Luminex®

xTAG® CYP2D6 Kit v3

Qualitative genotyping assay to be used as an aid to clinicians in determining therapeutic strategy for therapeutics metabolized by the CYP2D6 gene product.†

Cytochrome P450 2D6 Overview: Clinical Relevance

- Cytochrome P450 2D6 (CYP2D6) alone is thought to be active in the enzymatic breakdown of 20-25% of all medicines prescribed (Table 1).
- Cardiovascular drugs, anti depressants and analgesics, the top three classes of therapeutics prescribed are all metabolized by CYP2D6.

Table 1: Examples of Drugs Metabolized by CYP2D6[1, 2]

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

- Polymorphisms of the CYP2D6 gene may potentially induce clinically important effects across a wide range of therapeutic areas.[3]
- 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.[4]

xTAG® CYP2D6 Kit v3: Genetic Variations[8]

- Comprehensive allele coverage, including gene deletion and duplication genotypes.
- Genotyping panel detects major alleles associated with variant drug metabolism.

*Genotype	SNPs detected by xTAG CYP2D6 Kit v3	Frequency in the U.S. Caucasian population[5]	Frequency in the African American population[5]	Predicted Enzyme Activity
*1	None	37 to 40%	29 to 35%	Normal
*2	-1584C>G, 1661G>C, 2850C>T, 4180G>C	26 to 33%	18 to 27%	Normal
*3	2549A>del	1%	0.2 to 0.6%	None
*4	100C>T, 1661G>C, 1846G>A, 2850C>T, 4180G>C	18 to 20%	6 to 9%	None
*5	deletion	2 to 4%	6 to 7%	None
*6	1707T>del, 4180G>C	1%	0.5%	None
*7	2935A>C	Not known	Not known	None
*8	1661G>C, 1758G>T, 2850C>T, 4180G>C	Not known	Not known	None
*9	2613delAGA	2 to 3%	0.3%	Reduced
*10	100C>T, 1661G>C, 4180G>C	2 to 8%	0.3% to 0.4%	Reduced
*11	883G>C, 1661G>C, 2850C>T, 4180G>C	Not known	Not known	None
*15	138insT	Not known	Not known	None
*17	1023C>T, 1661G>C, 2850C>T, 4180G>C	0.2 to 0.3%	15 to 26%	Reduced
*29	1659G>A, 1661G>C, 2850C>T, 3183G>A, 4180G>C	Not known[6]	Not known[6]	Reduced
*35	-1584C>G, 31G>A, 1661G>C, 2850C>T, 4180G>C	7.4%[7]	1%[7]	Normal
*41	1661G>C, 2850C>T, 2988G>A, 4180G>C	9%[7]	11%[7]	Reduced

xTAG CYP2D6 Kit v3: Performance Data[8]

- Diagnostic accuracy greater than 98% on Luminex® 100/200™ platform for all genotypes.

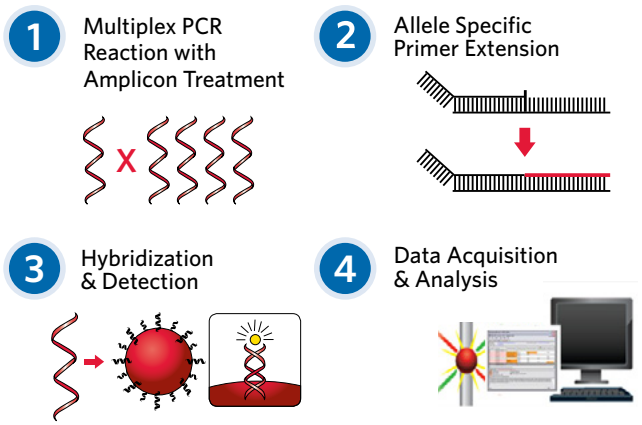
Diagnostic Accuracy and Lot-to-Lot Reproducibility on Luminex 100/200*

CYP2D6 genotype	Accuracy**	Reproducibility
*5/*17	100.0%	100.0%
*17/*29	100.0%	100.0%
*29/*29	100.0%	100.0%
*1/*4	100.0%	100.0%
*2/*2	100.0%	100.0%
*1/*5	100.0%	100.0%
*1/*41	100.0%	100.0%
*4/*35	100.0%	100.0%
*2/*4, DUP	100.0%	100.0%
*35/*41	100.0%	100.0%
*17/*17	100.0%	100.0%

* A subset of data shown here from the xTAG CYP2D6 Kit v3 Package Insert (2013).
** After allowable re-runs.

xTAG CYP2D6 Kit v3: Workflow

- xTAG CYP2D6 Kit v3 incorporates multiplex PCR and multiplex Allele Specific Primer Extension with Luminex's Universal TAG sorting system on the proven Luminex 100/200 platform.
- Result reporting with the TDAS CYP2D6 Analysis Software makes automated genotype calls for each mutation easy.
- Utilize scalability of the Luminex 100/200 platform to increase throughput effectively.



xTAG CYP2D6 Kit v3: Kit configuration[8]

- The xTAG CYP2D6 Kit v3 includes all ancillary reagents and enzymes necessary to run the assay.
- Add value to your lab menu through expanded testing on the Luminex 100/200 platform.

xTAG CYP2D6 Kit v3: Kit Components

Reagents in xTAG CYP2D6 Kit v3
Primer Mixes
xTAG 2D6 v3 PCR Primer Mix A
xTAG 2D6 v3 PCR Primer Mix B
xTAG 2D6 v3 ASPE Primer Mix
Enzymes and Buffers
xTAG Reporter Buffer
Platinum® Tfi Exo(-) DNA Polymerase
Platinum Tfi Reaction Buffer, 5x
Tfi 50 mM MgCl2
xTAG Exonuclease I
xTAG Shrimp Alkaline Phosphatase
xTAG Hot Start Taq (Long Acting)
xTAG 10x Taq Buffer (Long Acting)
Beads & Reporter
xTAG 2D6 v3 Bead Mix
xTAG Streptavidin, R-Phycoerythrin Conjugate

Ordering Information

Product Name	Kit size	Registration status	Catalog Number
xTAG CYP2D6 Kit v3 (US)	48 tests	US IVD	I030B0373
xTAG CYP2D6 Kit v3 (EU)	48 tests	EU IVD	I030B0374
TDAS CYP2D6 Analysis Software CD (US)	N/A	US IVD	S030-0254
TDAS CYP2D6 Analysis Software CD (EU)	N/A	EU IVD	S030-0255

REFERENCES

1. J Pharmacol Exp Ther 1994 Jul;270:414-423
2. N Engl J Med 2005;352:2211-2221
3. Table of pharmacogenomics biomarkers in drug labels. FDA (Internet). Cited 2013 Sep. http://www.fda.gov/Drugs/ScienceResearch/ResearchAreas/Pharmacogenetics/ucm083378.htm.
4. Preventable adverse drug reactions: A focus on drug interactions. FDA (Internet). Cited 2013 Sep. http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/ druginteractionslabeling/ucm110632.htm.
5. Bradford, LD. CYP2D6 allele frequency in European Caucasians, Asians, Africans, and their descendants. Pharmacogenomics 2002;3(2):229-43
6. Wennerholm, A, Johansson I, et al. Characterization of the CYP2D6*29 allele commonly present in a black Tanzanian population causing reduced catalytic activity. Pharmacogenetics 2001;11(5):417-427
7. Gaedigk, A, Ryder DL, et al. CYP2D6 poor metabolizer status can be ruled out by a single genotyping assay for the -1584G promoter polymorphism. Clin Chem 2003;49(6 Pt 1):1008-11.
8. xTAG CYP2D6 Kit v3 Package Insert, 2013.

+ Intended Use:
The xTAG CYP2D6 Kit v3 is a device used to simultaneously detect and identify a panel of nucleotide variants found within the highly polymorphic CYP2D6 gene located on chromosome 22 from genomic DNA extracted from a whole blood sample. This kit can also identify gene rearrangements associated with the deletion (*5) and duplication genotypes. 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. This kit is not indicated for stand-alone diagnostic purposes. This test is not intended to be used to predict drug response or non-response.

For In Vitro Diagnostic Use Only. Products are region specific and may not be approved in some countries/regions. Contact Luminex to obtain details for your country.

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