

RANDOX

CONTRACT MANUFACTURING

*Your Global
Partner of Choice*



BETTERING PATIENT OUTCOMES

THROUGH DIAGNOSTIC
MANUFACTURING

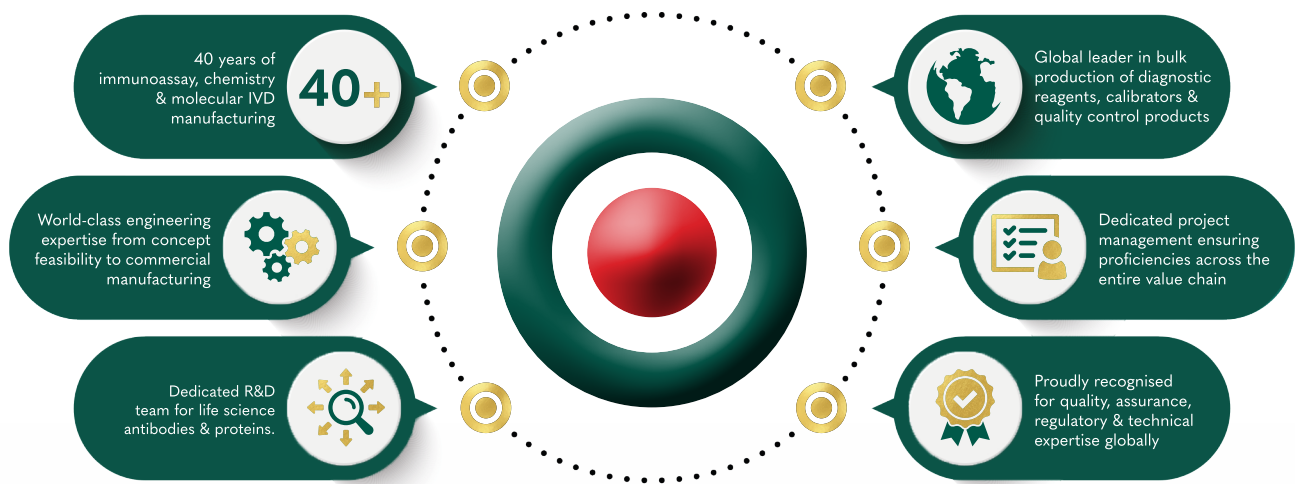
300+ GLOBAL PARTNERS



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.

- DIAGNOSING 5% OF THE WORLD'S POPULATION - OVER 370 MILLION PEOPLE
- SUPPLYING OVER 100,000 LABORATORIES GLOBALLY - MANUFACTURING 12% OF CHOLESTEROL TESTS WORLDWIDE
- WORLD LEADING PROFICIENCY PROVIDER
- 4TH LARGEST MANUFACTURER OF CHEMISTRY REAGENTS

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**.
- Randox are capable of dispensing volumes into any container shape and size from microcuvettes, Micro Titre Plates, reagent bottles, glass vials, IBCs and beyond.
- Advanced lyophilization technology produces Lyobeads at a rate of up to **40,000 beads per hour**.
- Fully end-to-end manufacturing from custom build, bulk, labelling and packaging solutions.
- Accredited to ISO:13485 and MDSAP standards.

13,000,000

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).



Custom qPCR assays, primers, probes, lyobeads, and spheres design and manufacturing tailored to customer specifications, supported by our advanced technologies and quality control processes.



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 CAPABILITIES AT A GLANCE

Customised quality controls & calibrators

Leader in custom end-to-end contract manufacturing for automated bulk production

Customised qPCR assays, primers, probes, lyobeads and spheres

Ab/Antigen development, characterisation & sequencing

Full process control to ensure quality & traceability

Immunoturbidimetric & immunoassay development capabilities

Quality, assurance, regulatory, technical & project management expertise

Facilities across the UK, Europe, Asia & the USA

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



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.

CURRENT QC RANGE

ANTIOXIDANTS

BLOOD GAS

CARDIAC

COAGULATION AND
HAEMATOLOGY

DIABETES AND
WHOLE BLOOD

IMMUNOASSAY

IMMUNOLOGY/PROTEINS

INFECTIOUS DISEASE
(SEROLOGY)

LIPIDS

SPECIALITY AND
RESEARCH

THERAPEUTIC DRUGS

URINE CHEMISTRY

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.

REAGENTS

In addition to our existing extensive range of off-the-shelf reagents, we also offer a unique reagent contract manufacturing service - including design, assay development, 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**.



CURRENT REAGENT RANGE

OVER 100

Over 100 diagnostic reagents covering more than 100 disease markers.

RAPID TESTS & SEROLOGY

SPECIFIC PROTEINS

THERAPEUTIC DRUG
MONITORING

ANTIOXIDANT TESTING

CARDIOLOGY &
LIPID TESTING

CLINICAL CHEMISTRY
TESTING

DIABETES TESTING

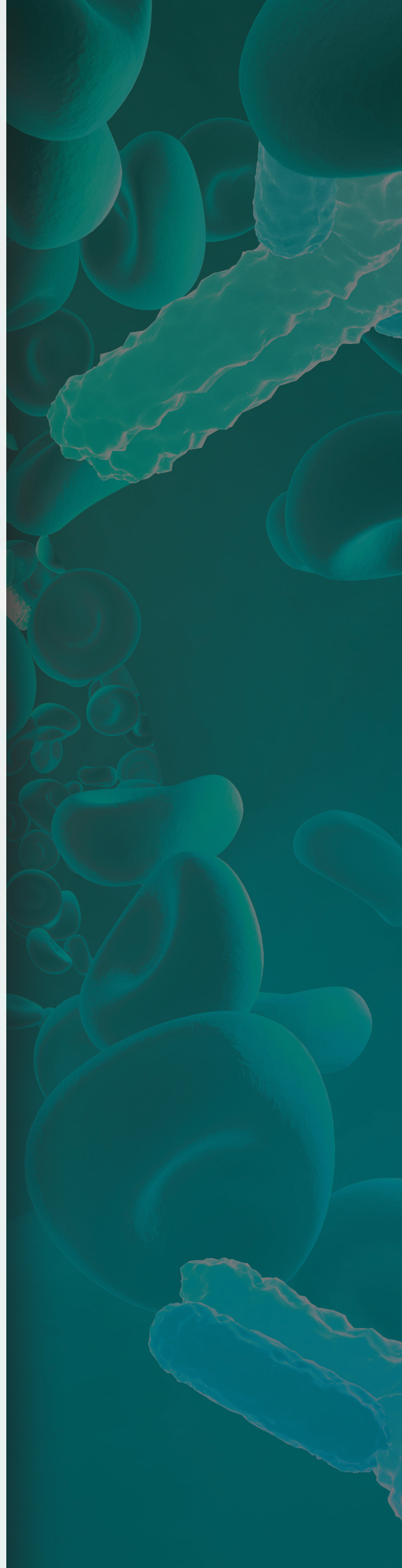
AB / ANTIGEN DEVELOPMENT

Randox have been developing and manufacturing antibodies, proteins and conjugates for over 40 years for use in Randox Laboratories diagnostic kits and for supply to diagnostic kit manufacturers.

We are able to offer a world class service meeting all customer requirements including custom developments upon request. Our scientists have the ability to design, develop and manufacture novel monoclonal, polyclonal and recombinant antibodies and proteins

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- Monoclonal Ab Manufacturing
 - Polyclonal Ab Manufacturing
 - Antibody Fragment Manufacturing
 - Human Recombinant Protein Manufacturing
 - Conjugate Manufacturing

**WE CONTROL
BULK CUSTOM
MANUFACTURING,
FROM Ab & ANTIGEN
DEVELOPMENT, ASSAY
DESIGN & PRODUCT
COMMERCIALISATION**





qPCR SOLUTIONS

We offer robust qPCR assay development and manufacturing services, ensuring high sensitivity and specificity tailored to specific diagnostic applications. Our capabilities include custom synthesis of primers and probes, designed to meet high specificity and sensitivity requirements. They also produce lyophilized PCR mixes (Lyobeads), which are stabilised to extend shelf life and enhance performance. This comprehensive approach ensures that Randox can meet diverse customer needs in molecular diagnostics with precision and reliability.

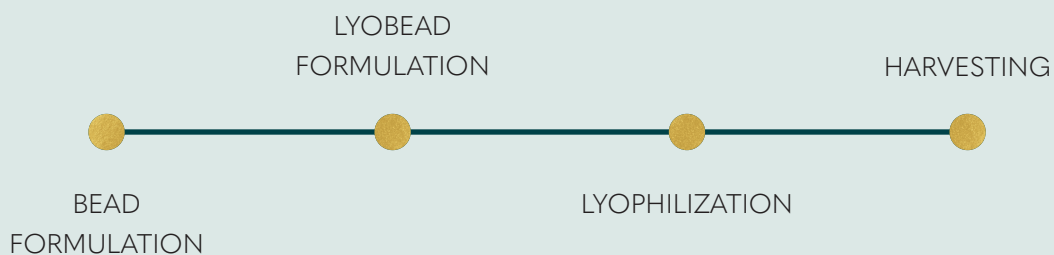
LYOBEADS MANUFACTURING

Randox also specialise in the production of Lyobeads, designed to enhance the stability and shelf life of PCR mixes, making them usable for over two years. We employ advanced biodot dispensers and freeze-drying technology to produce up to **40,000 beads per hour**. Our automated bead QC systems ensure that each bead meets strict quality standards, thus enhancing reliability and performance. This capability allows us to provide high-quality, customised lyophilised reagents tailored to specific diagnostic needs.

40,000



FULL END-END PROCESS DESIGN & IMPLEMENTATION



PRIMER AND PROBE CUSTOMISATION

We offer comprehensive customisation of primers and probes, ensuring high-quality production under Good Manufacturing Practice (GMP) conditions, ideal for molecular diagnostic applications. Utilising a proprietary synthesis platform, Randox manages many components in-house to guarantee high-quality oligonucleotides. The facilities are ISO 13485:2016 certified and provide custom labeling services with an “open door” audit policy. This approach allows customers to define and monitor all aspects of their product’s manufacture, ensuring tailored solutions that meet specific diagnostic requirements.

SPHERES DESIGN AND FORMULATION

Randox excels in the design and formulation of diagnostic spheres, integrating novel markers and developing custom assays to meet specific diagnostic needs. Utilising advanced particle technologies, we create sophisticated diagnostic reagents and assays. Comprehensive quality control processes are implemented across all stages of manufacturing, from raw material inspection to final product release. This meticulous approach ensures that every sphere produced meets the highest standards of performance and reliability, tailored precisely to the customer’s specifications.

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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