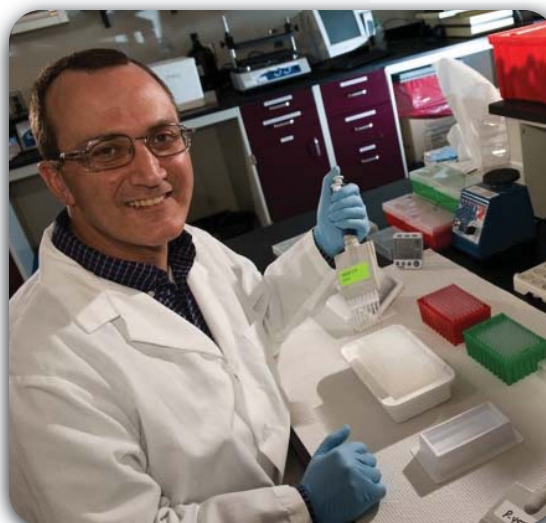


## • CYP450 Inhibition Services

## Service Overview



### Cytochrome P450 (CYP450) Inhibition Services

- Definitive *in vitro* drug interaction data to support clinical studies
- Eight isoform-selective LC/MS/MS assays for seven human liver microsomal CYP isoforms:
  - 1A2, 2B6, 2C8, 2C9, 2C19, 2D6, 3A4 (2 substrates)
- Validated methodology utilizing stable isotope-labeled internal standards
- Endpoints: percent inhibition; absolute or relative IC<sub>50</sub>

### Customize

Many aspects of our assays can be customized to provide our clients with the endpoints and degree of quality assuredness that is required.

- Flexible plate design: number of test compound concentrations and replicate reaction mixtures
- Microsomal protein and substrate concentrations
- Reaction time
- Alternative control inhibitors
- Extent of peer review and quality assurance review

### Method Development and Validation

Looking for an additional CYP isoform or alternative substrate? We welcome the opportunity to develop and to validate alternative methodology as needed.

**Advion is a premier bioanalytical services laboratory. Collaborate with Advion and expect quality, flexibility, timeliness, and a commitment to scientific excellence.**



## Why Choose Advion?



### Quality

- High purity substrates, control inhibitors, and reference compounds
- Established run acceptance criteria
- Low protein and organic solvent concentrations
- Low substrate depletion
- Assay selectivity and enzyme activity controls
- Control inhibitors diluted in parallel with test compounds to ensure accurate preparation
- Analyses carried out to the standards of GLP
- Peer and QA review of data
- Adherence to the FDA Draft Guidance<sup>1</sup> and PhRMA white paper<sup>2</sup> on drug interaction studies

### Fast Turnaround

Preliminary data can be provided in 1–3 weeks depending on the number of CYP isoforms and test compounds analyzed. One additional week is typically required for QA review.

### Expertise

Advion utilizes state-of-the-art instrumentation and talented scientists to produce high-quality data. Established leadership, frequent communication, and expertise with GLP studies provide our clients with the highest level of confidence.

<sup>1</sup> Guidance for Industry: Drug Interaction Studies—Study Design, Data Analysis, and Implications for Dosing and Labeling, USFDA, Draft Guidance, Sep 2006.

<sup>2</sup> Bjornsson, TD et al. (2003) The conduct of in vitro and in vivo drug-drug interaction studies: a Pharmaceutical Research and Manufacturers of America (PhRMA) perspective. *Drug Metab Dispos* 31:815-832.