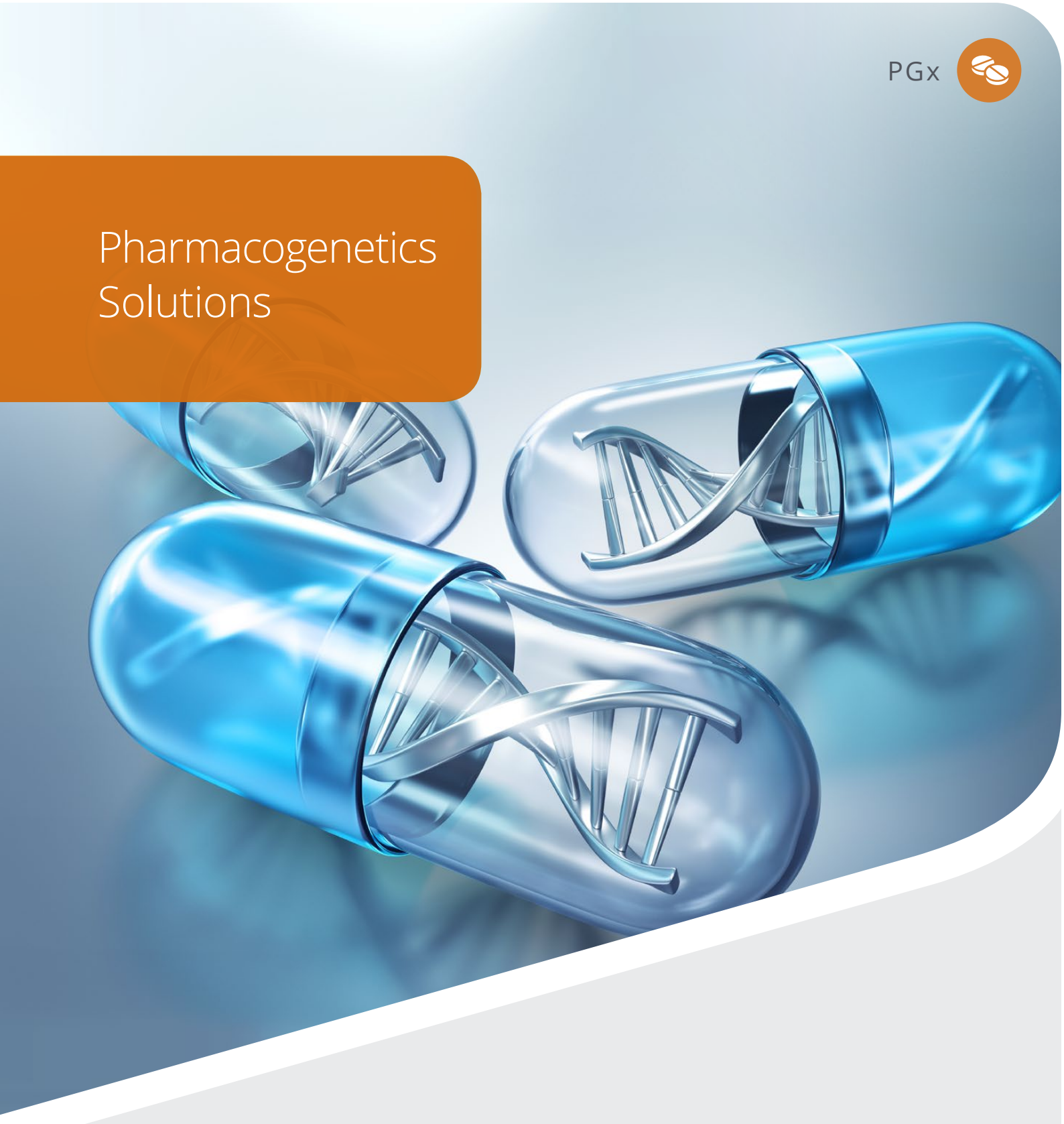
PGx

Pharmacogenetics Solutions



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Agena® BIOSCIENCE

The TRUE Cost of PGx Testing

COMMON CHALLENGES

Many technologies have inherent inefficiencies which drive up testing costs, waste resources, and make PGx testing difficult. Many labs soon discover the TRUE cost:

- **TOO EXPENSIVE** – Even before unexpected inefficiencies, high reagent costs make testing expensive.
- **REPEAT SAMPLES** – High assay failure rates force labs to run multiple replicates for each sample to avoid re-testing.
- **UTILIZATION INEFFICIENCIES** – Running with less than a full run's worth of samples wastes reagents, time, and money.
- **EXCESSIVE WORKFLOWS** – Genotyping and copy number detection requires separate workflows.

EXISTING TECHNOLOGIES ARE EXPENSIVE AND INEFFICIENT

Many PGx technologies promise an efficient workflow at low cost but labs soon discover that couldn't be further from reality.

Lengthy setup procedures require significant hands-on time. Multiple workflows and complex reflex algorithms must be implemented to accurately detect targets.

Sample failures, duplicate testing, extra labor, and wasted reagents all contribute to additional costs. After accounting for these unexpected expenses, the cost per test is significantly higher than what was promised, leaving labs frustrated and disillusioned with PGx.

Labs need a solution which makes PGx testing easy and cost-effective. **Is there a better way?**

A Better Way with the MassARRAY® System

Agena provides cost-effective, efficient, targeted PGx testing without unexpected costs or waste.

Flexible Throughput

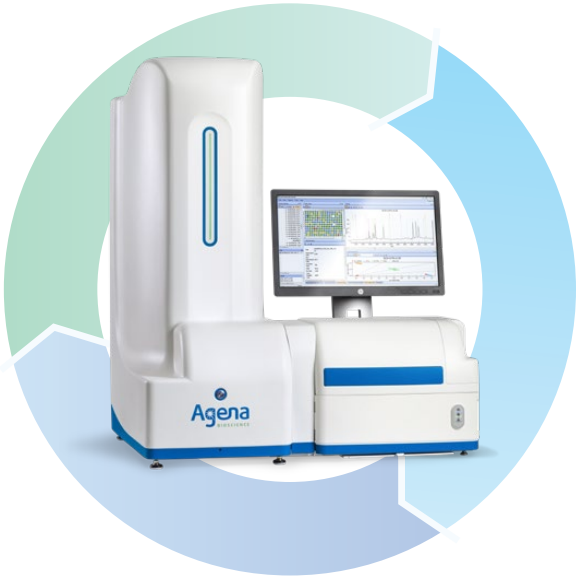
Process up to 100s or 1000s of samples per day with no minimum run size.

Combined PGx Detection

Simultaneously perform copy number detection and genotyping.

Common Workflow

Run multiple panels in different focus areas at the same time, using the same instrument.



Efficiency

Obtain results in a single day with limited hands-on time.

Results Visualization

Automated software with diplotype, haplotype and CNV calls in a single report.

Robust Performance

High assay success rate without the need for duplicate samples.

Pre-Designed PGx Panels

Our pre-designed panels are available for on-demand ordering to get you testing samples quickly. Each panel leverages our proven iPLEX® Pro chemistry. Panels can be run simultaneously using the same workflow from beginning to end.

Combined with the accuracy and flexibility of the MassARRAY System, identifying key biomarkers in pharmacogenetics is easier than ever.

VERIDOSE® CORE PANEL

The VeriDose Core Panel targets the most relevant variants in 16 key genes implicated in drug metabolism pathways. It provides genotype information for 85 SNPs/INDELs recommended by leading societies for pharmacogenetics analysis.

- **Focused Content –** Includes 85 SNPs/INDELs across 16 genes, as recommended by leading PGx societies for comprehensive pharmacogenetics analysis (Tier 1 and Tier 2).
- **Efficient Workflow –** Run on the same plate with the VeriDose CYP2D6 CNV Panel.
- **Clear Reports –** Software provides diplotype, haplotype, and CNV data.

VERIDOSE® CYP2D6 CNV PANEL

The VeriDose CYP2D6 CNV Panel detects CNVs even in the presence of difficult to detect hybrid alleles. It interrogates 22 points in 7 regions of the *CYP2D6* gene using a single well. This panel can be run simultaneously with genotyping panels, seamlessly integrating genotyping and CNV research workflows.

- **Broad Coverage –** Interrogates 7 regions of the *CYP2D6* gene, eliminating the need for multiple assays or reflex testing.
- **A Single Assay –** One-well panel makes it easy to run alongside genotyping panels.
- **Hybrid Allele Detection –** Accurate CNV calling, even in the presence of difficult-to-detect hybrid alleles.

VERIDOSE® DPYD PANEL

The VeriDose DPYD Panel targets a set of 9 *DPYD* variants commonly researched to understand severe toxicity risk, including key variants recommended by leading agencies and consortias. The single-well panel can be run either alone or side-by-side with other genotyping research panels.

CYP2D6 COPY NUMBER DETECTION

CYP2D6 copy number variation (CNV) detection is a critical aspect of PGx testing, as variations in the *CYP2D6* gene affect drug metabolism. However, not all *CYP2D6* alleles are functionally similar. Depending on ethnicity, up to 45% of the population possesses non-functional *CYP2D6* hybrid alleles[1] including exon 9 exchanges, *13, and *68. Many copy number detection methods cannot differentiate between these non-functional hybrid alleles and other *CYP2D6* alleles, resulting in an incorrect gene copy number or incorrect drug metabolism rate determination.

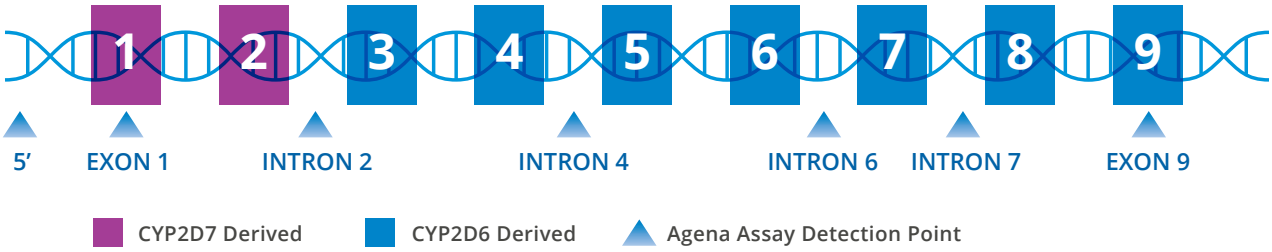
The VeriDose CYP2D6 CNV Panel accurately detects CNVs even in the presence of difficult-to-detect hybrid alleles. This assay can be run simultaneously with Agena's genotyping panels, seamlessly integrating genotyping and CNV analysis.

Depending on ethnicity, **up to 45% of the population** possesses non-functional hybrid alleles[1]

The importance of broad gene coverage

Many copy number detection methods only use a single section of the *CYP2D6* gene to determine copy number. They cannot detect common hybrid alleles and may return inaccurate gene copy number or drug metabolizer status. The broad gene coverage provided by the VeriDose CYP2D6 CNV Panel detects these alleles, resulting in accurate copy number determination.

***13 CYP2D7-CYP2D6 Hybrid**



Common Challenges to PGx Expansion

Whether you are just getting started or looking to expand, Agena's PGx solutions prepare you for all stages of success.

GETTING STARTED

Labs face pressure to get an assay up and running quickly. Design and validation can be challenging.

AGENA OFFERS:

- Ready to use pre-designed panels based on society recommendations
- Assay design services to streamline custom panel creation

TESTING BEGINS

The panel is live and samples must be processed quickly and efficiently while managing limited resources and unpredictable sample volumes.

AGENA OFFERS:

- Efficient workflow to maximize resources
- Flexible throughput to minimize waste on low-volume days

GROWTH

Sample volumes are increasing and the lab must keep up with growing demand on its staff and testing technology.

AGENA OFFERS:

- The ability to process 100s or 1000s of samples daily with a single instrument
- Automation-friendly workflow to make scaling up easy

EXPANSION

Continued success often requires panel iteration or expansion into additional focus areas.

AGENA OFFERS:

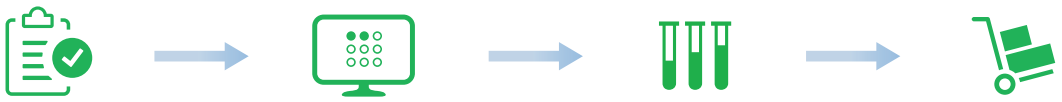
- Easily updated content
- The ability to run multiple panels using the same instrument and workflow.

Need a unique solution? Agena can help with custom assay design services

Agena Bioscience® provides two different options for users interested in creating custom genotyping, somatic mutation, or epigenetic assays. You can independently design and develop content using our online assay design software, or partner with our scientists for assay development and verification services. Both options use the same chemistries, simple workflow, and application software for analysis.

Reduce your assay development time with Assays by Agena services. Our highly skilled scientists design and verify your research-use assays in the laboratory for superior performance.

FROM MARKERS OF INTEREST TO WORKING ASSAYS



START	2 – 3 days	4 – 6 weeks	1 week
Customer provides markers of interest	**Agena performs in silico assay design**	**Assay performance testing**	**Assays ready for laboratory evaluation**
○ RS numbers ○ FASTA sequences ○ CpG regions ○ COSMIC IDs	Highly multiplexed assays designed to ensure efficiency and robustness	Functional testing performed with HapMap DNA	Verified oligos are mixed and packaged for shipment

* The timeline is based on developing germline genotyping assays and may differ for other chemistries/applications.

Our scientists functionally test all assays using cell lines and deliver ready-to-use oligonucleotide mixes for easy implementation in your research laboratory. Software services to simplify data analysis are also available.

ORDERING INFORMATION

Catalog No.	Item	# of Samples	Chip format
13386F	VeriDose Core v2.0 Panel Set - CPM (2x96)	64	96 CPM
13387F	VeriDose Core v2.0 Panel Set - CPM (10x96)	320	96 CPM
13372F	VeriDose CYP2D6 CNV v2.0 Panel Set - CPM (2x96)	192	96 CPM
13360F	VeriDose CYP2D6 CNV v2.0 Panel Set - CPM (10x96)	960	96 CPM
13362D	VeriDose CYP2D6 CNV v2.0 Panel Set - CPM (2x384)	768	384 CPM
13361D	VeriDose CYP2D6 CNV v2.0 Panel Set - CPM (10x384)	3,840	384 CPM
02005	VeriDose CYP2D6 CNV Panel 2N Control	200	N/A
13366F	VeriDose DPYD Panel Set - CPM (2x96)	192	96 CPM
13330F	VeriDose DPYD Panel Set - CPM (10x96)	960	96 CPM
13331D	VeriDose DPYD Panel Set - CPM (10x384)	3,840	384 CPM

ASK ABOUT OUR OTHER APPLICATIONS

The MassARRAY System is a versatile genetic analysis tool and not limited to a single application. Ask for information regarding our other applications including oncology, hereditary genetics and sample integrity.

References

1. Soyama et al, Sequence-based analysis of the CYP2D6 *38-CYP2D6 *10 Tandem-type arrangement, a major CYP2D6 *10 haplotype in the Japanese population. Drug metab. Pharmacokinet. 21 (3): 2018-216 (2006).

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