LifeNet Health®
LifeSciences

CYP Induction Assay

Evaluating new drug candidates for their potential to induce Cytochrome P450 (CYP) enzymes is an important step in the drug discovery and development process as it offers important information on:

- **Safety of induced metabolites:** CYP induction may lead to changes in the pharmacokinetics of a drug, leading to unexpected toxicity
- **Efficacy of co-medications:** The induction of CYP enzymes for one drug may reduce the therapeutic efficacy of other medications

Your Partner in CYP Induction Assays

Our services team offers a standardized protocol for assessing both CYP induction-induced gene expression and enzyme activity for accurate prediction of drug metabolism in the body. This ensures high-quality data with the speed and accuracy needed for early drug discovery. We provide study designs suitable for IND submissions and collaborate with you to tailor the study to your specific research needs.

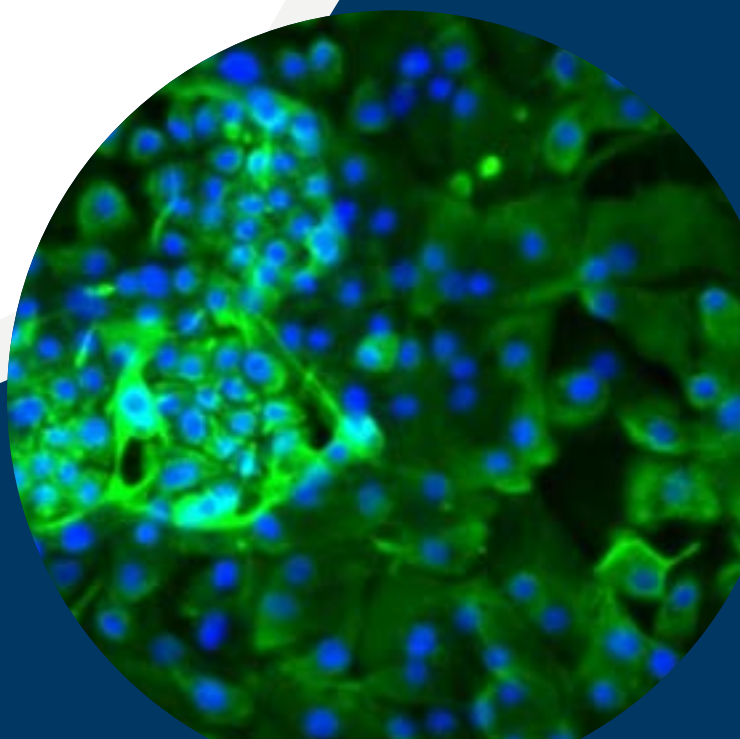
Benefits of Our Services:

Accurate and reliable data for informed decision-making

Fast turnaround times to keep your drug development on track

FDA guidance-based studies to meet regulatory requirements

Collaborative approach to ensure the study addresses your research questions



Additional LifeNet Health LifeSciences Services | *Click to learn more:*

- *In vitro* assay services
- DMPK/ADMET assays
- OECD safety studies
- Cytotoxicity assays

FDA Guidance Based Methods

LifeNet Health LifeSciences Cell-Based Assays Services offers two CYP inductions assays — Method 1: Gene Expression Fold-Change and Method 2: Enzyme Activity. Both methods are based on the ***FDA Guidance document entitled, In Vitro Metabolism and Transporter Mediated Drug-Drug Interaction Studies****.

The evaluation focuses on the primary CYPs, such as CYP1A2, CYP2B6, and CYP3A4/5, with further assessment of other CYP2C enzymes recommended if significant induction of CYP3A4/5 occurs.

Standard Protocol for *In Vitro* Cytochrome P450 (CYP) Induction

ASSAY PARAMETER	PROTOCOL
Test system (panel of donors for client selection)	Human primary hepatocytes (pooled) (rat, dog, and NHP also available)
Qualified hepatocyte lots	Characterized for induction studies
Plate format	24-well collagen-coated
Cell density at seeding	0.3 x 10^6 / well in 24-well plate
CYP enzymes	1A2, 2B6, 3A4 (human)
Test articles	1
Reference drugs	3 (Omeprazole, Phenobarbital, Rifampicin)
Replicates	3
Test concentrations	6 plus 0
Exposure time	72 hr
Amount of test compound required	10 mg
Analytical method	mRNA fold changes (qRT-PCR)
Analytical method (CYP enzyme activity)	CYP-glo from Promega or equivalent; LC/MS/MS analysis quoted upon request
Cell health markers	LDH ELISA for protein leakage
Time to complete	2-3 weeks
Regulatory	Non-GLP or GLP compliant
Deliverables	Emax, EC50, full report, graphs/tables

*U.S. Department of Health and Human Services Food and Drug Administration | Center for Drug Evaluation and Research (CDER). (2017, October 24). In vitro metabolism-and transporter-mediated drug-drug interaction studies guidance for industry. U.S. Food and Drug Administration.

How can we help?

Talk with one of our experts for help with general inquiries, protocol details, or becoming a new client.

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