ESTABLISHED INNOVATIONS IN DIAGNOSTICS

Pharmacogenetic CYP2D6 testing

Determination of genetic variants and copy number changes associated with poor, intermediate or ultra-rapid CYP2D6 metabolizer status.

Cytochrome P450 2D6 and drug metabolism

The cytochrome P450 2D6 (CYP2D6) is a liver enzyme involved in the metabolism of more than 25% of the most frequently used drugs in the clinical field. Variants of the highly polymorphic *CYP2D6* gene are associated with altered enzymatic function, ranging from a complete lack of activity to an ultrarapid metabolization of drugs.

This altered CYP2D6 activity causes an inter-individual variability in drug-response. Patients with a defective or over-active CYP2D6 enzyme are either at risk to develop severe adverse events or do not reach the therapeutic window for effective treatment with a specific drug. Hence, pharmacogenetic guidelines recommend a CYP2D6-related dose-adjustment for numerous drugs.

The ViennaLab **PGX-CYP2D6 XL StripAssay®** in combination with the **CYP2D6 RealFast™ CNV Assay** identifies patients with an altered CYP2D6 enzyme function. Comprehensive *CYP2D6* genotyping optimizes the choice of medication and/or the adjustment of drug dosage and consequently reduces the risk of adverse events or lowered treatment efficacy.

Key features

- Comprehensive *CYP2D6* analysis
- PGX-CYP2D6 XL StripAssay® for detection of the most prevalent *CYP2D6* alleles
- CYP2D6 RealFast™ CNV Assay for identification of *CYP2D6* deletions or duplications
- Cost-efficient technologies
- Rapid and simple workflow

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Order information: • PGX-CYP2D6 XL StripAssay®: 4-770 (20 tests) • CYP2D6 RealFast™ CNV Assay: 7-420 (100 reactions)

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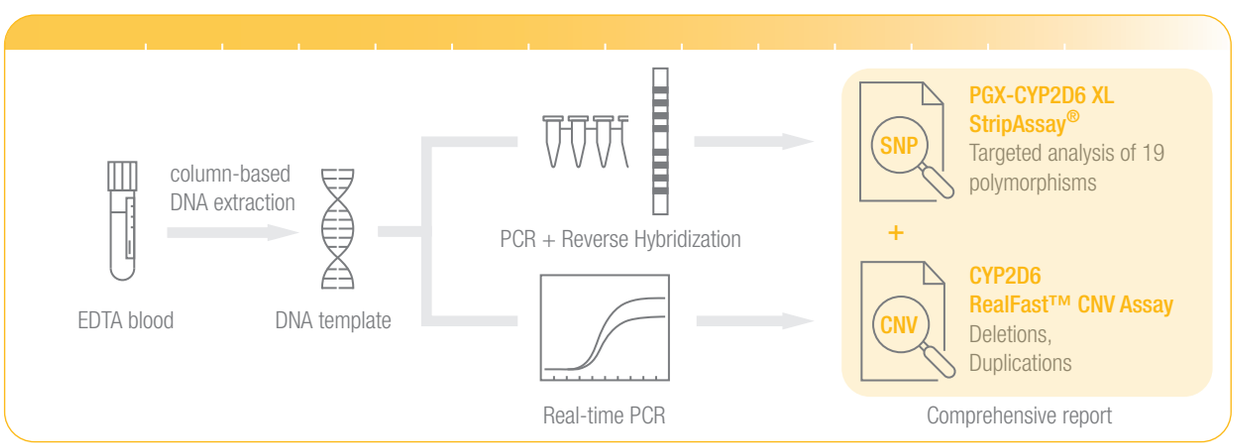
Comprehensive *CYP2D6* analysis with ViennaLab Assays

Single variants or a combination of variants in the *CYP2D6* gene define a *CYP2D6* allele. The PGX-CYP2D6 XL StripAssay® is a qualitative genetic test for the targeted analysis of 19 polymorphisms of the human *CYP2D6* gene.[1] In addition, the CYP2D6 RealFast™ CNV Assay determines the *CYP2D6* gene copy number. The combination of both assays provides a comprehensive picture of the CYP2D6 metabolizer status in different populations including European, American, Central/South Asian, Latino, Sub-Saharan African, and many more, thereby reaching a coverage of 0.81 – 0.98.

Reporting is based upon the activity score system, where each allele is assigned to an activity value, corresponding to enzymatic activity.[2] As a consequence, phenotype classification leads to clinically actionable recommendations (European Medicines Agency, PharmGKB).[3,4]

ViennaLab Assay	REF	Covered *CYP2D6* alleles	CYP2D6 enzyme activity
PGX-CYP2D6 XL StripAssay®	4-770	*3 - *8, *11, *12, *15, *40, *69, *114	no function
		*9, *10, *14, *17, *29, *41	decreased function
		*1, *2, *34, *35, *39	normal function
CYP2D6 RealFast™ CNV Assay	7-420	*CYP2D6* deletion	no function
		CYP2D6 duplication	increased function

Workflow of ViennaLab CYP2D6 Assays



References:

[1] Gaedigk A at al. Prediction of CYP2D6 phenotype from genotype across world populations. Genet Med. 2017; 19: 69-76
[2] Caudle KE et al. Standardizing CYP2D6 Genotype to Phenotype Translation: Consensus Recommendations from the Clinical Pharmacogenetics Implementation Consortium and Dutch Pharmacogenetics Working Group. Clin Transl Sci. 2020; 13:116-124
[3] JK Hicks JK et al. Clinical pharmacogenetics implementation consortium guideline (CPIC) for CYP2D6 and CYP2C19 genotypes and dosing of tricyclic antidepressants: 2016 update. Clin Pharmacol Ther. 2017; 102: 37-44
[4] Hicks JK et al. Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline for CYP2D6 and CYP2C19 Genotypes and Dosing of Selective Serotonin Reuptake Inhibitors. Clin Pharmacol Ther. 2015; 98: 127-34

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