

Cytochrome P450 2C19 (CYP2C19)

Tools to help identify the right drug in the right dose for the right patient

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: Examples of drugs that are metabolized by CYP2C19*

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

- Genetic variations of CYP2C19 gene among patients is a major cause of variability in drug response to medications that are metabolized by CYP2C19.¹
- The wild-type (WT) allele, CYP2C19*1, is the most common genotype. Several genetic variants resulting in reduced or no enzyme function have been identified.
- Functionally impaired variants of CYP2C19 result in abnormal enzyme levels leading to impaired metabolism of drugs and 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%).
- 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 that are metabolized by the CYP2C19 gene product.

xTAG CYP2C19 Kit v3: Genetic Variations

- Broad coverage panel that 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
*4	1A>G	Non-functional
*5	90033C>T	Non-functional
*6	12748G>A	Non-functional
*7	19294T>A	Non-functional
*8	12711T>C	Decreased function
*9	12784G>A	Decreased function
*10	19153C>T	Decreased function
*17	-806C>T	Increased function

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

² xTAG CYP2C19 Kit v3 Package Insert, 2013

xTAG CYP2C19 Kit v3: Performance Data

- Diagnostic accuracy greater than 98% on Luminex® 100/200™ and MAGPIX® platform 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).

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/*9	100%	100%
*1/*10	100%	100%
*1/*17	100%	100%
*2/*2	100%	100%
*2/*3	100%	100%
*2/*17	100%	100%
*3/*17	100%	100%
*4/*17	100%	100%
*9/*17	100%	100%
*17/*17	100%	100%

¹ After allowable re-runs

xTAG CYP2C19 Kit v3: Kit Configuration

Cost-effective solution with a complete kit that includes enzymes and reagents for 48 tests

Reagents in 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

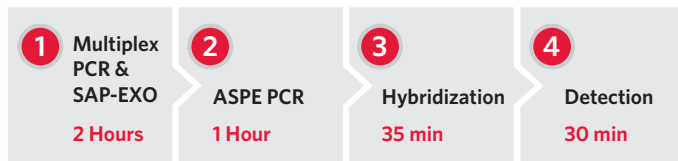
- xTAG® CYP2C19 Kit v3 Bead Mix
- xTAG® Streptavidin, R-phycoerythrin Conjugate G75

Ordering Information

Product Name	Kit size	Registration status	Catalog Number
xTAG CYP2C19 Kit v3	48 tests	EU/ROW IVD	I046B0428
TDAS CYP2C19 Analysis Software CD	N/A	EU/ROW IVD	S046-0276

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 the laboratory



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

*xTAG CYP2C19 Kit v3 is not indicated for stand-alone diagnostic purposes. The information provided from this test may supplement decision making and should only be used in conjunction with routine monitoring by a physician. Because of the variability in the knowledge of clinical utility with specific drugs that are metabolized by CYP2C19, clinicians should use professional judgment in the interpretation of results from this test. Results from this type of assay should not be used in predicting a patient's response to drugs for which the drug metabolizing enzyme activity of that allele, or the drug metabolic pathway, has not been clearly established.

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

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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|--|--|--|--|---|---|---|---|--|
| Barcelona
93 645 50 28
barcelona@rafer.es | Bilbao
94 499 85 80
bilbao@rafer.es | La Coruña
981 59 54 54
galicia@rafer.es | Madrid
91 365 15 70
madrid@rafer.es | Málaga
639 359 792
malaga@rafer.es | Sevilla
954 369 334
sevilla@rafer.es | Valencia
96 340 48 00
levante@rafer.es | Zaragoza
976 23 74 00
rafer@rafer.es | Lisboa
21 154 19 98
lisboa@rafer.es |
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