PGx

Pharmacogenetics Solutions

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Agena BIOSCIENCE

The True Cost of PGx Testing

EXISTING TECHNOLOGIES ARE EXPENSIVE AND INEFFICIENT

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

Lengthy setup procedures require significant hands-on time from lab staff. Multiple workflows and complex reflex testing algorithms must be implemented to accurately detect the necessary targets.

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

COMMON CHALLENGES IN PGx TESTING

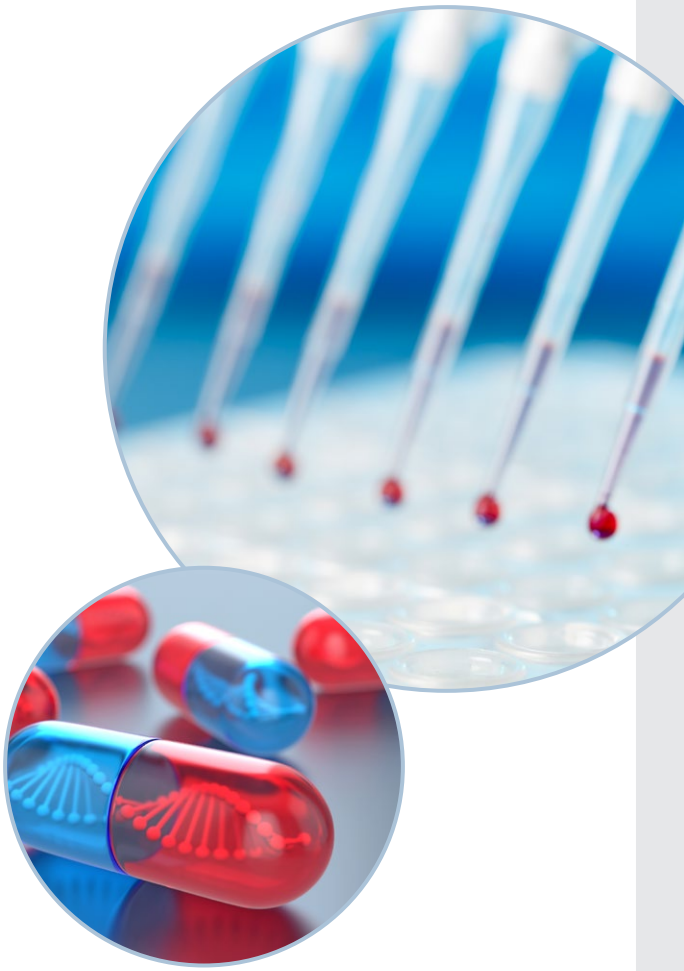
Many technologies have inherent inefficiencies which drive up testing costs, waste resources and make PGx testing difficult.

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

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

PGx Testing on the MassARRAY® Platform

Agena delivers accurate and efficient PGx testing without unexpected costs or waste.



Accuracy

Accurately detect genotype and copy number

Combined Detection

Simultaneously perform PGx copy number detection and genotyping using the same workflow.

Common Workflow

Perform multiple panels during the same run using the same instrument.

Flexible Throughput

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

Efficiency

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

Results Visualization

Automated software provides diplotype, haplotype and CNV call in a single report.

Robust Performance

High assay success rate. No need for duplicate samples.

The Challenges of Growth

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
- 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.

Panel Selection

Getting started does not have to be difficult. Agena provides tools which enable your lab to get up and running quickly, with the content you need. Choose from our menu of pre-designed panels, design your own custom content or mix and match to create the perfect panel.

PRE-DESIGNED PANELS

Our pre-designed panels are available for on-demand ordering to get you testing samples quickly. Each panel leverages the 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 Platform, identifying key biomarkers in pharmacogenetics is easier than ever.

IPLEX PRO PGX74 PANEL

The iPLEX Pro PGx74 panel is a pre-designed assay that targets the most relevant variants in 20 principle genes implicated in drug metabolism pathways. The panel provides genotype information for 69 SNPs/INDELs across 20 genes, plus 5 CNV targets in CYP2D6.

- 74 targets across 21 of the most relevant genes
- Complete reagent set with everything you need to get started
- Ready to ship

Genes Analyzed with iPLEX® PGx 74 Panel				
• ABCB1	• CYP2B6	• CYP3A4	• F5	• PNPLA5
• APOE	• CYP2C19	• CYP3A5	• GLP1R	• SLCO1B1
• COMT	• CYP2C9	• DRD2	• MTHFR	• SULT4A1
• CYP1A2	• CYP2D6	• F2	• OPRM1	• VKORC1

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" including *36, *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. Seamless integration consolidates genotyping and CNV workflows.

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

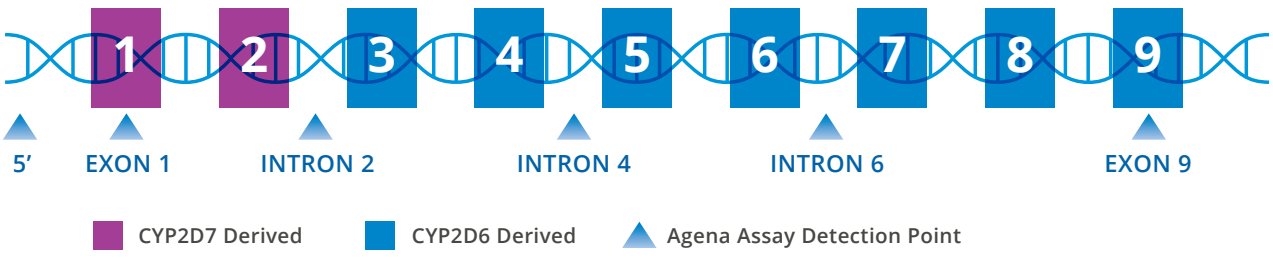
VeriDose™ CYP2D6 CNV Panel

- **Broad Coverage**
  The VeriDose CYP2D6 CNV Panel is designed to interrogate 6 regions of the CYP2D6 gene in a single assay.
- **A Single Assay**
  Broad gene coverage eliminates the need for multiple assays or reflex testing.
- **Hybrid Allele Detection**
  Accurate CNV calling; even in the presence of difficult to detect hybrid alleles.

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**



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.

› DESIGN

Design SNP, insertion, deletion, translocation, copy number variant, somatic mutation, and methylation assays.

› VERIFY

Functional testing of multiplexed assays for accuracy, robustness, and performance.

› DELIVER

Receive ready-to-use assays and custom reports for easy implementation in the lab.

Options for Custom Assay Development:

Assay Design Tools

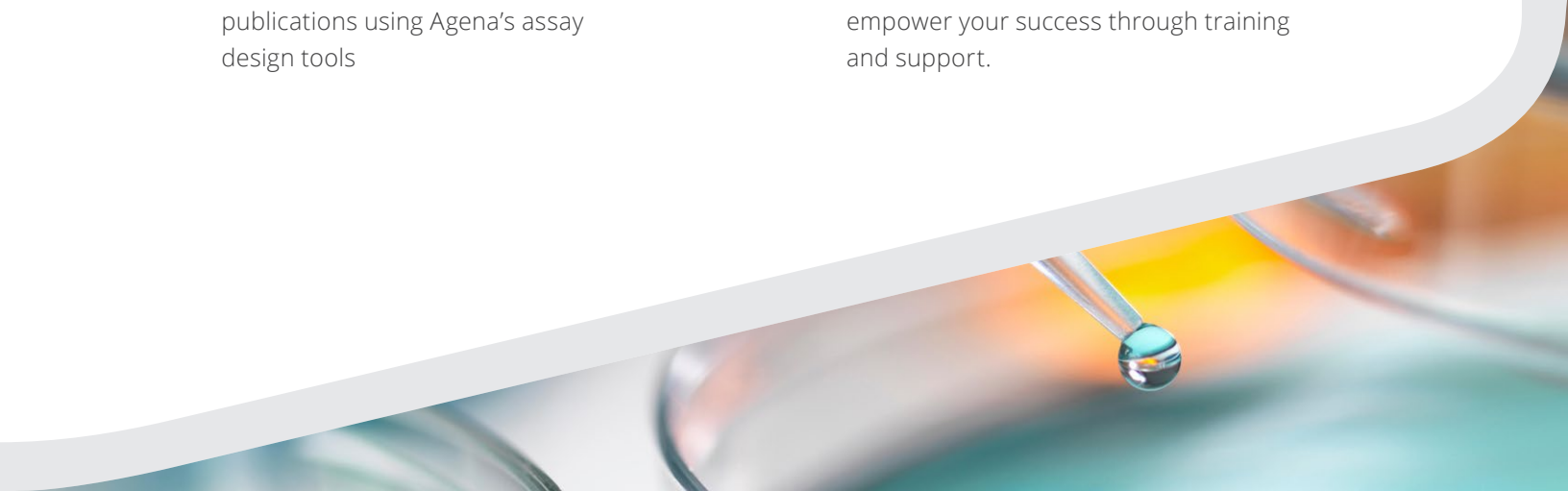
Design and develop your assays with user-friendly online tools.

- **EASY** – Simplified assay design with online tools.
- **QUICK** – Design large multiplexed assays in less than an hour.
- **PROVEN** – Over 3,000 peer-reviewed publications using Agena's assay design tools

Custom Assay Services

Partner with Agena scientists to design and verify assays.

- **EXPERT** – Assays designed and developed by Assays by Agena scientists.
- **ASSAY VERIFICATION** – Assays are functionally verified in the laboratory.
- **COLLABORATIVE** – Our scientists empower your success through training and support.



ASK ABOUT OUR OTHER APPLICATIONS

The MassARRAY is a versatile genetic analysis tool and not limited to a single application. Ask for information regarding our other applications including Oncology, Hereditary Genetic Testing and Sample Integrity.

ORDERING INFORMATION

Catalog No.	Item	# of Samples	Chip format
13160	Complete PGx 74 v1.0	320	96
13160F	Complete PGx 74 v1.0	320	96 CPM
13161	Complete PGx 74 v1.0	1280	384
13178	VeriDose CYP2D6 CNV & PGx74	240	96
13179	VeriDose CYP2D6 CNV Panel	960	96
13180	VeriDose CYP2D6 CNV Panel	192	96

ADDITIONAL PRE-DESIGNED PGX PANELS

- CYP2C19: 31 SNPs in the CYP2C19 gene
- CYP2C9/VKORC1: 51 SNPs across 4 genes
- UGT1A1: 4 repeats in the UGT1A1 gene
- SLC6A4: INDEL and 1 SNP detection in the SLC6A4 gene

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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