



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 metabolism 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



Order information: • PGX-CYP2D6 XL StripAssay®: 4-770 (20 tests)

• CYP2D6 RealFast™ CNV Assay: 7-420 (100 reactions)

Comprehensive *CYP2D6* analysis with ViennaLab Assays

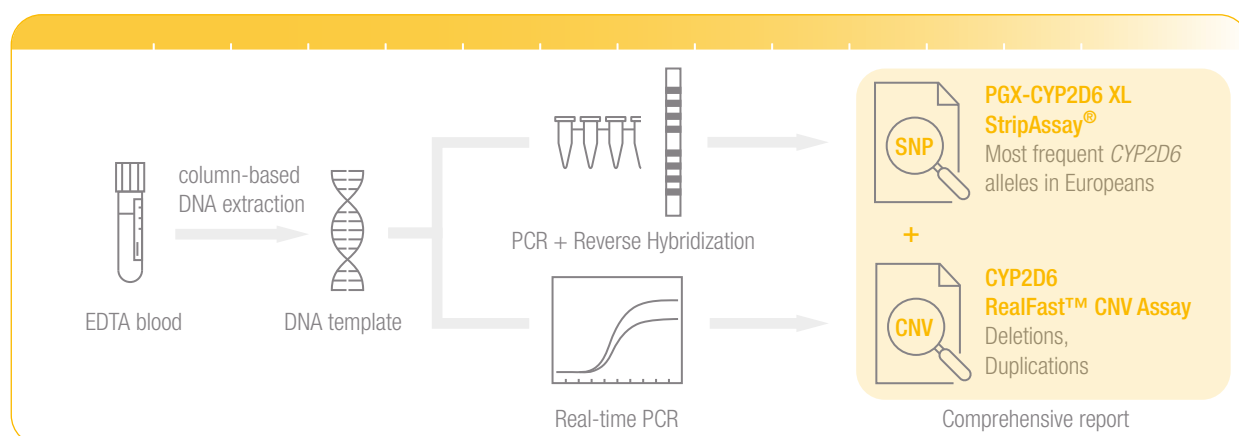
Single variants or a combination of variants in the *CYP2D6* gene define a *CYP2D6* allele. The PGX-*CYP2D6* XL StripAssay® detects the most common *CYP2D6* alleles within the European population.¹ In addition, the *CYP2D6* RealFast™ CNV Assay determines the *CYP2D6* gene copy number. The combination of both assays provides a comprehensive picture of the

CYP2D6 metabolizer status of an individual.

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 <i>CYP2D6</i> alleles	<i>CYP2D6</i> enzyme activity
PGX- <i>CYP2D6</i> XL StripAssay®	4-770	*3 - *8, *11, *12, *15, *40, *58, *114	no function
		*9, *10, *14, *17, *29, *41	decreased function
		*1, *2, *35, *39	normal function
<i>CYP2D6</i> RealFast™ CNV Assay	7-420	<i>CYP2D6</i> deletion	no function
		<i>CYP2D6</i> duplication	increased function

Workflow of ViennaLab *CYP2D6* Assays



References:

- ¹ Gaedigk A et 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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