grade are developed under full design control and ISO13485 accreditation, and we have expertise in a wide range of disease areas and assay formats.

SAMPLE TESTING

Randox have ISO17025, ISO15189 and GCP accredited laboratories located throughout the UK and Ireland, with US laboratories being mobilised in 2022 and 2023. Our laboratories can be utilised to meet your clinical trial and post approval sample analysis needs.

We also have a strong global network with 3rd party laboratories to ensure your clinical trial requirements are met across the world.

VERIFICATION AND VALIDATION

Randox performs in depth multi lot verifications following CLSI guidelines to ensure full performance requirements are met and to support regulatory submissions and approvals. We will validate assay performance and reproducibility across multiple sites.

REGULATORY SUBMISSION

Highly experienced regulatory teams inhouse at Randox can prepare IVD/CDx submissions and applications for approval, thus, providing full regulatory support to help get your drug to the market as quickly as possible.

Development and regulatory teams will work hand-in-hand throughout the whole process and in collaboration with the Pharma partner, to ensure a timely submission while also keeping in line with country specific requirements.

We currently have 954 licenses across the globe and over 3800 licensed products to date, with continuous expansion ongoing including progression to IVDR regulation.

DEVELOPMENT OF CRITICAL REAGENTS

We have strong global laboratory and distribution networks, in-house sales and marketing teams, with operations and partners in over 145 countries.

We have capabilities in manufacturing customised sample collection kits and offer CDx specific proficiency testing programmes.

We can provide pre- and post-launch support with laboratory, clinician, patient and KOL engagement and can also conduct sample analysis at our clinical laboratories.

RANDOX

BIOSCIENCES

COLLABORATIONS



Advancing scientific discovery, drug development and diagnostics globally

randox.com



Information correct at time of print.

Randox Laboratories Limited is a subsidiary of Randox Holdings Limited a company registered within Northern Ireland with company number N.I. 614690. VAT Registered Number: GB 151 6827 08.

Product availability may vary from country to country. Please contact your local Randox representative for information. Products may be for Research Use Only and not for use in diagnostic procedures in the USA.