

# PharmiGENE

The global leader of pharmacogenetic tests

Product  
Patented PGx  
detection reagent

Service  
Diagnostic reagent  
OEM/ODM/CDMO



# About Pharmigene

Pharmigene is established in 2005 and located in Taipei, Taiwan.

Our goal is to innovate and commercialize diagnostic tests that enable individuals to be better informed about their genomic makeup and to make decisions that better their health.

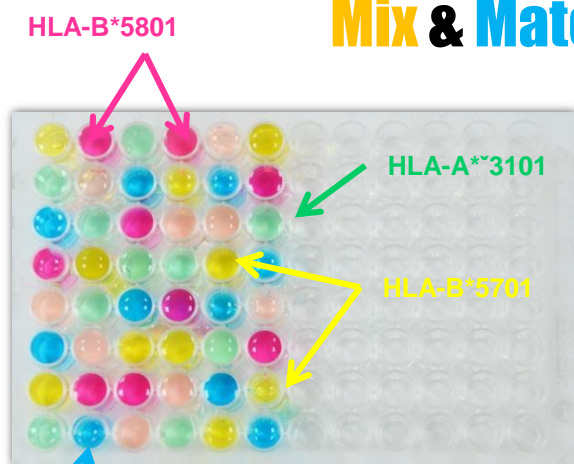
We have licensed exclusive world-wide rights and transferred key know-how from Academia Sinica relating to the genetic markers that are associated with adverse drug reactions caused by several popular drugs. We have obtained ISO 13485 and GMP certifications, and are manufacturing our DNA genetic tests under the most stringent guideline. In developing our DNA genetic tests, we also have validated our tests with clinical studies that involved hundreds and thousands of patients. Today our certified DNA genetic tests are available world wide.

## What Pharmigene products offer

- 1000 + real DNA samples includes Caucasians and Asians, and tested & validated by DNA sequencing.
- Over 99+% sensitivity & over 99% specificity compared with sequencing data.
- genomic DNA to results in ~2 hours.
- Compatible with most real-time PCR systems.
- Unique design to perform different genotyping tests at one time.



## Mix & Match Design...



HLA-B\*1502

**Making your  
real-time PCR testing  
easier & faster!**

# What is pharmacogenetics ?

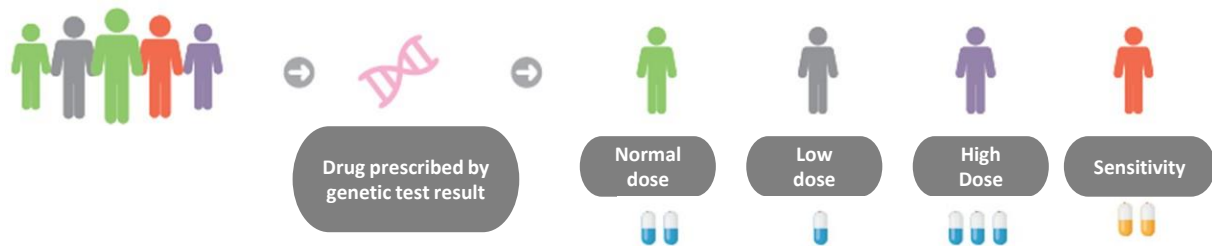
“Pharmacogenomics is the study of how genes affect a person’s response to drugs. This relatively new field combines pharmacology (the science of drugs) and genomics (the study of genes and their functions) to develop effective, safe medications and doses that will be tailored to a person’s genetic makeup.”

-What is pharmacogenomics? <https://ghr.nlm.nih.gov/primer/genomicresearch/pharmacogenomics>

Before, drug can only be prescribed by indications



Now, drug can be prescribed not only by indication but also by pharmacogenomics result

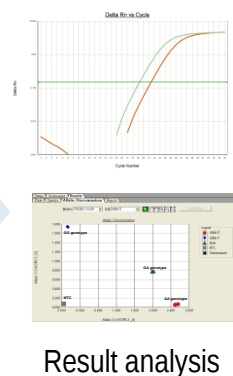


## How Pharmigene PGx products work

Sample collection  
Buccal swab or blood

DNA extraction

Target amplification  
by qPCR systems



Result analysis

# Hypersensitivity

## Drug Sensitivity

Drug sensitivity is the abnormal reaction of human immune system caused by medication. Any medication may have the possibility to induce the immune storm – drug sensitivity. The symptoms of drug sensitivity vary like hives, rash or fever. Sometimes, severe events such as Stevens-Johnson syndrome or Toxic epidermal necrolysis can occur and may cause death.

Product Name	Catalog #	Pack Size	Sample Size	Regulation	Description
PG1502 Detection Kit	PG-1502C-024	24 reactions	10 samples	TFDA NMPA HSA CE IVD	HLA-B*1502 gene has been found a strong association with <b>carbamazepine</b> induced severe cutaneous adverse reactions such as Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis. HLA-B*1502 gene is common in south-east Asia, South China and Taiwan.
	PG-1502C-048	48 reactions	20 samples		
	PG-1502C-096	96 reactions	40 samples		
PG1502 Companion Kit- RT	PG-1513C-012	12 reactions	10 samples	RUO	HLA-B*1513 gene is common (8-15%) in south-east Asians. Using this kit to distinguish HLA-B*1502 and HLA-B*1513 can help physicians identifying the patient from south-east Asia who has high risk to take <b>carbamazepine</b> .
	PG-1513C-024	24 reactions	20 samples		
	PG-1513C-048	48 reactions	40 samples		
PG5801 Detection Kit	PG-5801C-024	24 reactions	10 samples	TFDA NMPA HSA CE IVD Korea MFDS	HLA-B*5801 gene has been found a strong association with <b>Allopurinol</b> induced severe cutaneous adverse reactions such as Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis.
	PG-5801C-048	48 reactions	20 samples		
	PG-5801C-096	96 reactions	40 samples		
PG5701 Detection Kit	PG-5701C-024	24 reactions	10 samples	CE IVD	HLA-B*5701 gene has been found a strong association with <b>Abacavir</b> , a drug for HIV treatment, induced hypersensitivity.
	PG-5701C-048	48 reactions	20 samples		
	PG-5701C-096	96 reactions	40 samples		
PG3101 Detection Kit	PG-3101C-024	24 reactions	10 samples	RUO	HLA-A*3101 gene has also been found an association with <b>Carbamazepine</b> induced severe cutaneous adverse reactions. HLA-A*3101 gene is common in Japan, Korea, Europe and America.
	PG-3101C-048	48 reactions	20 samples		
	PG-3101C-096	96 reactions	40 samples		
PG1301 Detection Kit	PG-1301C-024	24 reactions	10 samples	RUO	HLA-A*1301 gene has also been found an association with <b>co-trimoxazole</b> (Baktar), <b>Dapsone</b> and <b>Phenytoin</b> induced severe cutaneous adverse.
	PG-1301C-048	48 reactions	20 samples		
	PG-1301C-096	96 reactions	40 samples		

# Metabolism

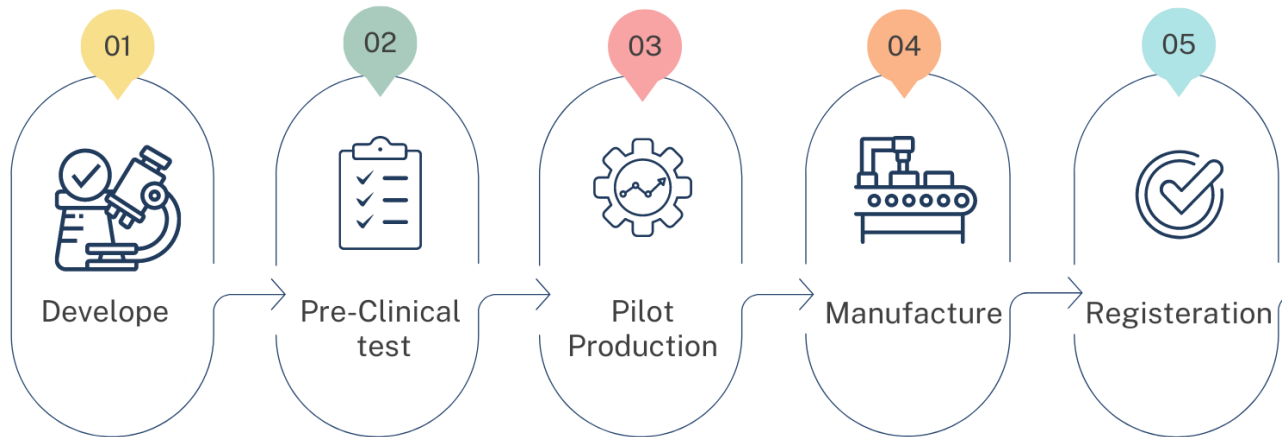
## Drug Metabolism

Drug metabolism has been recognized as the most important part to evaluate the real factor for drug efficiency. Drug metabolism is the metabolic breakdown of drugs by living organisms, usually through specialized enzymatic systems modulated by genes. Many of the major pharmacokinetic interactions between drugs are due to hepatic cytochrome P450 (P450 or CYP) enzymes being affected by previous administration of other drugs. The ability of CYP enzymes can be illustrated by genotyping.

Product Name	Catalog #	Pack Size	Sample Size	Regulation	Description
PG1639 Detection kit	PG-1639C-024	24 reactions	10 samples	TFDA CE IVD HSA	VKORC1-1639 SNP has been found a strong linkage with the maintain dosage of <b>warfarin</b> , a wide use anticoagulant. To test the different SNP type of VKORC1-1639 with CYP2C9*2(0430) and CYP2C9*3(1075) can help physician adjust the starting dose of warfarin and then quickly reach the maintain dose.
	PG-1639C-048	48 reactions	20 samples		
	PG-1639C-096	96 reactions	40 samples		
PG0430 Detection kit	PG-0430C-024	12 reactions	10 samples	TFDA CE IVD HSA	CYP2C9*2(0430) SNP has been found a strong linkage with the maintain dosage of <b>warfarin</b> , a wide use anticoagulant. To test the different SNP type of VKORC1-1639 with CYP2C9*2(0430) and CYP2C9*3(1075) can help physician adjust the starting dose of warfarin and then quickly reach the maintain dose.
	PG-0430C-048	24 reactions	20 samples		
	PG-0430C-096	48 reactions	40 samples		
PG1075 Detection kit	PG-1075C-024	24 reactions	10 samples	TFDA CE IVD HSA	CYP2C9*3(1075) SNP has been found a strong linkage with the maintain dosage of <b>warfarin</b> , a wide use anticoagulant. To test the different SNP type of VKORC1-1639 with CYP2C9*2(0430) and CYP2C9*3(1075) can help physician adjust the starting dose of warfarin and then quickly reach the maintain dose.
	PG-1075C-048	48 reactions	20 samples		
	PG-1075C-096	96 reactions	40 samples		
PG0681 Detection Kit	PG-0681C-024	24 reactions	10 samples	RUO	<b>Clopidogrel</b> is an antiplatelet agent which prevents platelet aggregation and is used for treatment of cardiovascular disease. For Clopidogrel to work, enzymes in the liver (particularly CYP2C19) must convert the drug to its active form. People with genotypes CYP2C19*2(0681) or CYP2C19*3(0636) are poor metabolizer (PM) of the drug and should avoid taking Clopidogrel.
	PG-0681C-048	48 reactions	20 samples		
	PG-0681C-096	96 reactions	40 samples		
PG0636 Detection Kit	PG-0636C-024	24 reactions	10 samples	RUO	<b>Clopidogrel</b> is an antiplatelet agent which prevents platelet aggregation and is used for treatment of cardiovascular disease. For Clopidogrel to work, enzymes in the liver (particularly CYP2C19) must convert the drug to its active form. People with genotypes CYP2C19*2(0681) or CYP2C19*3(0636) are poor metabolizer (PM) of the drug and should avoid taking Clopidogrel.
	PG-0636C-048	48 reactions	20 samples		
	PG-0636C-096	96 reactions	40 samples		

# IVD CDMO Service

Contract Development and Manufacturing Organization (CDMO) is to provide comprehensive services from product development through product manufacturing in medical field.



## Pharmigene CDMO service can help you

- From ideas to products.
- Prototype development.
- Materials purchasing and qualification.
- Product verification and validation.
- Scale-up manufacturing.
- Regulatory consultation.

Partial service is welcome : Easy in-n-out. Don't need to pay for the unnecessary service.

## Quality Management System

Manufacturer is certified by Europe and SAE (ISO13485), Taiwan (QMS), China (NMPD), Korea (KGMP).



Taiwan QMS



ISO 13485



Korea GMP

# Why Choose Pharmigene?

Because Pharmigene is your most **flexibility** and **economic** choice

- We are well-experienced in full process of the R&D and manufacturing of molecular diagnostic products, enzyme-linked assays, *in-situ* hybridization products, cell culture mediums, and general purpose reagents.
- Varieties : Gene, Enzyme, Stain, Culture ..... All we can help.
- Cost : Affordable price with incredible outcomes.
- Production Scale : amount is never a question !

## Our CDMO Product

### Application Field

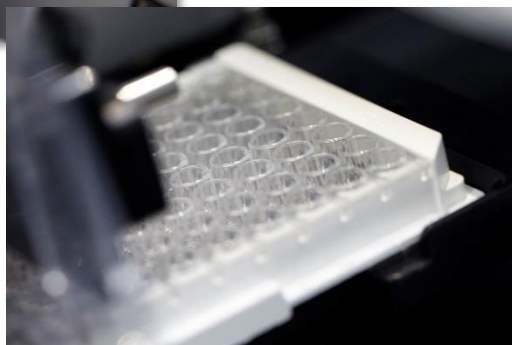
Infectious disease detection  
Cancer detection panel  
Cancer prognosis detection  
Cancer drug evaluation  
Histology  
Cell therapy

### Product Category

IVD or ASR  
RUO

### Technology Platform

Fluorescence probe  
ELISA  
qPCR





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