

Molecular Biology

Charles River Laboratories' Molecular Biology groups perform a comprehensive array of genomics-based assays to support all phases of drug development from discovery and preclinical studies through clinical trials in either singleplex or multiplex formats. Regulatory guidance recommends the inclusion of pharmacogenomic investigations during the drug or biological product development process.

Our Molecular Biology facilities have custom-designed, dedicated laboratories with separate sample processing (nucleic acid extraction), reagent preparation, and amplification/product detection areas in order to minimize the possibility of cross-contamination.

Charles River isolates and purifies DNA and RNA from a variety of tissues, body fluids, and cells in culture. Our extraction procedures are optimized to provide the highest quality real-time Q-PCR results; both quality and yield of extracted nucleic acid samples are assessed prior to being used in the Q-PCR assay.

Technical Capabilities

Charles River has invested in leading-edge, real-time PCR platforms capable of supporting multiple fluorescent chemistries, such as TaqMan® and SYBR® Green, to facilitate the development of the most sensitive and robust Q-PCR assays for your products.

The Luminex-based QuantiGene® system enables high throughput gene expression analysis of up to 30 different mRNA targets in a single assay directly from crude cell lysates or tissue homogenates. The QuantiGene® technology is highly complementary to microarray analysis and RNAi validation.

Bioluminescent reporter gene assays have many applications in molecular and cellular biology due to their exquisite sensitivity, precision, and compatibility with high throughput platforms. Charles River has conducted quantitative reporter gene assays in support of preclinical and clinical safety and efficacy studies. The real-time PCR platform is also capable of performing allelic discrimination assays using next-generation TaqMan® probe chemistry.

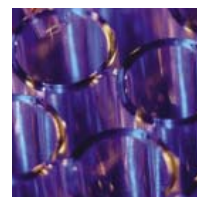
Services

- Nucleic acid therapeutic assessments
 - Biodistribution studies
 - Pharmacokinetics
- Gene expression analysis
- Cytokine mRNA profiling in immune response
- Biomarker assessment
- Real-time Quantitative PCR (Q-PCR)
- Reverse Transcriptase PCR (RT-PCR)
- QuantiGene® Plex
- Reporter gene assays
- Allelic discrimination assays (SNP genotyping)
- Genomic and plasmid DNA isolation
- Restriction mapping
- Gene copy number
- DNA detection in mammalian and microbial cells
- Residual DNA detection by hybridization analysis
- Microbial contamination
- Assay feasibility, development, and validation
- Biological sample analysis
- GLP/non-GLP study designs and reporting



Regulatory Expertise and Compliance

Charles River has considerable scientific and technical expertise in the development of assays for gene expression studies or target gene detection. Our expertise includes assay development, sample processing, and data analysis and interpretation. Molecular assays are validated to Food and Drug Administration (FDA)/International Conference on Harmonisation (ICH) guidelines and are in compliance with Good Laboratory Practice (GLP), as required.



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