

Diagnostic services

Accelerate diagnostic test development and manufacture



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Our diagnostic services help you break through barriers to get from idea to commercialization faster, with an effective diagnostic test.

Whether you need a customized membrane or magnetic bead, access to specialized infrastructure, or the expertise our team can bring, we provide solutions designed to meet your needs.

Accelerate assay development

Molecular and immunodiagnostic applications

Molecular and immunodiagnostic tests using nucleic acid and protein-based assays are now an essential component in the evaluation and early detection of many diseases. Applications include the areas of infectious diseases, oncology, inherited disorders, and prediction of genetic disease risk, with new applications coming to market every day.

We offer laboratory infrastructure, technical expertise, training and consultation services to diagnostic developers looking to convert an idea into a rapid diagnostic test or access additional capacity to upscale or manufacture a diagnostic assay successfully. When you work with Cytiva you get access to a wide selection of high performance, customizable components and solutions for molecular and immunodiagnostic applications, as well as the extensive capabilities offered by our ISO-certified (9001 and 13485) manufacturing centers.

Take advantage of Cytiva's extensive experience and expertise from the design stage through launch to minimize costs and accelerate the timeline for commercialization. Our team of scientists and manufacturing specialists will work with your in-house teams to help you optimize components and identify the best-suited technologies. This enables you to expand your customer base and address new markets and applications that may previously have seemed out of reach.



Contact us to learn more about our Diagnostic Services



The right infrastructure, as and when you need it

We provide our development, customization, lyophilization and manufacturing services at our purpose-built facilities in Cardiff, UK, in Dassel, Germany, and in Tonglu, China. Our facilities provide state-of-the-art lab space designed to meet rigorous cGMP and cGMP standards.

Acquiring specialized infrastructure requires capital investment, time to implement, and potentially staffing up, or up-skilling

existing staff. Contract manufacturing converts this to an expense, part of the cost of goods. You can utilize our infrastructure, as and when you need it.

Our dedicated Proof of Principle facility is capable of small-scale optimization and validation of up to 50 plates, facilitating transition through to manufacturing and commercialization of your stabilized assay.

Stringent standards meet regulatory requirements

- HEPA filtered air
- Humidity and temperature control
- UV scrubbers
- Dry nitrogen dispensing cabinet
- Clean room environment



Secure, global supply chain

High quality products which deliver reliable and consistent performance start with a reliable, secure supply of consistent raw materials. To achieve this, we take a proactive approach to security of supply, from a comprehensive raw material supplier risk management program and risk mitigation plans, through to rigorous product release testing based on agreed QC specifications to support performance claims.

Through our supplier risk management program, we:

- Reduce the number of high-risk suppliers
- Mitigate risk through improved knowledge and assessment of potential incidents
- Use the most resource effective activities to reduce supplier risks
- Establish multi-sourcing and multi-manufacturing options for critical materials

Effective risk assessment and mitigation strategies require a cross-functional, data-driven commitment to supplier risk management. We take a proactive and strategic stance to global supply-chain risk management to ensure that we are prepared to react quickly and decisively to unforeseen events. By assessing risk in advance, we can determine and plan for the potential impact of raw material variability and availability. Having identified high-risk areas, we can prioritize and implement initiatives to address them. We continuously monitor the points susceptible to potential compromise, with an overarching goal of identifying unexpected issues quickly, facilitating a timely response, and reducing risk in a measurable and objective way.



[Watch our webinar to learn more](#)

Component and service design process

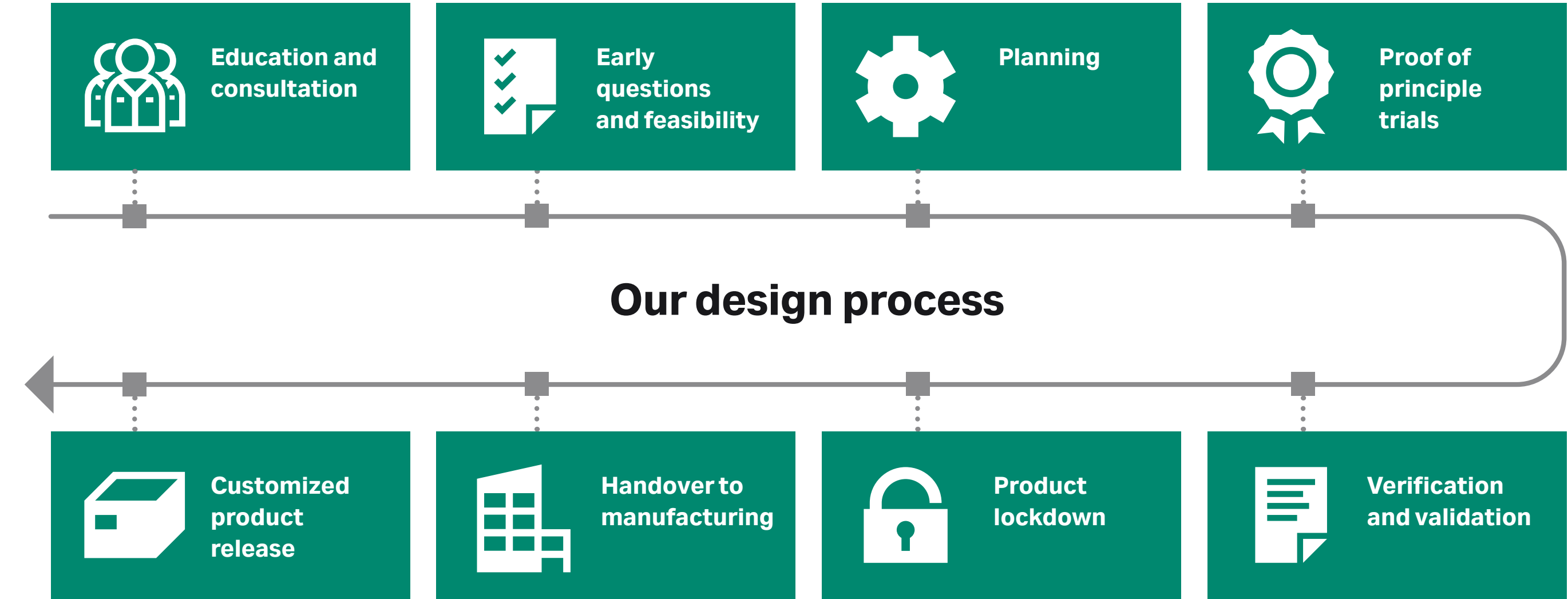
Our custom design function comprises an inter-disciplinary team of engineers, biologists, and filtration and separation experts.

With extensive capabilities and proven methodologies for design concept, optimization, and platform development, we focus on supporting your concept with design for optimal manufacturing. We solve specific design issues with custom components, such as membranes, vials and reagents.

Our structured process enables you to benefit from Cytiva's extensive experience and expertise, not only when unexpected issues emerge, but from design stage through launch helping minimize costs, trial and error and development time.

Our custom design process advantages:

- Minimize design complexity and optimize for efficient manufacturing
- Generate prototypes for functional proof-of-principle testing
- Reduce costs of product development cycles
- Shorten time-to-market



Point-of-care immunoassay consultation and development

Rapid point-of-care (POC) tests are among the most widely used analytical technologies in diagnostics.

The development of a point of care testing device is a time- and cost-intensive process, with technical, financial, and regulatory hurdles in developing a marketable lateral flow assay. Getting from idea to proof-of-principle as quickly as possible is vital for releasing the next stage of funding. The Cytiva Diagnostic Services team makes that process as speedy as possible for early stage developers by:

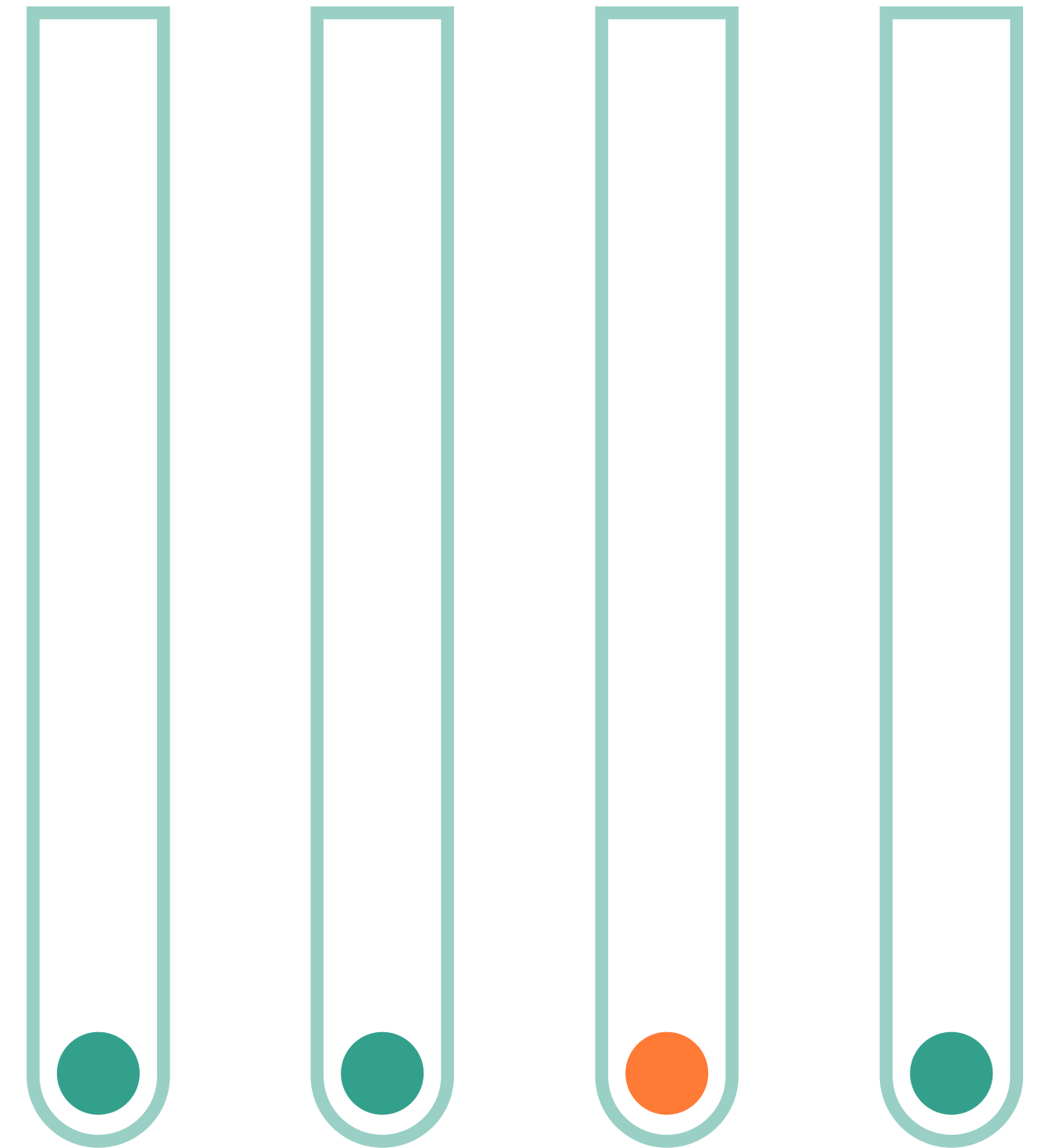
- Providing access to state-of-the-art laboratories and manufacturing facilities
- Offering the benefit of over 40 years' experience in developing diagnostic tests, assays and kits
- Applying proven methodologies to accelerate progress between key development stages

Our team of assay development experts has enabled many early stage development successes. We work with complete transparency in state-of-the-art laboratories in Dassel, Germany and Tonglu, China to solve challenges and optimize your prototype development, shortening your path to market.

We perform the entire assay development process with transparency. We involve you throughout, sharing the lessons we have learned, and document everything to make sure you have complete confidence in the scientific design and robustness. You will have the flexibility to use all or just some of our services, according to your needs.

Development expertise to bridge the gaps in your capacity:

- Method development
- Method transfer
- Method qualification
- Troubleshooting
- Full outsourcing of development
- Reference standard characterization
- Stability studies
- Lot release testing
- Raw material inspection testing



Custom components for point-of-care immunodiagnostic assays

The team has considerable experience and capabilities in the selection and customization of test components, as well as an understanding of the underlying science of rapid diagnostic test design. We can help with design robustness, work with different design formulations in parallel to minimize time and cost and optimize test conditions so they are repeatable at both small- and large-scale quantities.

Cytiva standard technology components for point-of-care immunodiagnostic assays can be customized to meet the requirements of your assay.

- Lateral flow **membranes and pads**
- Flow-through **membranes and pads**
- Dipstick colorimetric **membranes and pads**
- Track etched **membranes**

Training and education to help your staff get up to speed

As part of Cytiva Diagnostic Services we also provide hands-on training and education, on-site at our Dassel, Germany facility or off-site at locations convenient to you. Our training and education services maximize our collaboration and help position you to take your lateral flow assay development forward and be in a fully informed position for your next project.

- On-site access and participation during all development activities
- Test development lab for proof of concept
- Support staff at your site for start-up activities
- Access to process, equipment, and development training
- Site safety training
- Classroom, on-site, and online education
- Workshop format to work through specific issues



Stabilization services

Lyo-Stable™ lyophilization

The Lyo-Stable™ service provides access to expertise, equipment, proprietary excipients, and decades of experience gained from developing off-the-shelf and custom lyophilized products based on well-established Ready-To-Go™ technology.

Our patented lyophilization technology stabilizes individual proteins and reagents, as well as complete multiplex assays, by providing a molecular environment that protects against conformational changes in protein structure. From simple buffers to multi-component kits, our Lyo-Stable™ custom stabilization service can develop and manufacture custom products in small or large batch sizes.

Along with your user-defined components, such as primers, probes, and enzymes, your made-to-order cake or bead will contain our proprietary excipient mix to stabilize your temperature-sensitive assay for storage and shipping at ambient temperature. All you need to add is your sample and you are ready to go!

Advantages of Lyo-Stable™ lyophilization

- **Reliability:** Sample integrity maintained for up to two years at room temperature with no activity loss
- **Simplification:** Requires less sample handling and fewer pipetting steps to simplify workflows
- **Minimal waste:** Reduced contamination risk due to pre-dispensed, single dose reagents
- **Convenience:** Room temperature shipping and storage reduce costs and enable the opportunity for point-of-care field use

 [Learn more about our Lyo-Stable™ service](#)



Find out more about the process and benefits of lyophilization in our knowledge article.



Lab-based custom services

Your specific needs for certain products may fall outside of our standard configurations, formulations, and concentrations. With this in mind, we can customize a comprehensive range of protein and nucleic acid sample preparation, labeling, and detection products with a proven track record of performance and reliability. If desired, we can incorporate these products into the manufacturing of kits that you design.

Our services include:

- Custom conjugation
- Custom plates
- Custom Whatman™ 903 Proteinsaver sample collection cards
- Custom biology



Custom conjugation

There are many types of magnetic beads available. Different surface coatings and chemistries give each type of bead its own binding properties, which can be used for magnetic separation (isolation and purification) of nucleic acids, proteins, or other biomolecules in an easy, effective, and scalable way.

Even with all these surface chemistry options, it's impossible to cover every need and eventuality. That's where custom conjugation comes in. Custom conjugation optimizes reagents and magnetic beads using concentration, reformulation, binding and adaption of particle sizes and functionalities. This service is possible for any of our protein and nucleic acid sample preparation, labeling and detection products, including. [Sera-Mag™](#) magnetic beads and SpeedBeads, and [Mag Sepharose™](#) magnetic beads

The convenience and ease-of-use of magnetic beads, customized for your assay

Drawing on our R&D and manufacturing resources, and the deep experience of our expert team, we provide custom magnetic bead technology that is ready to use with little or no need for further modification. From completing complex conjugations, to performing quality control tests before the beads leave our factory, we are equipped to meet your needs.

Customization options for reagents and magnetic beads

- Concentration: particles and reagents over a wide range of concentrations
- Formulation: modifications to buffer composition, containers, dispense volumes
- Conjugation: enzymes, antibodies and custom ligands
- Custom particles: non-standard sizes or functionalities
- Packaging and kitting: from lab pack to bulk, and custom kits



[Learn more about our conjugation service](#)

**Use our guide** to compare the different surface chemistries and find the type for your application.



Custom plates

Standard and custom multi-well, filter and microplates can be designed for sample collection, analysis, and purification of sequencing reactions. We will work with you to develop a complete custom product including dispensing, packaging and labeling to provide you with a product that is customer-ready.

We apply our expertise in membranes, resins and mold tooling to develop custom plates for a range of applications and sample throughput levels. Our proprietary process to encapsulate the filter media minimizes contamination between wells. The plates are optimized for automated filling, allowing for greater efficiency.

Our dedicated coating facilities are environmentally controlled, meeting strict quality standards. Plates can be tailored to your specifications in terms of labeling and quantity per case.

[!\[\]\(65669ef2a9341eca7c5ba6092e766555_img.jpg\) Learn more about custom plates](#)

Sample collection

As diagnostic applications continue to drive personalized medicine, standardized biosample collection techniques are becoming increasingly important for the ambient-temperature collection, transport, and storage of a range of biomolecules including human blood, buccal (cheek) cells, and saliva.

Regardless of where a sample is collected, information about each sample must be recorded and catalogued. Building on our [Whatman™ 903 Proteinsaver cards](#), we configure and manufacture customized ready-to-use cards for sample collection prior to diagnostic assays for use in large sampling studies.

Custom biology

When our off-the-shelf products do not meet your specific application requirements, our Cytiva Diagnostic Services team can tailor the configurations, formulations, pack sizes and concentrations to your needs, while ensuring the same quality, performance and reliability as our standard catalogue products. Custom biology services are possible for any of our protein and nucleic acid sample preparation, labeling and detection kits.

Examples of kits which we have customized:

- [PCR Grade Nucleotides](#)
- [CyDye™ fluorescent dyes](#)
- [PuReTaq™ DNA polymerase](#)
- [Thermo Sequenase](#)
- [AutoScreen-96](#)

[!\[\]\(43fda5baa5446493352974e4b4060607_img.jpg\) Learn more about our custom biology service](#)

Custom plate options

- Plate material
- Color
- Well bottom shape
- Media
- Surface coating
- Plate well configurations



Contract manufacturing

Access expertise and manufacturing capabilities to move your project to commercialization

Reagent immunoassay and kit manufacturing in partnership with us allows you to take advantage of our extensive knowledge and experience as we guide you through the process of developing your minimum viable product to a commercial product.

Our designated team will carry out a full transfer process from the initial proof of concept through to batch validation and into production to improve your existing process and allow a more seamless transition to large scale manufacturing.

With ISO-certified facilities capable of accommodating manufacture of simple buffers through to multi-component kits for both low- and high-throughput customers, we can comfortably manufacture your specific product(s) for use in pharmaceuticals, diagnostic applications, and life science research.

[Learn more about contract manufacturing](#)

Stay small, but play big

Utilize our contract manufacturing services to avoid the need to staff up or make capital investments in manufacturing. Bridge your resource gaps with our services to keep costs down while gaining productivity.

- Sourcing and validating raw material
- Custom design services
- Custom formulations, volumes and concentrations
- Custom packaging and labeling
- Custom testing and documentation
- Secured supply and delivery
- Scale-up capabilities to meet your needs
- Stability studies
- Full OEM services



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