

Spartan

Rapid DNA Testing for Everyone



Products are region specific and may not be approved in some countries. Please contact your authorized Spartan representative for availability in your region.

The Spartan Cube CYP2C19 System

Rapid CYP2C19 genotyping helps doctors treat patients with the most effective anti-platelet therapy, which can improve clinical outcomes. Spartan's test identifies CYP2C19 *2, *3, and *17 mutations which are in charge of metabolising Clopidogrel.

- Portable size - The Spartan Cube is the size of a coffee cup.
- Simple Cheek Swab - Non-invasive test and no sample preparation or pipetting.
- 15 Peer-Reviewed Studies have used Spartan's technology – including POPular Genetics (published in NEJM), TAILOR-PCI (Mayo Clinic), RAPID GENE (published in Lancet).



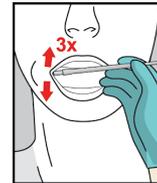
The Spartan Cube Platform

The World's Smallest DNA Analyser

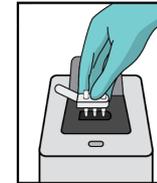
WORKFLOW

- Sample Types: swabs.
- Hands-On Time: <4 minutes
- Sample Preparation: None
- Pipetting Steps: None
- Run Time: <60 minutes

Collect Sample



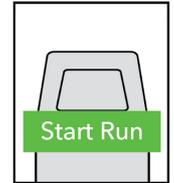
Put cartridge in Spartan Cube



Put samples in Spartan Cube



Start Run



SPECIFICATIONS

Regulatory

- CE IVD Mark
- ISO 13485

Size and Weight

- 10x10x10cm
- Cube: 1.6kg

Current Test Menu

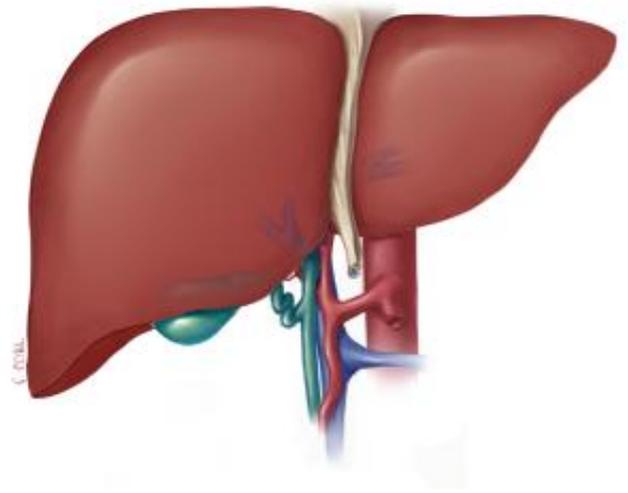
- CYP2C19 for precision medicine.

Spartan

Genetic Mutations Impair Drug Response

Clopidogrel (Plavix®) is a prodrug that is activated by CYP2C19

- 30 to 50% of patients carry CYP2C19 loss-of-function gene mutations that impair drug response.
- For heart attack patients, most complications from poor clopidogrel response occur in first 24-48 hours after cardiac stenting.



FDA “Black Box” Warning For Clopidogrel

WARNING: DIMINISHED EFFECTIVENESS IN POOR METABOLIZERS
See full prescribing information for complete boxed warning.

- Effectiveness of Plavix depends on activation to an active metabolite by the cytochrome P450 (CYP) system, principally CYP2C19.
- Poor metabolizers treated with Plavix at recommended doses exhibit higher cardiovascular event rates following acute coronary syndrome (ACS) or percutaneous coronary intervention (PCI) than patients with normal CYP2C19 function.
- Tests are available to identify a patient’s CYP2C19 genotype and can be used as an aid in determining therapeutic strategy.
- Consider alternative treatment or treatment strategies in patients identified as CYP2C19 poor metabolizers.

CYP2C19 Carriers In Different Ethnic Populations

CYP2C19 Allele	CYP2C19 Enzyme Activity	Carriers of 1 or 2 alleles (% of population)				
		African American	Asian	European	Indian	Middle Eastern
*2	Decreased	28	50	28	58	23
*3	Decreased	1	17	<1	5	2
*17	Increased	29	5	38		

*2: loss-of-function (LOF)

*3: loss-of-function (LOF)

*17: gain-of-function (GOF)

CYP2C19 Influence On Clopidogrel Outcomes

Meta-analysis of 9 trials and 9,685 clopidogrel-treated high-risk patients

- 91% of patients underwent Percutaneous Coronary Intervention (PCI)
- 55% of patients had Acute Coronary Syndrome (ACS)

Outcome	LOF vs non-LOF
Major Adverse Cardiac Events (MACE)	Hazard Ratio: 1.57 (1.13-2.16)
Stent Thrombosis	Hazard Ratio: 2.81 (1.81-4.37)

Ticagrelor And Prasugrel Have Side Effects

Increased bleeding risk relative to clopidogrel

- Ticagrelor: 10-fold increase in fatal intracranial bleeding (0.1% vs. 0.01%)
- Prasugrel: 0.6% increase in life-threatening bleeding

Shortness of breath leading to discontinuation of medication

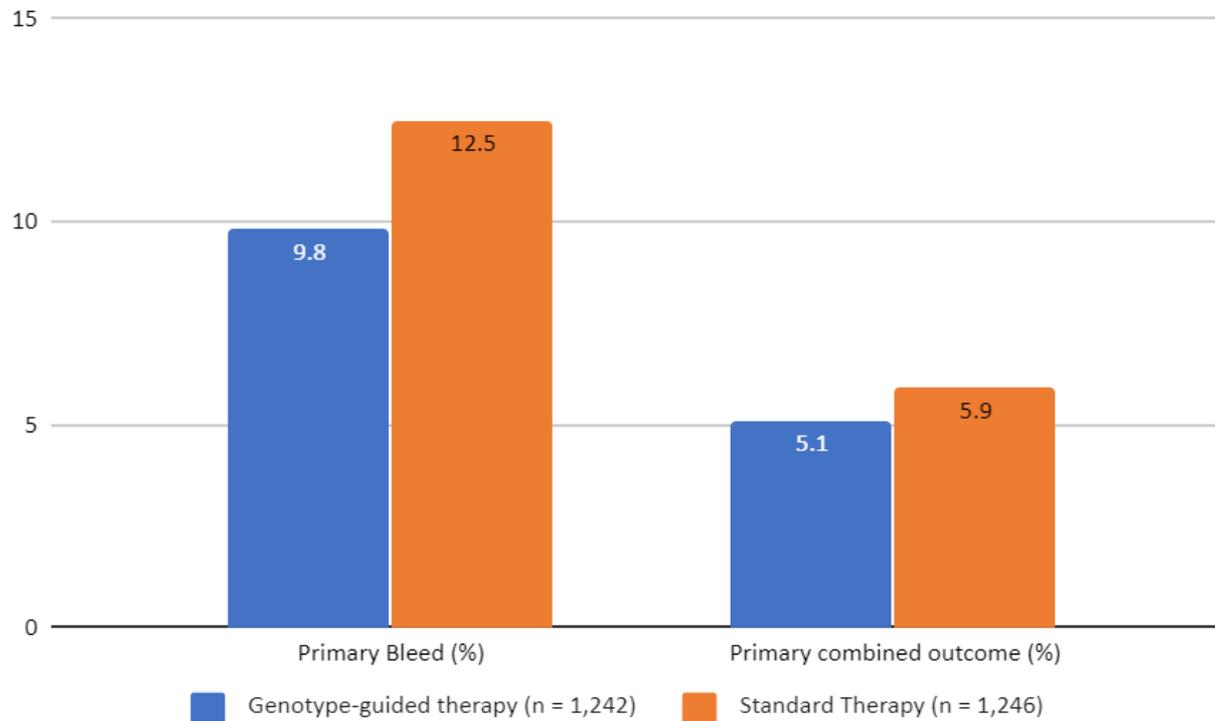
- This side effect and non-compliance affected 4.55-6.5% of patients on ticagrelor

10-20X more expensive than generic clopidogrel

Up to 70% of patients do not have a CYP2C19 mutation affecting their response to clopidogrel

CYP2C19-Guided Therapy Significantly Reduced Bleeding Events Without Increasing Thrombotic Risk

Genotype-guided anti-platelet therapy was safer and just as effective than a “one drug for all” approach.



Summary Results

TAILOR-PCI was a 7-year 5,300-patient clinical trial of precision medicine for cardiac stent patients that was funded by Mayo Clinic and the National Institutes of Health (NIH). TAILOR-PCI is the largest trial of genetics in cardiology history. Spartan's FDA-cleared rapid CYP2C19 genotyping test was used to personalise anti-platelet therapy

- Genotype-guided therapy resulted in 34% fewer adverse events after 12 months such as death, stroke, second heart attack, and stent thrombosis.
- Genotype-guided therapy resulted in 80% fewer adverse events in the first 3 months. According to principal investigator Dr. Naveen Pereira: “This finding suggests that the lion’s share of the benefit of genetically guided therapy may occur during this high-risk period.”

Influence Of CYP2C19 On Clopidogrel Efficacy For Acute Ischemic Stroke Or Transient Ischemic Attack

- 15 studies of 4,762 patients with stroke or TIA treated with clopidogrel, carriers of CYP2C19 loss-of-function alleles (*2, *3) were at increased risk in comparison with non-carriers:
 - Stroke - 12.0% vs. 5.8%; $P < 0.001$
 - Composite vascular events - 13.7% vs. 9.4%; $P = 0.01$
- Bleeding rates were similar between groups (2.4% versus 3.1%; $P = 0.59$)
- Carriers of CYP2C19 loss-of-function alleles are at greater risk of stroke and composite vascular events than non-carriers among patients with ischemic stroke or TIA treated with clopidogrel

Cost-Effectiveness Of CYP2C19 Genotyping

Multiple third-party analyses have found that personalised therapy can result in cost savings:

Genotype-guided therapy study shows improved patient outcomes and cost reduction in Spanish patients undergoing PCI:

- Reduction in risk of myocardial infarction (MI) (5.23%), stroke (2.25%) and major bleeding (0.99%)
- Reduction in hospitalisation cost by €342/patient

CYP2C19-guided therapy in ACS/PCI patients is cost effective (data from “Real world” implementation):

- 3 primary strategies for DAPT were compared: universal clopidogrel, universal ticagrelor, or genotype-guided therapy
- Only CYP2C19-guided therapy was cost-effective across multiple willingness-to-pay thresholds (\$42,365/QALY)

VerifyNow Platelet Function Test

- Measures P2Y₁₂-mediated platelet aggregation in order to assess a patient's response to anti-platelet therapy (so only relevant for elective cases after a period of preloading, not relevant for acute scenarios).
- Test requires multiple blood draws and the accuracy/reliability depends on a highly demanding maintenance requirements policy.
- Test may have to be performed multiple times as patient's platelet response changes over time.



Spartan's DNA test uses a non-invasive cheek swab and only needs to be performed once because a patient's genotype does not change.