

Real-time PCR Diagnostics in the Pharmaceutical Industry

Real-time PCR (or qPCR) is now accepted as a mainstream and commonplace technique. Assays based on qPCR have rapidly expanded into fields such as pharmagenomics, food testing, environmental testing, human/animal diagnostics, and bioterror screening, providing results at incredible speed. Though qPCR is a technology nearing maturation, researchers are finding new applications which advance developments even more rapidly within their industry.

Thanks to revolutionary improvements in the manufacture and design of quality oligonucleotides by companies such as Biosearch Technologies, Inc. (Biosearch), the use of fluorescence-quenched probes in gene expression profiling has become routine practice for drug discovery and development. For example, the fine-tuning of labeled oligonucleotides, such as Biosearch's BHQplus™ probes, enables close study of human genetic variation by resolving SNPs (Single Nucleotide Polymorphisms) that influence disease susceptibility and predict drug efficacy.

Another trend in molecular diagnostics is toward multiplexed qPCR, allowing simultaneous detection of several target

sequences within a single reaction. This method offers enhanced control over reaction variation and sample consumption, and performs at its best when the probes incorporate a BHQ® (Black Hole Quencher®) dye, a cost-effective and highly efficient dark quencher from Biosearch with no native fluorescence. Multiplexed PCR also requires the use of several fluorophores with distinct spectral characteristics, such as Biosearch's CAL Fluor® and Quasar® dye series, specifically made to partner with the BHQ dye. With a wide selection of fluorophores and quenchers available, Biosearch's R&D team, along with outside collaborators, have clearly demonstrated that 5-plex qPCR can be practiced reproducibly; this capability offers an enormous advantage in drug development.

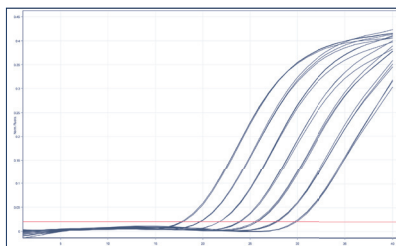


Figure 1: A four-fold dilution series of a gene of interest is amplified by a qPCR assay. Such assays detect and quantify target sequences with incredible sensitivity, and across an impressive dynamic range.

Scientists today well understand that fluorescence-quenched probes are indispensable tools for genetic analysis - tools which are driving the life science industry from individual therapeutics towards predictive personalized medicine.

To further enable the use of synthetic DNA in the pharmaceutical industry, Biosearch has established GMP compliant manufacturing and formulation facilities to produce oligonucleotides with rigorous quality control and documentation required by the industry for clinical trials and expression analysis. Biosearch Technologies also offers an array of solutions to aid its pharmaceutical clients, such as consultation in assay design, and accommodations in custom manufacturing, formulation, purification, and quality specifications.

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**Jerry L. Ruth,
Ph.D.**
Director of R&D

Jerry L. Ruth, Ph.D., recently joined Biosearch Technologies as Director of R&D. After his Ph.D. in organic chemistry at the University of California, Davis, and post graduate work at the University of North Carolina, Chapel Hill, Dr. Ruth spent many years building biotech companies in the San Diego area, eventually serving as Vice President of Research and Development for a molecular diagnostics company.

Moving back to his native Oregon, Dr. Ruth developed DNA forensic techniques for the U.S. Fish and Wildlife Service Forensic Lab in Ashland. After accepting the position of Director of Genomics and Proteomics at Molecular Probes in Eugene, and directing the R&D there for four years, he left after the company was acquired by Invitrogen. Dr. Ruth brings a unique combination of skills and expertise in molecular biology, genetics, clinical diagnostics, nucleic acid chemistry, forensics, genomics, and proteomics to Biosearch Technologies.

About Biosearch Technologies

Biosearch Technologies, Inc. (Biosearch) is an innovative ISO 9001:2000 biotechnology company based in northern California, USA, who strives to lead the oligonucleotide forefront in the molecular diagnostic movement. As the inventor and patent holder of the world-renowned BHQ (Black Hole Quencher) dye series, Biosearch has ramped up its efforts in developing GMP manufacturing facilities.

Biosearch has decades of experience synthesizing linear, dual-labeled Taq-Man®, Molecular Beacons, Scorpions™, Amplifluor® and Plexor™ probes and primers, which all follow a stringent manufacturing process that involves HPLC purification and mass spec analysis of all oligonucleotides. Many companies trust Biosearch for custom projects such as high throughput, private labeling of oligonucleotides and ready-for-inventory assay sets.



Real-time qPCR Assay Design Software
Your Blueprint for Success

Whether you're a novice or seasoned expert in qPCR, Biosearch's website offers RealTimeDesign™, a real-time qPCR assay design software. RealTimeDesign will ensure that your probes and primers demonstrate robust amplification and detection. The customizable software links directly to NCBI to put your design process at ease, whether you're designing a single assay or high-throughput batches.

Early 2009, Biosearch Technologies will launch two new design modules, one to allow the design of multiplex qPCR assays, and another to design gene expression assays for BHQplus probes, Biosearch's new compact, fortified probes with duplex stabilizing technology.

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