

RANDOX

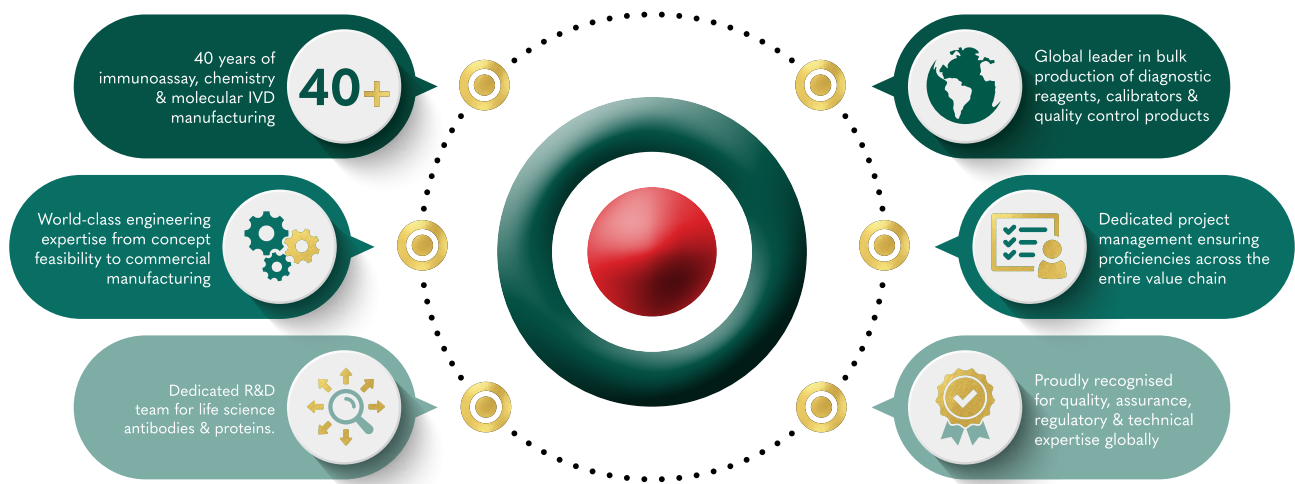
CONTRACT MANUFACTURING

Your Global Partner of Choice

THE RIGHT IVD SUPPLIER MAKES ALL THE DIFFERENCE

Bringing a diagnostic or life science product to market globally requires continuous commitment, innovation, quality materials, and navigation through the regulatory and commercial landscape.

With over 40 years of experience, Randox has been operating at the forefront covering the entire value chain helping to bring new solutions to market faster, supporting all phases of product development, from concept development to full end-to-end commercialization.



THE RANDOX WAY

Our exceptional technical expertise in quality control, calibrator and reagent manufacturing has enabled us to become an industry leader. Our extensive range of technologies and tools designed for use in a variety of formats in molecular, chemistry and immunodiagnostics development allow us to meet industry standards, supporting each customer's unique needs through our experienced commercial supply team.

CAPABILITIES AT A GLANCE

CUSTOMISED QUALITY CONTROLS & CALIBRATORS

Complementing our large range of Reagents, Randox are also able to offer customised quality control and calibrator solutions. With currently over 390 parameters in our current range, these can be manufactured to your exact specifications to include the analytes, analyte concentrations, vial sizes, quantity and any labelling or packaging required. As a primary manufacturer, we pride ourselves on our ability to offer rare and specialist analytes, which other manufacturers may not have developed. We are able to offer these in a number of formats from assayed kits to bulk vials and either labelled or unlabeled.

366 912 000

Enough calibrator and control capacity to dispense over **366,912,000** vials per year with lot-to-lot consistency and dedicated value assignment if required.

REAGENTS



In addition to our existing extensive range of off-the-shelf reagents, we also offer a unique reagent contract manufacturing service - including dispensing, capping, labelling for a wide variety of containers, packing and kit assembly. This flexibility enables Randox to be an all-encompassing manufacturer – offering the greatest level of flexibility to our partners.

Building on our large catalogue of general applications, Randox are also able to offer reagents for use on a wide range of analysers; and the applications and formats across **chemistry, immunoassay and molecular diagnostics**.

10,500,000

DELIVERING MORE



Liquid batching and filling.



Immunoassay development in a wide range of formats such as ELISA.



Ab / Antigen development & characterization (Monoclonal and polyclonal antibody production for life science usage).



qPCR assays, primers, probes, lyobeads and spheres design to customer specifications.



Ab sequencing capabilities ensuring quality supply.



Immunoturbidimetric development capabilities.



Method development, characterization, and validation.



Manufacturing capacity greater than 10,500,000 liters per year.

MANUFACTURING WITHOUT LIMITS

- Manufacturing expertise for IVD companies with facilities and workforce capacity across the UK, Europe, Asia and the USA.
- Annual packing capacity of 13 million kits utilising both manual and automated processes.
- Randox are capable of dispensing volumes into any container shape and size from microcuvettes, Micro Titre Plates, reagent bottles, glass vials, IBCs and beyond.
- Fully end-to-end manufacturing from custom build, bulk, labelling and packaging solutions.
- Accredited to ISO:13485 and MDSAP standards.



13,000,000

QUALITY



Consistency – managed through product improvements and change control.



Quality Assurance – quality services to customers individual needs.



Traceability – All documentation is available upon request.

Full process control for manufacturing to ensure during and end of line quality checks from robotic vision systems, optical character recognition and dispense level detections across all product lines.

Accredited to industry standards including ISO/EN ISO 13485:2016, ISO/IEC 17043:2010, ISO/IEC 17025:2017, ISO 27001:2013, BSI, UKAS & MDSAP compliance.



ENGINEERING, TECHNOLOGIES & SOFTWARE

- World-class engineering expertise from concept feasibility to commercial manufacturing.
- Engineering services include design, FEA, product testing and metrology.
- Design capabilities across freeze drying, dispense lines, 3D printing, CNC machining and cable manufacturing.
- Custom manufacturing creation for product lines to assembly of instrumentations, technologies, software and automation.
- Dedicated IT and project management team dedicated to improving processes across a broad range of IT specialisms including web development, infrastructure, enterprise support, information security, software development and software testing.



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