

Custom Solutions

Custom
Assay
Development

Bulk Supply

Custom
Packaging

Private Label
OEM
Manufacture

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Given the increasing demand for expert support to expedite the development of molecular diagnostic tests, Bioline has recently expanded its Custom Solutions group. Learn more about our:

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Our Services

Since Bioline was first established, we have always responded quickly to meet the novel requirements of our industrial partners.

With a proven track record for quickly and efficiently meeting the most stringent product and service requirements, we at Bioline offer a broad range of custom solutions, which can be tailored to meet your individual needs, including: custom assay development, bulk supply of catalog and custom reagents, custom packaging, private label manufacturing, validation support, scheduled deliveries and technical support.

Our Team

The Custom Solutions division of Bioline offers custom assay development services, conducted by our highly-experienced, London-based R&D team. This team has been developing assays since Bioline was established in 1992 and has earned a reputation for formulating assays that perform reliably in even the most challenging conditions. Our unparalleled understanding of enzymology, buffer chemistry and how they can be adjusted to influence assay performance have enabled us to design assays that meet a very broad range of performance criteria.

Assay Optimization

Our development experts are adept at making adjustments to reagent formulations to achieve the highest performance levels in terms of assay sensitivity, reproducibility, accuracy, inhibitor tolerance and specificity. We understand that achieving target performance levels can be about optimizing magnesium concentration, reaction volume, dNTP concentration, pH, dUTP concentration, the inclusion of PCR stabilizers and additives, the choice and concentration of salt, fluorescent dye selection and/or thermal cycling parameters. In the pursuit of reliable assays, we routinely verify thermal stability, assay reproducibility and freeze-thaw stability.

We place quality at the heart of our actions. Hence, all test development work is performed in accordance with ISO 13485. To ensure the successful, rapid application of the tests we develop, it's our R&D team that provides any post-launch technical support.

Meridian Bioscience, Inc.

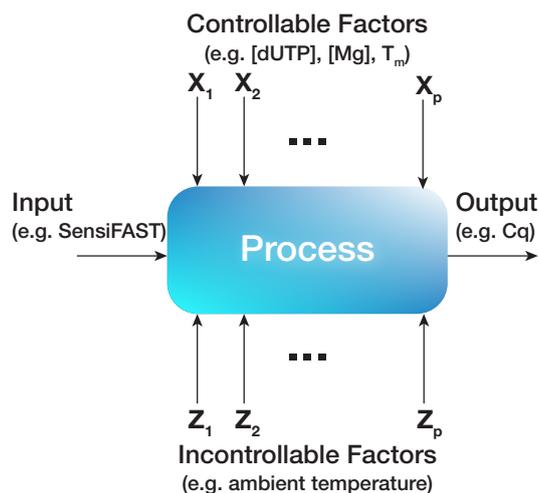
Bioline is a wholly-owned subsidiary of Meridian Bioscience, Inc. (NASDAQ:VIVO). Meridian is a life science company that develops, manufactures, markets and distributes a broad range of innovative diagnostic test kits, rare reagents, specialty biologicals and components.

The Meridian expertise extends to the development of diagnostic tests that demonstrate the required performance and consistency to meet FDA and CE-IVD regulatory requirements. Bioline has shaped its own development efforts according to the methodology Meridian applies in the development of diagnostic kits.

ASSAY DEVELOPMENT METHODOLOGY

Development Paths

In the pursuit of optimal assay performance, our Bioline Custom Solutions group follows two alternative, but often complementary development paths, namely our fast and standard development tracks. Typically, if a development project is considered multi-variant (e.g. one-step RT-qPCR), our R&D team follows our fast-development track, which applies leading-edge Design of Experiments (DoE) methodology.



Design of Experiments

DoE is a well-established and proven statistical method that can be applied to assay development. DoE is defined as a systematic method to determine the relationship between factors affecting a process and the output of that process. The use of DoE in assay development often speeds up assay optimization and facilitates a more thorough evaluation of assay variables. Typically there are several levels of design which can be applied.

The simplest level of investigation includes experiments to identify which determinants, including components (e.g. master mix composition) and experimental conditions (e.g. thermal cycling conditions), are most critical to assay performance. This is followed by more thorough analyses that enable identification of significant correlations between performance determinants. The more complex final stage facilitates finer optimization of these factors and improvement of assay robustness.

Our fast-track process applies DoE methodology to predict the best combination of multiple assay variables. Our standard track process is applied either when a development project is considered to be single variant (e.g. normalization of gene expression analysis), or when we are verifying the performance of an assay formulation predicted by our fast-track process.

Application

Our complete portfolio of reagents, which can be customized to meet your individual assay performance specifications, encompasses NGS library preparation, qPCR, reverse transcription, RT-qPCR and end-point PCR.

Our custom portfolio includes:

- JetSeq™ DNA Library Preparation Kits for NGS
- SensiFAST™ qPCR Mix
- SensiFAST™ Lyo-Ready qPCR Mix
- SensiFAST™ One-Step RT-qPCR Mix
- SensiFAST™ Reverse Transcriptase
- IMMOLASE™ Covalently-Modified Hot-Start DNA Polymerase
- IZOPOL Isothermal DNA Polymerase
- MyTaq™ PCR Mix
- MyTaq™ One-Step RT-PCR Mix
- Glycerol-free Taq DNA Polymerase
- High-Concentration Taq DNA Polymerase
- dU qPCR Mix (visualization dye & anti-Taq antibody)
- Nucleotides

If you have alternative requirements, our assay development capabilities mean that we are in a strong position to provide assistance. We maintain a full development pipeline of new products, meaning that our portfolio of custom reagents is evolving rapidly. We are willing to consider undertaking any development project.

Assay Format

Modifying the format of the assay can bring advantages in terms of delivery, storage, cost and even performance. Bioline has considerable experience of lyophilizing reagents to convert aqueous phase assays in to lyophilized, or lyo-ready analogs that both meet the highest standards of performance and improve accessibility to end-users. The advantages of lyophilization include:

- Maximization of reagent quality and performance
- Simplification of workflow
- Provision of room temperature stability
- Enabling incompatible reagents to co-exist
- Removal of water from the assay for increased sample volume
- Reducing manufacturing and delivery costs
- Streamlining product time to market
- Improving storage capacity without increasing overheads

REAGENT MANUFACTURING



Bioline, together with our collaborators are able to lyophilize almost any reagents whilst achieving reproducibility, sensitivity and specificity of target assays.

Support

Bioline has 25 years of expertise reagent manufacturing. Outsourcing your reagent manufacture to Bioline allows you to focus on other important issues such as new product development and continuous improvement. We can help you determine the target specifications for your product, including reproducibility, stability, batch size and format. Furthermore, we can shorten your product time-to-market and minimize your start-up costs.

Facilities

We manufacture over 300 off-the-shelf and custom reagents in our production facility, which is located near Berlin. Our Production team includes over 30 dedicated manufacturing scientists and technicians, as well as eight dedicated QC scientists. Our German facility employs state of the art equipment and is capable of small-scale to multi-liter volumes of reagent production. The capacity and flexibility of our production facility enables us to respond quickly to any throughput requirements.

Bioline understands the importance of adhering to high-quality standards when manufacturing reagents; all manufacturing is performed in accordance with ISO 13485.

BULK REAGENT SUPPLY

Flexibility

Bioline offers reagents with the same technical specifications as our catalog products but in larger, more convenient pack sizes. Furthermore we can supply both catalog and custom products in bulk quantities. Our production facility is highly flexible, meaning that we are able to respond very quickly and can manufacture reagents in a very broad range of batch sizes, to meet your individual throughput requirements. Custom packaging is also available for when your individual reagent volume requirements necessitate novel product assembly.



Advantages

Sourcing bulk quantities of product from Bioline offers:

- **Consistency:** we provide bulk quantities as single batches to support you through the development of robust, reliable assays
- **Confidence:** bulk quantities of a single batch enable multiple technicians to remove another potential source of variability
- **Convenience:** Bioline offers a range of formats, volumes and packaging options to allow these to be used directly without any further processing
- **Value:** bulk reagent volumes qualify for discounts as they take advantage of economies of scale in the manufacturing process

Objectives

Our quality policy is comprised of four main objectives that govern our working practices. These are:

- Comprehensive organization of co-operation with partners and suppliers
- Economic efficiency and avoidance of nonconformities
- Clear and transparent instructions and operational sequences for the realization of customers' demands
- Positive external effect and creation of total confidence in the company on the part of the customer

ISO 13485 Compliance

Bioline understands the importance of adhering to the ISO 13485 quality standards when developing and supplying custom reagents. Hence, all custom work is performed in accordance with ISO 13485. Our ISO certification confers the following benefits to our stakeholders:

- Complete confidence in Bioline
- Reassurance of risk definition & management
- Order trail
- Supply chain security
- Materials traceability
- Manufacturing consistency
- Reproducible high standard of quality

Our adherence to the ISO quality standards not only confirms our commitment to being a reliable and technically competent partner, it also means that we have greater understanding of our customers' and partners' requirements and are committed to further developing our industrial partnerships.

“Business commitment for continuous improvement at Bioline is at the center of our innovation culture. Bioline recognizes that the implementation and use of internationally accepted standards of quality management provides assurance of our products performance and business processes. This has been accomplished through the implementation of ISO 9001 and ISO 13485 across our global operations.”

Through the act of putting quality at the center of all we do, we aim to instill a high level of confidence with all our stakeholders and present Bioline as the company of choice.”

Chris Weatherall, Senior Director Quality Assurance & Regulatory Affairs.

Certification

Visit bioline.com to view:

- Bioline GmbH ISO 13485:2003 Certificate
- Bioline Reagents Limited ISO 13485:2012 Certificate
- Press Release entitled “Bioline is certified to the ISO 13485 Quality Standard”.



INDUSTRIAL PARTNERSHIPS



Proven Track Record

Our industrial partners belong to many sectors, including agricultural biotechnology, pharmaceuticals, in vitro diagnostics, contract research and veterinary diagnostics. The assays we have developed with our partners span many applications and are being routinely applied to crop research, food testing, animal health, pathogen detection, biomarker and drug discovery.

Before embarking on a project, we consult with you to discuss your requirements, including the draft technical specifications for your assay, volume requirements, your development budget and who the key stakeholders are in your organization.

Collaboration

Bioline has worked and continues to work successfully, alongside life scientists in industry to support the development of tests that improve human, animal and plant health. By leveraging the expertise of your organization and ours, in assay development, customization, production and quality control, we can help you to commercialize your product as quickly and efficiently as possible.

Confidentiality

Bioline guarantees absolute confidentiality. We are conscious that any information that you provide to us is sensitive and needs to be handled with exceptional care and consideration. All information that you provide to us will be kept confidential. We shall also take the time to establish the best way to communicate with you, to protect your privacy.

If it is your preference, before discussing your technical requirements, we can draft a Non-Disclosure Agreement (NDA) for co-signing.

Unravelling DNA *To Enable Your Discovery*

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