For seamless, scalable, flexible design and production of your Molecular diagnostic kits

Biofortuna offers custom IVD assay development and manufacturing services. Combining state-of-the-art facilities with proven clinical diagnostic know-how our services include design, development, manufacturing, freeze-drying (lyophilisation), dispensing and kitting. The company's proprietary freeze-drying expertise enables complete amplification reagents to be transformed into instantly soluble freeze-dried pellets.

BIOFORTUNA™
SIMPLY DIAGNOSTICS

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Biofortuna IVD Contract Services

Molecular Diagnostic Assay Development and Manufacture

- Design and Development
- Manufacturing
- Freeze Drying
- Dispensing and Kitting

BIOFORTUNA™
SIMPLY DIAGNOSTICS

IVD Molecular Diagnostic Assay Development and Manufacture Services

Biofortuna's contract manufacturing and development division offers state-of-the-art facilities for the development and production of your IVD kits, including freeze-drying (lyophilisation). As an FDA-registered site and ISO 13485 company, we work with both multinationals and small start-ups, manufacturing an array of assay technologies. We pride ourselves on understanding our customers requirements and design projects to meet their needs.

Design & Development

We can develop complete molecular diagnostic assays to meet your specific needs, from designing primers and probes to creating custom mastermixes and buffers. Our experienced team can work with you from initial assay design through to final product development and validation. Our services include the following:

- Primer and probe design
- Assay development, stabilisation and validation
- Freeze-drying
- Technology transfer to production

By combining assay design skills, effective communication and project management, we can help you go quickly from concept to high quality assays. Our stabilisation technologies enable the development of freeze-dried, air-dried and liquid format assays for qPCR, multiplex PCR, melt curve analysis and end-stage PCR. These stabilising methods work well with enabling technologies such as hotstart, hydrolysis probes, isothermal tests (such as LAMP) and intercalating dyes such as SYBR green.

Manufacturing

Our FDA registered and ISO 13485 certified manufacturing facilities allow us to provide everything from small-scale pilot batch manufacture to full commercial production, with a range of automated liquid handlers, semi-automated plate sealers and bag sealers. We will carry out a full transfer to production process, with triple batch validation, to ensure your kits are made to the highest of standards.

We can provide a full range of manufacturing services, including:

- Custom reagent and kit production
- Full project and production management assistance
- Flexibility in scale and process
- Dedicated quarantine and development facilities
- Quality and Regulatory Support

Freeze-Drying

Our lyophilisation expertise and proprietary cryo-preservatives enable us to transform thermolabile molecular reagents into instantly soluble freeze-dried pellets. We also have a range of proprietary master mixes for qPCR end-stage PCR and one-step RT PCR, which have been optimised for freeze-drying and offer excellent performance for multiplexed PCR.

Our infrastructure includes:

- Temperature and relative humidity controlled 5%RH manufacturing, for improved stability of freeze-dried products
- Several production grade manufacturing freeze-driers, as well as a pilot freeze-dryer
- Core analytical services using Freeze-Drying Microscopy (FDM) and Differential Scanning Calorimerty (DSC) to determine critical drying parameters
- Karl Fischer titration to determine moisture content of lyophilised reagents

Dispensing and Kitting

Our state-of-the art, FDA registered and ISO 13485 certified production suite is specifically set up for dispensing, assembly and packaging of both dried and liquid assay kits. We use a versatile approach to offer dispensing into vials, plates, strips or cartridges to suit the individual needs of your assay.

Our services include:

- Dispensing and labelling
- In-process and finished goods QC
- Kit assembly and packaging
- Shipping

Our process

1 Design and feasibility studies
- Experts in the design of complex PCR kits
- Selection of stabilisation method and appropriate reagents
- Conversion of liquid assay to stabilised dry assays or lyophilised format

2 Development and validation
- Extensive kit optimisation and validation
- Create design history files

3 Technology transfer and production
- Transfer of assays from development to production
- Triple batch validation
- Low humidity, environmentally controlled production suite

4 Quality
- Raw material, in-process and product release QC
- FDA registered and ISO certified facility
- Full documented control processes