iPLEX® ADME CYP2D6 Panel v1.0

Assays by Agena

THE SCIENCE OF MAKING IT PERSONAL

Fast turnaround time

DESIGN

CUSTOMIZE

RUN

Not just assays, verified results

Investigate and confirm pharmacogenetic biomarkers in *CYP2D6* associated with drug metabolism with high accuracy and rapid results.

The iPLEX® ADME CYP2D6 Panel v1.0, developed by Assays by Agena for use on the MassARRAY System, is a set of 35 pre-designed and pre-verified SNP assays for use in the screening of polymorphisms in *CYP2D6*. Screening for variants in *CYP2D6* allows clinical researchers to develop dosing protocols and surveillance techniques for model drugs and experimental biomarkers.

- Analyze 35 mutations in the pharmacogenetically relevant *CYP2D6* gene.
- Perform high value CNV analysis using 5 CNV assays.
- Obtain biologically relevant data covering most of the known *CYP2D6* haplotypes.
- Use as little as 30 ng of DNA per sample.
- Use included *AMELX/Y* marker to assist in sample identification.
- Use included iPLEX WorkFlow Controls to assist in troubleshooting failed wells.

Agena Bioscience also offers the iPLEX ADME PGx Pro Panel, covering 36 key genes known to influence drug ADME/T, as well as panels for in-depth analysis of *CYP2C19* and *CYP2C9/VKORC1*.
See ***www.agenabio.com/pharmacogenomics*** for more information.

HAPLOTYPES[1] INCLUDED IN THE iPLEX ADME CYP2D6 PANEL v1.0

*1, (*2;*28;*32;*55;*59)[2], (*2A;*31;*51), *2D, (*2L;*45B;*46), *2M, *3, *4, *4B, *4J, *4K, *4M, *4N;P, *5[3],*6, *6C, *7, *8, *9, (*10A;*37;*54), (*10B;*47;*49;*52;*72), *11, *12, *14A, *14B, *15, *17, *18, *19, *20, *21ª, *21B, *27, *29, *30, *34, *35, *36, *38, *39, *40, *41, *42, *44, *45A, *56A, *56B, *57, *58, *63, *64, *65, *68, *69, *70, *71, *82, *83, *84

vA

Disclaimer: CNV for different alleles (*NxN) uses incorporated CNV assays and needs Excel file provided. Nomenclature is based on http://www.cypalleles.ki.se/cyp2d6.htm

[1] Rare haplotypes may only be validated for wild type allele.

[2] Haplotypes represented by mutations not present in the ADME CYP2D6 Panel are considered *1. Also haplotypes that are indistinguishable are grouped with most likely haplotype in front.

[3] The ADME CYP2D6 Panel only detects the number of *CYP2D6* copies present. It does not identify samples where a duplication of one allele AND a deletion of another allele is present (e.g., *2x2/*5 is called *2/*2).

PHARMACOGENOMICS

For Research Use Only. Not for use in diagnostic procedures.

Agena BIOSCIENCE

CYP2D6 ALLELE NOMENCLATURE

ALLELE	NUCLEOTIDE CHANGES	AMINO ACID CHANGE	dbSNP IDs	CNV ASSAYS
*1	None	None		
*1XN	None	N active		CNV>2
*2;*28;*32;*59	1661G>C; 2850C>T; 4180G>C	R296C; S486T	rs1058164; rs16947; rs1135840	
*2A;*31;*51	-1584C>G; -1235A>G; 1661G>C; 2850C>T; 4180G>C	R296C; S486T	rs1080985; rs28735595; rs1058164; rs16947; rs1135840	
*2D	2850C>T; 4180G>C	R296C; S486T	rs16947; rs1135840	
*2L;*45B;*46	-1584C; -1235A>G; 1661G>C; 2850C>T; 3790C>T; 4180G>C	R296C; S486T	rs1080985; rs28735595; rs1058164; rs16947; rs28371731; rs1135840	
*2M;*31	-1584C; -1235A>G; 214G>C; 1661G>C; 2850C>T; 3790C>T; 4180G>C	R296C; S486T	rs1080985; rs28735595; rs1080995; rs1058164; rs16947; rs28371731; rs1135840	
*2XN (N=2, 3, 4, 5 or 13)	1661G>C; 2850C>T; 4180G>C	R296C; S486T	rs1058164; rs16947; rs1135840	CNV>2
*3	2549delA	259Frameshift	rs35742686	
*4	100C>T; 1661G>C; 1846G>A; 4180G>C	P34S; splicing defect; S486T	rs1065852; rs1058164; rs3892097; rs1135840	
*4B	100C>T; 1846G>A; 4180G>C	P34S; splicing defect; S486T	rs1065852; rs3892097; rs1135840	
*4J	100C>T; 1661G>C; 1846G>A	P34S; splicing defect	rs1065852; rs1058164; rs3892097	
*4K	100C>T; 1661G>C; 1846G>A; 2850C>T; 4180G>C	P34S; splicing defect; R296C; S486T	rs1065852; rs1058164; rs3892097; rs16947; rs1135840	
*4M	-1235A>G; 1661G>C; 1846G>A;	splicing defect	rs28735595; rs1058164; rs3892097	
*4N;*4P	-1416C>T; -1235A>G; 100C>T; 1661G>C; 1846G>A; 4180G>C; exon 9 conversion	P34S; splicing defect; S486T	Rs28588594; rs28735595; rs1065852; rs1058164; rs3892097; rs1135840	
*4XN	See CYP2D6*4			CNV>2
*5	CYP2D6 deleted	CYP2D6 deleted		CNV<2
*6	1707delT	118Frameshift	rs5030655	
*6C	1707delT; 4180G>C	118Frameshift; S486T	rs5030655; rs1135840	
*7	2935A>C	H324P	rs5030867	
*8	1661G>C; 1758G>T; 2850C>T; 4180G>C	G169X; R296C; S486T	rs1058164; rs5030865; rs16947; rs1135840	
*9	2615_2617delAAG	K281del	rs5030656	
*9x2	2615_2617delAAG	K281del	rs5030656	CNV>2
*10;*37;*54	100C>T; 1661G>C; 4180G>C	P34S; S486T	rs1065852; rs1058164; rs1135840	
*10B; *47; *49; *52; *72	-1416C>T; -1235A>G; 100C>T; 1661G>C; 4180G>C	P34S; S486T	rs28588594; rs28735595; rs1065852; rs1058164; rs1135840	
*10X2	See CYP2D6*10A			CNV>2
*11	883G>C; 1661G>C; 2850C>T; 4180G>C	Splicing defect; R296C; S486T	rs5030863; rs1058164; rs16947; rs1135840	
*12	124G>A; 1661G>C; 2850C>T; 4180G>C	G42R; R296C; S486T	rs5030862; rs1058164; rs16947; rs1135840	
*14A	100C>T; 1758G>A; 2850C>T; 4180G>C	P34S; G169R; R296C; S486T	rs1065852; rs5030865; rs16947; rs1135840	
*14B	214G>C;1661G>C; 1758G>A; 2850C>T; 4180G>C	G169R; R296C; S486T	rs1080995;rs1058164; rs5030865; rs16947; rs1135840	
*15	137_138insT	46Frameshift	rs72549357	
*17	1023C>T; 1661G>C; 2850C>T; 4180G>C	T107I; R296C; S486T	rs28371706; rs1058164; rs16947; rs1135840	
*17XN	See CYP2D6*17			
*18	4125_4133dupGTGCCCACT	468_470dupVPT	G4125_4133T	
*19	1661G>C; 2539_2542delAACT; 2850C>T; 4180G>C	255Frameshift; R296C; S486T	rs1058164; rs72549353; rs16947; rs1135840	

ALLELE	NUCLEOTIDE CHANGES	AMINO ACID CHANGE	dbSNP IDs	CNV ASSAYS
*20	1661G>C; 1973_1974insG; 2850C>T; 4180G>C	211Frameshift; R296C; S486T	rs1058164; rs72549354; rs16947; rs1135840	
*21A	-1584C>G; -1416C>T; -1235A>G; 1661G>C; 2573_2574insC; 2850C>T; 4180G>C	267Frameshift; R296C; S486T	rs1080985; rs28588594; rs28735595; rs1058164; rs72549352; rs16947; rs1135840	
*21B	-1584C>G; -1235A>G; 214G>C; 1661G>C; 2573_2574insC; 2850C>T; 4180G>C	267Frameshift; R296C; S486T	rs1080985; rs28735595; rs1080995; rs1058164; rs72549352; rs16947; rs1135840	CNV>2
*29	1659G>A; 1661G>C; 2850C>T; 4180G>C	V136I; R296C; V338M; S486T	rs61736512; rs1058164; rs16947; rs1135840	
*30	1661G>C; 1863_1864insTTTCGCCCC; 2850C>T; 4180G>C	174_175insFRP; R296C; S486T	rs1058164; rs72549356; rs16947; rs1135840	
*34	2850C>T	R296C	rs16947	
*35	-1584C>G; 31G>A; 1661G>C; 2850C>T; 4180G>C	V11M; R296C; S486T	rs1080985; rs769258; rs1058164; rs16947; rs1135840	
*35X2	31G>A; 1661G>C; 2850C>T; 4180G>C	V11M; R296C; S486T	rs769258; rs1058164; rs16947; rs1135840	
*36	-1416C>T; 100C>T; 1661G>C; 4180G>C; exon 9 conversion	P34S; S486T	rs28588594; rs1065852; rs1058164; rs1135840	
*38	2587_2590delGACT	271Frameshift	rs72549351	CNV>2
*39	1661G>C; 4180G>C	S486T	rs1058164; rs1135840	CNV<2
*40	1023C>T; 1661G>C; 1863_1864insTTTCGCCCCx2; 2850C>T; 4180G>C	T107I; 174_175insFRPx2; R296C; S486T	rs28371706; rs1058164; rs72549356; rs16947; rs1135840	
*41	-1584C; -1235A>G; 214G>C; 1661G>C; 2850C>T; 2988G>A; 4180G>C	R296C; splicing defect; S486T	rs1080985; rs28735595;rs1080995; rs1058164; rs16947; rs28371725; rs1135840	
*42	-1584C; 1661G>C; 2850C>T; 3259_3260insGT; 4180G>C	R296C; 363Frameshift; S486T	rs1080985; rs1058164; rs16947; rs72549346; rs1135840	
*44	2950G>C	Splicing defect	rs72549349	
*45A	-1584C; 1661G>C; 2850C>T; 3790C>T; 4180G>C	R296C; S486T	rs1080985; rs1058164; rs16947; rs28371731; rs1135840	
*56A	-1584C>G; -1235A>G; 214G>C; 1661G>C; 2850C>T; 3201C>T; 3790C>T; 4180G>C	R296C; R344X; S486T	rs1080985; rs28735595; rs1080995; rs1058164; rs16947; rs72549347; rs28371731; rs1135840	CNV>2
*56B	-1235A>G; 100C>T; 1661G>C; 3201C>T; 4180G>C	P34S; R344X; S486T	rs28735595; rs1065852; rs1058164; rs72549347; rs1135840	
*57	-1416C>T; 100C>T; 1661G>C; 4180G>C; exon 9 conversion	P34S; S486T	rs28588594; rs1065852; rs1058164; rs1135840	
*58	-1416C>T; -1235A>G; 214G>C; 1023C>T; 1661G>T; 1863_1864insTTTCGCCCC; 2850C>T; 2850C>T; 3790C>T; 4180G>C	T107I; 174_175insFRP; R296C; S486T	rs28588594; rs28735595; rs1080995; rs28371706; rs1058164; rs72549356; rs16947; rs28371731; rs1135840	CNV>2
*63	-1584C>G; -1235A>G; 214G>C; 1661G>C; 2850C>T; 3790C>T	R296C; S486T	rs1080985; rs28735595; rs1080995; rs1058164; rs16947; rs28371731	
*64	-1416C>T; -1235A>G; 100C>T; 1023C>T; 1661G>C; 4180G>C;	P34S; T107I; S486T	rs28588594; rs28735595; rs1065852; rs28371706; rs1058164; rs1135840	
*65	100C>T; 1661G>C; 2850C>T; 3790C>T; 4180G>C	P34S; R296C; S486T	rs1065852; rs1058164; rs16947; rs28371731; rs1135840	
*68	-1416C>T; -1235A>G; 100C>T	P34S;	rs28588594; rs28735595; rs1065852	
*69	-1416C>T; -1235A>G; 100C>T; 1661G>C; 2850C>T; 2988G>A; 3790C>T; 4180G>C	P34S; R296C; splicing defect; S486T	rs28588594; rs28735595; rs1065852; rs1058164; rs16947; rs28371725; rs28371731; rs1135840	
*70	1659G>A; 1661G>C; 4180G>C	V136I; S486T	rs61736512; rs1058164; rs1135840	
*71	-1584C>G		rs1080985	
*82	1023C>T	T107Y	rs28371706	
*83	4180G>C; exon 9 conversion	S486T	rs1135840	
*84	-1235A>G; 214G>C; 1661G>C; 2850C>T; 3790C>T; 4180G>C	R296C; S486T	rs28735595; rs1080995; rs1058164; rs16947; rs28371731; rs1135840	

iPLEX® ADME CYP2D6 Panel v1.0

THE MASSARRAY WORKFLOW

Each sample is subjected to PCR amplification and primer extension with the iPLEX ADME CYP2D6 reagents. The extension products are dispensed onto a SpectroCHIP® Array and detected via MassARRAY MALDI-TOF mass spectrometry. After the sample run, an automated software report provides the calls and mutation frequency for each sample as well as a confidence score.

THROUGHPUT

The iPLEX ADME CYP2D6 Panel v1.0 contains multiplexed assays in 3 wells, using 10 ng of input DNA per well. The panel can be run in 96-well format (32 samples per plate) or 384-format (128 samples per plate). Thirty-two to 1,024 samples can be processed per day, providing flexibility in sample throughput and batching requirements.

ORDERING INFORMATION

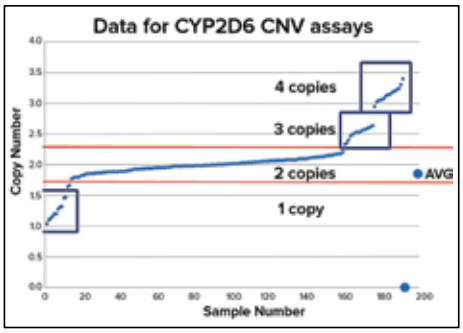
Choose the best approach for you:

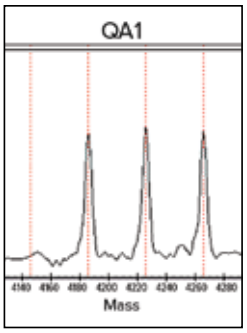
- Order the iPLEX ADME CYP2D6 Panel v1.0 components and run on your own MassARRAY System.
- Send your samples to our Assays by Agena Custom Services Laboratory and have our experienced scientists run the panel for you.

Please contact Agena Bioscience for more information.

COMPONENTS FOR RUNNING THE iPLEX ADME CYP2D6 PANEL v1.0

AMPLIFY	PCR Enzyme PCR Accessory Set ADME CYP2D6 PCR Primers
EXTEND	iPLEX Pro Reagent Set ADME CYP2D6 Extend Primers
DETECT	SpectroCHIP Array and Resin Kit
ANALYZE	Typer Software





Left: Example of copy number plot for 48 samples run in quadruplicate. All repeats show up in same copy number group.

Right: Picture of the WorkFlow Controls showing adequate addition of PCR, SAP, and Extend cocktails to the sample reaction.

AGENA BIOSCIENCE LOCATIONS

USA
Agena Bioscience, Inc.
3565 General Atomics Court
San Diego, CA 92121
Phone: +1.877.4.GENOME
Fax: +1.858.202.9220
Order Desk: +1.858.202.9301
Order Desk Fax: +1.858.202.9220
Order Desk Email:
orderdesk@AgenaBio.com
Web: agenabioscience.com

EUROPE
Agena Bioscience GmbH
Mendelssohnstraße 15D
D-22761 Hamburg
Germany
Phone: +49.40.899676.0
Fax: +49.40.899676.10
Order Desk Email:
orderdesk-europe@AgenaBio.com

ASIA PACIFIC
300 Herston Road
Herston, QLD 4006, Australia
Phone: +61.7.3088.1600
Fax: +61.7.3088.1614

JAPAN
Agena Bioscience, K.K.
PMO Nihonbashi Odemmacho
Bldg 5F, 6-8, Nihonbashi Odemmacho
Chuo-ku, Tokyo, 103-0011, Japan
Phone: +81.3.6231.0727
Fax: +81.3.3668.6088

CHINA
Beijing Representative Office
Technology Building, Suite 702B
No. 28, Tian-Zhu Rd,
Tian-Zhu Airport Industrial Zone A
Shunyi District, Beijing, China. 101312
Phone: +86.10.8048.0737
Fax: +86.10.8048.0740

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