SPMED, the frontier leader in personalized precision medicine.

SPMED

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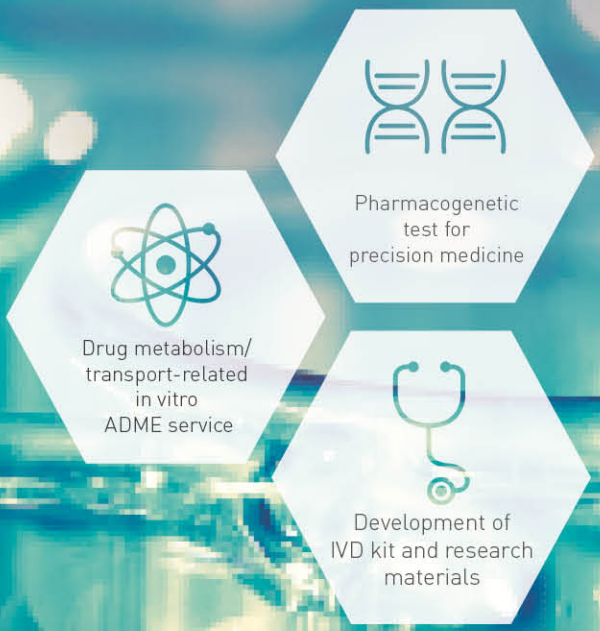
From Bench-to-Bedside !
From In vitro to In vivo !
From Research to Precision Medicine !

Full-range of knowledge based professional services

When patients expect precise treatment which is tailored to their personal genotype, genetic testing is the path to better treatment outcomes and quality of life.
Also, the pharmaceutical industry is driving the change and calling for maximized efficiency and professionalism in the bio-outsourcing market. SPMED, Ltd. is a spinoff of the PharmacoGenomics Research Center at Inje University, South Korea, With over a decade of experience providing personalized precision medicine, including biomarker discovery, preclinical validation, clinical validation, clinical utility validation and clinical implication



SPMED

Providing full range service, from new drug development to personalized precision medicine

Pharmacogenomic Service for Personalized Precision Medicine

SPMED

Pharmacogenomics Technology Platform

SPMED provides the clinically validated pharmacogenetic tests for detecting genetic biomarkers that are recommended by US FDA, etc. With our highly skilled technique, other genetic analysis related to drug metabolism enzymes, transporters, transcription factors, and pharmacodynamic genes are also available upon request.

Services	Items	Specific Items
Research Purpose	Phase I Drug Metabolism Enzyme	CYPs (CYP2C9, CYP2C19, CYP2D6, CYP3A4, CYP3A5, CYP4F2 etc.), ADH1B, ALDH2, etc.
	Phase II Drug Metabolism Enzyme	UGTs (UGT1A1, UGT1A4, UGT1A5, UGT2B7 etc.), TPMT, NAT2, SULTs (SULT1A1, SULT1A2, SULT1E1), etc.
	Transcription Factor	H1F1A, NR0B2, NR1H3, NR1H4, NR1I2, NR1I3, NR2A1, ONECUT1, TCF1, etc.
	Drug Transporter	ABCs (ABCB1, ABCG2, ABCC1, ABCC5 etc.), SLCs (SLCO1B1, SCL6A4, SLC10A1, SCL22A1, SLC22A2 etc.) ,etc.
	Pharmacodynamic Gene	VKORC1, P2Y12, PON1, POR, PROC, TYMS, ANXA6, APOE, CDA, CHD5, IL28B, ITGBL1, OPRM1, etc.
	Others	HLA Class I (HLA-A, HLA-B), HLA Class II (HLA-DQA1, HLA-DRB1), TGFBI, etc.
Research Support	Genetic Testing Methodology	Developing researcher-customized method for genetic testing (Full sequencing, SNaPshot, Real-time PCR, NGS, etc.)
	Haplotype, LD Analysis	Haploview, SNPAlyze, PLINK, Seattle SNPs Analysis
	SNP Functional Study, CNV Analysis	Real-time PCR using Polyphen, SIFT, Blasome, Transfec, CNV Prove, etc.
	Gene Expression Analysis	Quantitative Real-time PCR
Resource Management	Management of Samples and Control Materials	Sample and data anonymity for the protection of personal information; Qualitative/quantitative DNA/RNA QC using Nanodrop and Bioanalyzer; Immortalized cell line production with Epstein-Barr Virus and management (used as control materials in genotyping)
	Systematic Management of Research Resources	Simultaneous management of clinical material and its data, after research project.

Leading Pharmacogenetic Test

01 We provide genotype-based clinical/non-clinical research support services in the full range of drug development and Investigational New Drug (IND)/New Drug Application (NDA) approval.

02 Our technology based on direct sequencing, real-time PCR, SNaPshot and NGS enables the development of new target genes, methodologies/kits and companion diagnostic kits befitting the needs of customers.
ex) anti-cancer drugs, cardiovascular/ diabetes/endocrine diseases, immune-mediated adverse drug reaction (ADR) or hypersensitivity, other PK/PD genes

03 We offer professional and knowledge based consultation for personalized precision medicine with over a decade of experience in clinical pharmacological test, clinical research support and genetic testing, etc.

04 Our ONE-STOP website can helps you to request our service and get your results easily.

Request

Contact us via our website, e-mail or phone and request our service.

www.spmed.kr
help@spmed.kr / +82-51-362-1101

Preparation

Deliver below documents and sample to us.
(Documents/Blood Sample)
Genetic Testing Request Form, Informed Consent Form/ Whole blood

Testing

SPMED performs the testing and other additional research support, and verifies the results according to international standards.

Report

You can see your result within a week.

Development of IVD Kit and Research Materials

SPMED™ Genotyping Kit

Pharmacogenetic test kit to support drug prescription

Introducing SPMED™ Genotyping Kit

The effects of a drug can differ from person to person, due to the individual's genetic characteristics.
SPMED™ Genotyping Kit is a convenient tool which enables the user to test clinically verified pharmacogenomic biomarkers which are known to affect drug response.
The results can be used to guide drug prescription to help the optimize treatment outcomes.

Features

01
Highly-efficient and high-throughput multiple testing

02
Ability to target specific mutations by taking ethnicity into account

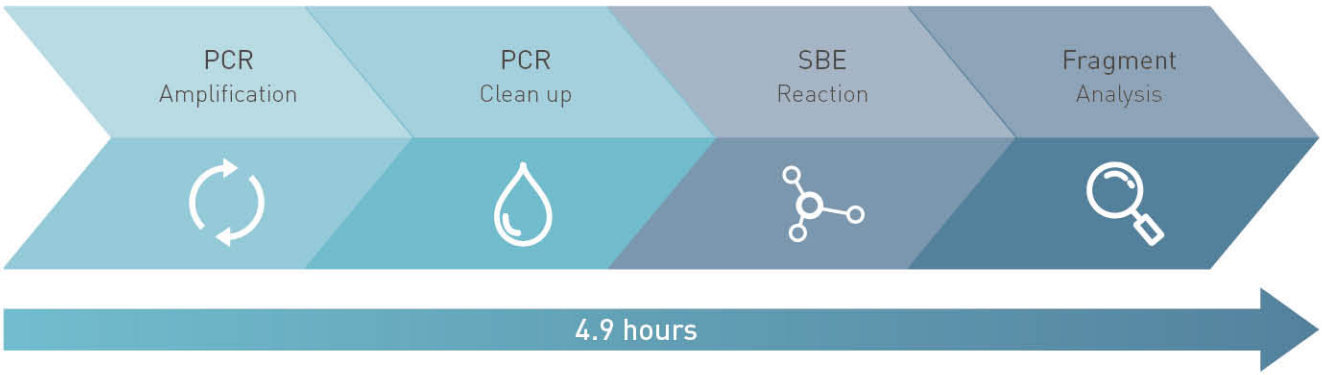
03
Highly accurate dual-check system capable of confirming both peak-color and size

04
High specificity and sensitivity using the HotStart PCR system

05
Easy-to-handle using master mix

06
Good reliability and reproducibility providing standard control DNA and very accurate results according to predetermined patterns

Testing Procedure using SPMED™ Genotyping Kit



SPMED™ Human Recombinant Enzymes

Customized drug metabolism enzyme for drug development and bio-medical research

Introducing SPMED™ Human Recombinant Enzymes

SPMED™ Human Recombinant Enzymes can be used in essential assays (reaction phenotyping, inhibition study and metabolic stability, etc.) across a variety of pharmaceutical fields, especially new drug development.
These are the major enzyme lists of cytochrome P450 (CYPs), UDP-glucuronosyltransferase (UGTs) and more, which recommended by the US FDA for drug development and drug interaction study.
SPMED can help your research providing high-quality products.

Features

01 High-expression system and quality control: providing excellent quality products in high activity

02 Guaranteed reliability by providing performance results including activity, kinetic assay, etc.

03 Customized metabolic enzyme production considering genetic variant

04 Reduction of time and cost by mass production within Korea

Products

Customized orders are also available for other enzymes according to the requests, other than the existing items.

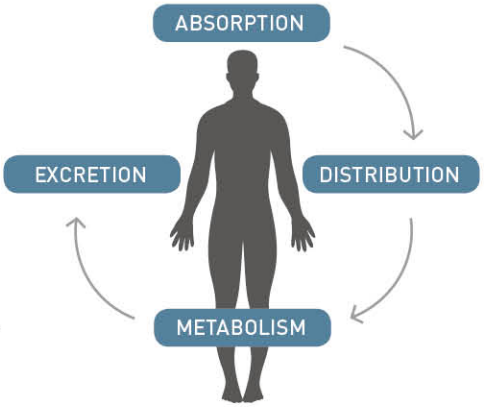
Categories	Items
Human P450 Enzymes	CYP1A2, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP3A4, CYP3A5, etc.
Human UGT Enzymes	UGT1A1, UGT1A3, UGT1A4, UGT1A6, UGT1A9, UGT2B4, UGT2B7, UGT2B15, etc.

Drug metabolism and Transport related in vitro ADME Service

SPMED provides extensive in vitro ADME service from in vitro to in vivo cases. New method or strategy development is available as per client request.

What is a in vitro ADME service?

Evaluation of a drugs Absorption, Distribution, Metabolism, and Excretion are often required for verification and approval of the drug's safety and efficacy.



- ✓ Supporting the evaluation of drug candidates development
- ✓ Increasing the chances of success, while also decreasing the entire time required for the development

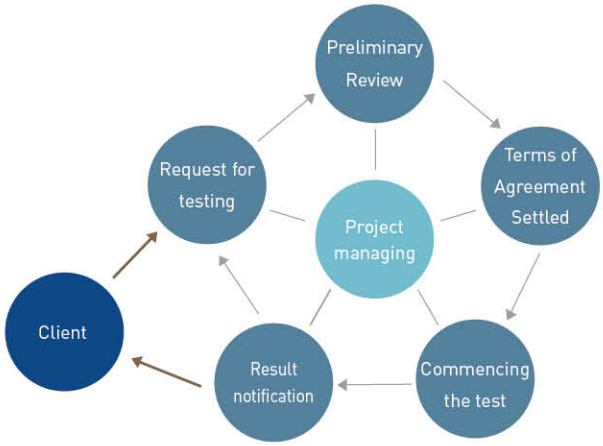
What SPMED provides in its in vitro ADME service

- In vitro ADME Testing according to US FDA recommendation
- Customized services according to clients needs
- Extensive ADME technology platform related to drug metabolism and transport
- Worldwide networks of highly qualified and experienced professional researchers with expertise in drug metabolism, transport as well as pharmacokinetics
- Professional research team with over a decade of experience in multiple nonclinical / clinical studies
- Access to the cutting-edge facilities and equipment provided by the Pharmacogenomics Research Center in Inje University

Operation Procedure of SPMED in vitro ADME Service

- Step-by-step deliberation for securing accuracy and expertise in testing
- Project management services to coordinate all aspects of a client's needs
- Quality assurance to ensure enhanced reliablity

Steps	Contents
Request	Interview request, confidentiality terms
Preliminary Review	Preliminary review and result notification
Agreement	Protocol writing and approval, review and conclusion of the contract, delivery of sample to test
Testing	Testing, ADME evaluation and examination, writing the draft report, delivery/review/discussion of the report
Informing the result and report	Writing and delivery of the final report. Archiving the data in accordance with contract and proceeding the expense settlement process.



in vitro ADME Technology Platform

Class	Subclass	Related Element Technology
Permeability	Drug absorption	Caco-2 cell permeability
	Hepatic excretion	Cryopreserved hepatocytes uptake
		Sandwich cultured hepatocytes
	Renal excretion	LLC-PK1 cell permeability
Drug Metabolism	Protein binding	Equilibrium dialysis
	Stability	Metabolic stability (microsomes, S9, hepatocytes)
		Species comparison (mouse, rat, dog, monkey, human)
		Plasma stability
	Metabolism	Reaction phenotyping : CYPs, UGTs, non-CYPs
		Enzyme systems (recombinant enzymes, microsomes, S9, hepatocytes)
		Kinetic studies (Km, Vmax , intrinsic clearance)
		Pharmacogenetics study (CYP2C19*10, 2D6*10B, 4F2*3…)
	Met ID	Metabolites profiling and Met ID
Drug Transport	Transporter substrate identification	Vesicle-based transporter assay
		Uptake transport screening in overexpressing cells or oocytes (OCTs, OATs, OATPs, NTCP)
		Efflux transport screening in overexpressing cells (MDR1, BCRP, MRP1, MRP2)
		Cryopreserved hepatocytes uptake
		Kinetic studies (Km, Vmax , intrinsic clearance)
		Pharmacogenetics study (OCT2A270S, OATP1B1*15, NTCP*2, MDR G2677T/A, BCRP Q141K)
Drug-Drug Interaction	Inhibition	Screening of inhibitory potential of CYPs (cocktail method), UGTs, Transporters
		Estimation of IC50 (Ki) value
	Time-dependent inhibition	IC50 shift assay, Kinact/KI assay
		Reversibility assay
	Induction	Reporter assay (PXR)
		mRNA expression level in human hepatocytes (CYPs, UGTs, Transporters)
		CYP activity in human hepatocytes
	IVIVE prediction	
Preclinical Study	Linearity/Bioavailability	IV/Oral administration PK
	Mass balance	Radio-labeled compound PK
	Distribution	Tissue distribution (brain, liver, kidney…)
	Met ID	Metabolites profiling and Met ID
	Biliary/Renal excretion	Bile cannulation
Early Phase Clinical Development	Preclinical Prediction of Human PKs	Microdosing study of hot compound and cold compound
		Allometry
		Physiologic Based Pharmacokinetics
	Phase I study	Pharmacologically guided dose escalation
		Human mass balance (cold/hot compound)
		Absolute bioavailability
		Drug-drug interaction potential study (cocktail study)
		Mechanism based drug-drug interaction study
		Genotype based ADME study
		Special population study (Renal/Hepatic dysfunction, Elderly, Gender)
		Bridging study
		Biologics
	Pharmacokinetics/ Pharmacodynamics	Non-compartmental/Compartmental Analysis
		Population Pharmacokinetics/Pharmacodynamics
		Dose-Effect/Concentration Effect analysis
		Development of Biomarker
Bioanalytical Services		

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