

xTAG® CYP2C19 Kit v3

CYP2C19 Overview: Clinical Relevance⁺

- CYP2C19 is an isoenzyme that mediates the metabolic activation and elimination, and hence the therapeutic effect of a variety of medications (Table 1).

Table 1: Classes of Drugs Metabolized by CYP2C19*

Therapeutic Area	Examples of drugs
Antiplatelet agent	Clopidogrel
Anticonvulsants	Mephenytoin, phenytoin
Antidepressants	Citalopram, fluoxetine
Antineoplastic drugs	Cyclophosphamide
Antiretroviral/antifungals	Voriconazole, nelfinavir
Proton pump inhibitors	Lansoprazole, omeprazole

- Genetic variations of the CYP2C19 gene among patients is a major cause of variability in drug response to medications metabolized by CYP2C19.¹
- The wild-type allele, CYP2C19*1, is the most common genotype.
- Variants of CYP2C19 may result in abnormal enzyme levels leading to impaired drug metabolism and can cause adverse reactions including drug toxicity, poor efficacy or non-responsiveness.
- Prevalence of a specific genetic variant is dependent on a patient's racial and ethnic background. The CYP2C19*2 allele is common in Asians (30%), Caucasians (14.7%) and Africans (17.3%).²
- CYP2C19*2 and CYP2C19*3 together account for approximately 99% and 87% of Asian and Caucasian poor metabolizers, respectively.²

xTAG® CYP2C19 Kit v3: Clinical Utility⁺

The xTAG CYP2C19 Kit v3 is an *in vitro* diagnostic qualitative genotyping assay which can be used as an aid to clinicians in determining therapeutic strategy for drugs metabolized by the CYP2C19 gene product.

xTAG CYP2C19 Kit v3: Genetic Variations

- Broad coverage panel includes clinically relevant CYP2C19 variant alleles (Table 2).
- Test identifies the major variant alleles, CYP2C19*17 and CYP2C19*2, in addition to rare alleles found in Caucasian populations.

Table 2: Genotypes Detected by the xTAG CYP2C19 Kit v3

CYP2C19 Alleles	SNP(s) Detected	Predicted Enzyme Activity
*1	None	Normal
*2	19154G>A	Non-functional
*3	17948G>A	Non-functional
*17	-806C>T	Increased function

xTAG CYP2C19 Kit v3: Workflow

- Optimized workflow on Luminex® 100/200™ and MAGPIX® instruments for same day results
- Flexibility in throughput to match needs of your laboratory

xTAG CYP2C19 Kit v3: Performance Data

- Diagnostic accuracy greater than 98% on Luminex 100/200 and MAGPIX instruments for all genotypes
- Assay reproducibility greater than 99% for all tested genotypes across three different sites
- Confidence in results with high diagnostic accuracy and reproducibility on both Luminex 100/200 and MAGPIX instruments (Table 3)

¹ Cleveland Clinical Laboratories, Technical Brief on Technical Brief Genetic Test of Cytochrome P450 2C19 (CYP2C19) for Drug Metabolism

² Cleve Clin J Med. 2011 April; 78(4): 243-257 & Clin Pharmacol Ther. 2011 August; 90(2): 328-332

Table 3: Diagnostic Accuracy & Reproducibility on Luminex 100/200 and MAGPIX

CYP2C19 Genotype ¹	Accuracy ¹	Agreement ¹
*1/*1	100%	100%
*1/*2	100%	100%
*1/*3	100%	100%
*1/*17	100%	100%
*2/*2	100%	100%
*2/*3	100%	100%
*2/*17	100%	100%
*3/*17	100%	100%
*17/*17	100%	100%

¹ After allowable re-runs

Kit Configuration

The complete kit includes the following enzymes and reagents in volumes suitable for 48 tests:

Reagents in the xTAG CYP2C19 Kit v3

Primer Mixes

- xTAG CYP2C19 Kit v3 PCR Primer Mix
- xTAG CYP2C19 Kit v3 ASPE Primer Mix

Enzymes & Buffers

- xTAG Shrimp Alkaline Phosphatase
- xTAG Exonuclease I
- xTAG Hot Start Taq
- xTAG 10x HS Taq Polymerase
- xTAG Reporter Buffer

Beads & Reporter

- xTAG CYP2C19 Kit v3 Bead Mix
- xTAG Streptavidin, R-phycoerythrin Conjugate G75

Ordering Information

Product Name	Kit size	Registration status	Catalog Number
xTAG CYP2C19 Kit v3	48 tests	US IVD	I046B0427
TDAS CYP2C19 Analysis Software CD	N/A	US IVD	S046-0275

Instruments: MAGPIX® and Luminex® 100/200™



Luminex 100/200 is a class 1(I) laser product

***Indications for Use**

The xTAG CYP2C19 Kit v3 is an in vitro diagnostic test used to simultaneously detect and identify a panel of nucleotide variants found within the highly polymorphic CYP450 2C19 gene, located on chromosome 10q24, from genomic DNA extracted from EDTA or citrate anticoagulated whole blood samples. The xTAG CYP2C19 Kit v3 is a qualitative genotyping assay which can be used as an aid to clinicians in determining therapeutic strategy for the therapeutics that are metabolized by the CYP2C19 gene product, specifically *2,*3 and *17. The kit is not indicated for stand-alone diagnostic purposes. This test is not intended to be used to predict drug response or non-response. The xTAG CYP2C19 Kit v3 is indicated for use with the Luminex 100/200 instrument or MAPGIX with xPONENT™ software systems.

♦xTAG CYP2C19 Kit v3 is not cleared for use in conjunction with any specific drugs or medications.

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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