

# Biodistribution and Expression Analysis



AppTec offers a GLP-compliant biodistribution and expression analysis program designed to assess the dispersal and activity of any nucleic acid sequence in a biological setting. Using real-time PCR technology, our program provides a powerful tool for evaluating the efficacy and safety of nucleic acid protocols by quantifying the copy number of a DNA or RNA target in a defined set of organs and tissues.

## Applications

AppTec's biodistribution technology is applicable to any study requiring quantification of a nucleic acid in a biological setting. Broad capabilities of this technology include:

- Gene therapies  
(viral and non-viral compounds)
- DNA vaccines
- Transgenic plants and animals
- Expression profiling
- Preclinical drug efficacy studies  
(antivirals and anticancer agents)

Direct consultation with our clients allows for the design of custom protocols and the development of specific assays tailored to particular applications.

## Technology

For its biodistribution and expression analysis studies, AppTec employs quantitative real-time PCR (qPCR). qPCR can quantify precise concentration, which is extremely useful for gene expression studies. Exceeding the limitations of classic end point PCR, qPCR offers a unique combination of sensitivity and quantification allowing rapid, accurate determination of DNA or RNA content by kinetic quantification.

Using kinetic quantification, the real-time PCR technologies offered by AppTec allow accurate measurements to be taken during the log-linear phase of PCR.

## Expertise

AppTec's knowledgeable scientists maintain an ongoing interactive collaboration with clients during every phase of the testing program. Toxicology, veterinary, and molecular biology staff members have many years of experience and are fully trained in GLP and GMP procedures. In addition, our advanced expertise allows AppTec to specialize in the development of custom assays.

AppTec is a unique single source for comprehensive GLP/GMP-compliant testing, contract research and development, and specialized cGMP manufacturing services for biopharmaceuticals, medical devices, cellular therapeutics, and tissue-based products. We provide our clients the highest level of state-of-the-art science, regulatory expertise and individualized customer service.

## PROGRAM PHASES

### 1 Project Planning

- Initial discussions with Account Manager
- Both animal and molecular study components designed with AppTec study directors
- Initial proposal prepared, specific probes made
- Protocol validated

### 2 Sample Receipt

- Sample submitted using custom submission form
- Sample received and assigned unique accession number(s) by validated database
- All test samples stored in continuously temperature-monitored freezers

### 3 Animal Studies

- Animals inoculated
- Tissues isolated individually to minimize cross contamination

### 4 Sample Preparation

- Tissues processed using industry-accepted practices to prevent cross contamination
- Nucleic acids isolated in designated room
- Nucleic acid concentration determined

### 5 Quantitative Real Time PCR

- Separate clean rooms used to prepare master mixes and negative controls
- Separate positive room used to prepare and store positive controls, and perform amplification
- PCR reactions performed and analyzed; data is acquired in real time

### 6 Quantification

- Spike controls used to measure potential assay interference
- Linear regression analysis performed to determine copy number
- All assays run in accordance with FDA guidelines

### 7 Final Report

- Final report completed
- Report reviewed by QA unit and signed by QA representative and study director
- Final report issued including: description of assay, results of the quantification, and tabulation of data



For more information about our wide range of services, contact an AppTec Account Manager at 888.794.0077.

[www.apptec-usa.com](http://www.apptec-usa.com)