

# Oligonucleotides and BHQ Probes for molecular diagnostics



Think success at full scale - right from the start





## Shorten your time to market by eliminating unforeseen challenges

- Scalability and consistency from development through commercialisation
- Dedicated technical team to help you at every stage of development
- Single stop OEM and contract manufacturing partner

LGC, Biosearch Technologies™ is a global leader in the design, development, and manufacture of sophisticated custom oligonucleotide-based tools and mission critical components for the molecular diagnostic, research and applied markets.

With a vertically integrated production model where sourcing of components are strictly controlled, Biosearch Technologies excels in providing consistently high quality oligos from early stage development through pilot scale and ultimately to production of your diagnostic kit.

Full speed ahead to full-scale production

## Why choose Biosearch Technologies?

Scalability and consistency from development through commercialisation

Designing oligos for a sequence is easy. What sets Biosearch Technologies apart is high reproducibility and consistency throughout your product development process, enabling you to quickly and easily bring your concept to commercialisation. Leveraging our experience in scale-up and lean operation, we understand how to maintain consistency from small to large scale production while ensuring the highest quality.

Dedicated technical team to help you at every stage of development

At Biosearch Technologies, we pride ourselves in supporting and partnering with our customers to help them achieve their goals. Your project will be directly managed by a dedicated and experienced project management professional, as well as a team of technical and manufacturing experts available for consultations and assistance throughout your development process.

## Biosearch Technologies is the patent owner and inventor of Black Hole Quencher™ (BHQ™), CAL Fluor™, and Quasar dyes.

Expertise and innovation in oligonucleotide synthesis

Biosearch Technologies has a legacy of innovation in oligonucleotide synthesis dating back to the SAM I DNA synthesizer that equipped Nobel laureate Kary Mullis to make the world's first PCR primers. With over 35 years of experience in oligonucleotide chemistry and manufacturing we offer the most comprehensive range of fluorescence-quenched probes for your molecular diagnostic assay development needs.

Single-stop OEM and contract manufacturing partner

In addition to specialty oligo manufacturing, your partners at Biosearch Technologies have extensive experience in synthesis, formulation, large-scale lyophilisation, custom packaging and private labelling to accelerate your assay to commercialisation. We can help fill in any gaps and get your product to market faster.

## Your oligo partner from design feasibility to product commercialisation

With multiple ISO-certified manufacturing facilities around the globe, Biosearch Technologies offers supply security and a comprehensive selection of high quality oligos for every phase of molecular diagnostic product development. Whether you need research-grade, pilot scale or GMP-compliant oligos, we are here to partner with you at every step.

#### **GMP**

- Full traceability
- Stringent pre-approved specifications
- Validated manufacturing processes
- Material release by QA review

### PilotDx™

- Designed for transition to full GMP
- Manufactured using qualified and controlled instrumentation
  - Process traceability

### Research grade

- Rapid turnaround time
- Ideal for design screening and feasibility testing
  - LIMS system for production tracking

Product commercialisation

**Design validation** 

**Design verification** 

Design feasibility

## Looking for high-throughput production? Or rapid turnaround GMP-grade oligos?

Ask us about our
HT-GMP and contract
non-GMP
oligo offerings
at techsupport@lgcgroup.com

## Custom oligos for every phase of development

	Research grade	PilotDx	GMР
Key differentiators	High quality, reliable oligonucleotides for early development stage research	Oligonucleotides for scale-up, design verification and validation     Quality and performance consistent with research grade oligos	Full traceability, stringent specifications and validated manufacturing processes and test methods
Delivery scale	10s to 100s nmol (small scale)	100s to 1,000s nmol (mid scale)	>100 nmol (large scale)
Available purification methods		Salt-free (desalted)     Reverse Phase HPLC     Salt-free (desalted)     Reverse Phase Cartridge (RPC)     HPLC (Single, Dual, Triple, Custom)	
Available delivery formats	Dry or in specific solutions     96- or 384-well plates on demand	Lyophilised or at specified concentrations/solutions     Custom labelling and kitting for Fill and Finish	Lyophilised or at specified concentrations/solutions     Custom labelling and kitting for Fill and Finish
Manufacturing standards	ISO 9001:2015	ISO 13485:2016	ISO 13485:2016     GMP compliant facility,     per 21 CFR Part 820
Quality control	Standard mass spectrometry	Standard mass spectrometry and analytical HPLC	Standard mass spectrometry and analytical HPLC
Turnaround time	2-7 business days	2-4 weeks	4-6 weeks

### **Production capabilities**

- Proprietary dual-labeled BHQ Probes, BHQplus<sup>™</sup> probes, Molecular Beacons, Scorpions<sup>™</sup> Primers, BHQnova<sup>™</sup>, CAL Fluor and Quasar dyes
- >250 modification options including amines, biotin, methylene blue, non-standard bases, and linkages, phosphate, spacers, thiol, etc and customisable client specific proprietary modifications
- Unmodified oligos up to 200 bases, rare specialty bases, RNA and DNA-RNA hybrids
- Flexible synthesis scales ranging from nmols to mmols
- Multiple purification methods available for desired purity specifications
- Dedicated HPLC purification columns and line clearance to eliminate contamination

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### **OEM commercial services solutions**



Biosearch Technologies provides comprehensive nucleic acid services for every phase of your product development process.

As a leading vertically integrated supplier, we offer unmatched control over costs and supply chain, while our dye/quencher IP allows you freedom to operate.

Ask us about our licensing programs for your diagnostic development projects

1.800.GENOME1 (1.800.436.6631/+1.415.883.8400) licensing@biosearchtech.com

## OEM Commercial Services

- Comprehensive range of final fill and finish solutions
- Customisable concentration formulations, including third-party reagents
- Oligo mixes
- Custom packaging, labelling and private labelling
- · OEM and kitting solutions
- Plate packaging and sealing solutions
- · Lyophilisation and dry-down solutions
- Flexible delivery formats: tubes, 96-well plates, 384-well plates and custom plastics

## **Analyte Specific** Reagents (ASR)

As an FDA registered medical device class I Analyte Specific Reagent (ASR) manufacturer, registration #3003009052, Biosearch Technologies offers a full range of oligonucleotides manufactured to ASR specifications.

Custom ASR oligos are fully compliant with federal regulations 21CFR820. In accordance with customer requirements and application, custom ASR oligos are manufactured and purified using techniques capable of meeting purity specifications ≥90%.

## Quality is our core

As a global leader in oligonucleotide and specialty chemical manufacturing, Biosearch Technologies is committed to adhering to the highest international quality standards ensuring controlled manufacturing processes, stringent QC/QA procedures and full traceability. Our quality management system is compliant with all relevant regulations and carries the following certifications:

- ISO 9001:2015
- ISO 13485:2016
- · US FDA Medical Device Manufacturer
- Registration number 3003009052

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Biosearch Technologies manufactures custom GMP and ASR oligos fully in compliance with FDA Federal regulations 21CFR820 where applicable.

#### Our quality system includes:

- Customer defined Certificates of Analysis (CoA)
- · Internal and external quality audits
- Full document control and traceability including retention of detailed batch records for ISO 13485 compliance
- Business agreements including non-disclosure and supply agreement
- Corrective and Preventive Action (CAPA) to ensure product conformance

All GMP oligos have unique part numbers and are manufactured following controlled specifications and processes. CoAs are provided to customers upon stringent quality assurance review prior to release.



## Integrated tools. Accelerated science.



biosearchtech.com



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