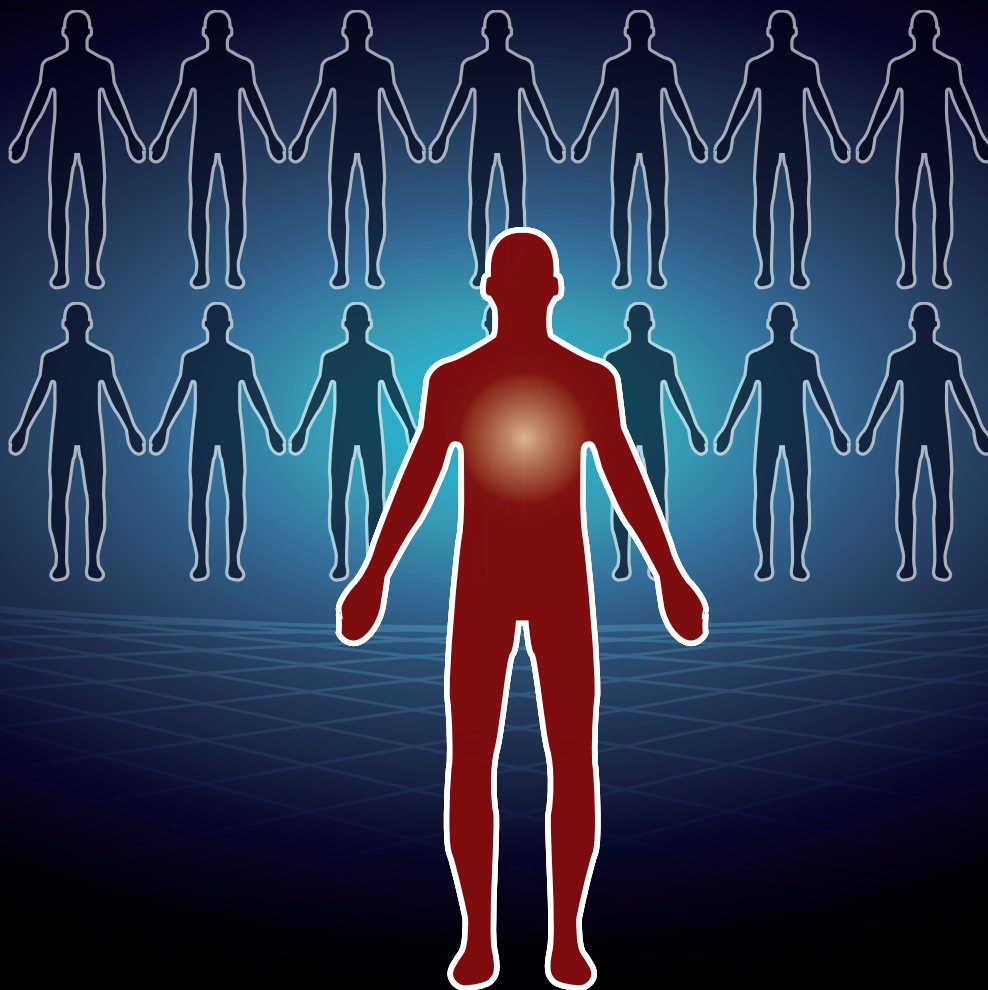


# Empowering Personalized Medicine

Tools to Identify the Right Drug at the Right Dose for the Right Patient



## xTAG<sup>®</sup> CYP2D6 Kit v3

Obtain reliable, actionable results with a comprehensive genotyping assay for CYP2D6 drug metabolism

*For performance characteristics and intended use refer to the IVD package insert for your region/country of residence.*

## Disease Overview

Adverse drug reactions in the European Union are increasing at twice the rate of the several million prescription medications dispensed yearly<sup>1</sup>. In the UK, antidepressants, analgesics and cardiovascular drugs are among the most prescribed therapeutic medications<sup>2</sup>. Many of these medications are metabolized by CYP2D6. Polymorphisms of the CYP2D6 gene may potentially induce clinically important effects across a wide range of therapeutic areas<sup>3</sup> (Table 1).

Variations in CYP2D6 enzyme activity can lead to a variety of problems in clinical practice such as drug toxicity, adverse drug reactions, inappropriate concentrations of drugs and their metabolites due to impaired clearance of the drug or inadequate therapeutic effect.

The European Commission estimates that adverse drug reactions kill 197,000 EU citizens annually, at a cost of €79 billion<sup>1</sup>. Identification of patient CYP2D6 genotypes can help clinicians tailor drug treatment to patients by selection of appropriate therapies. These measures may improve patient outcome by ensuring maximum drug efficacy with minimal adverse drug reactions<sup>4</sup>.

**Table 1: Examples of Drugs Metabolized by CYP2D6**

β-blockers	Antipsychotics
Antiarrhythmics	Analgesics/Opiates
Tricyclic antidepressants (TCA)	Selective serotonin reuptake inhibitors (SSRIs)

Source: J Pharmacol Exp Ther 270(1): 414-423, N Engl J Med 352(21): 2211-2221



## Clinical Utility of the xTAG CYP2D6 Kit v3

The xTAG CYP2D6 Kit v3 is a qualitative genotyping assay which can be used as an aid to clinicians in determining therapeutic strategy and treatment dose for therapeutics that are metabolized by the CYP2D6 gene product.

# xTAG CYP2D6 Kit v3 - Tailor Patient Care Through Accurate Genotyping

- The xTAG CYP2D6 Kit v3 is an in vitro diagnostic test with 100 % reproducibility\*\* and accuracy<sup>5</sup>
- Comprehensive allele coverage, including gene deletion and duplication genotypes

\*\*After allowable re-runs.

*Genotype or *Allele	SNPs detected by xTAG CYP2D6 Kit v3	Predicted Enzyme Activity
*1	None	Normal
*2	-1584C>G, 1661G>C, 2850C>T, 4180G>C	Normal
*3	2549A>del	None
*4	100C>T, 1661G>C, 1846G>A, 2850C>T, 4180G>C	None
*5	deletion	None
*6	1707T>del, 4180G>C	None
*7	2935A>C	None
*8	1661G>C, 1758G>T, 2850C>T, 4180G>C	None
*9	2613delAGA	Reduced
*10	100C>T, 1661G>C, 4180G>C	Reduced
*11	883G>C, 1661G>C, 2850C>T, 4180G>C	None
*15	138insT	None
*17	1023C>T, 1661G>C, 2850C>T, 4180G>C	Reduced
*29	1659G>A, 1661G>C, 2850C>T, 3183G>A, 4180G>C	Reduced
*35	-1584C>G, 31G>A, 1661G>C, 2850C>T, 4180G>C	Normal
*41	1661G>C, 2850C>T, 2988G>A, 4180G>C	Reduced
DUP	duplication	Increased

Source: Bradford 2002; Wennerholm, Johansson et al. 2001; Gaedigk, Ryder et al. 2003

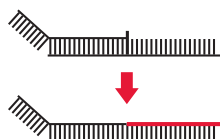
## xTAG CYP2D6 Kit v3 - Automated genotyping and optimized protocol provides same day results

- The xTAG CYP2D6 Kit v3 incorporates multiplex PCR and multiplex Allele Specific Primer Extension (ASPE) with Luminex's Universal TAG sorting system on the proven Luminex® 100/200™ platform
- Result reporting with the TDAS CYP2D6 software makes automated genotype calls for each mutation easy

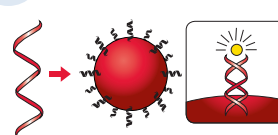
### 1 Multiplex PCR Reaction with Amplicon Treatment



### 2 Allele Specific Primer Extension



### 3 Hybridization & Detection



### 4 Data Acquisition & Analysis



