

Spartan RXTM

Spartan RX CYP2C19

Point-of-care DNA Testing System



Point-of-care DNA Results

Introducing the Spartan RX: The first point-of-care sample-to-result DNA testing system

Clinical Need

- 2.2 million Percutaneous Coronary Interventions (PCI) are performed worldwide each year.
- Plavix® is the leading anti-platelet drug for PCI.
- In March 2010, the FDA issued a “black box” warning for Plavix® regarding CYP2C19 genetic carriers.
- 30% of patients** carry the CYP2C19*2 gene.¹
- CYP2C19*2 carriers receiving Plavix® have a **42% higher risk of Major Adverse Cardiac Events (MACE)**.²
- Up to 50% of MACE occur in the first 48 hours after PCI.³

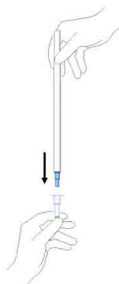
Solution

- Point-of-care results in 1 hour.
- Sample-to-result system may be operated by a non-technical user.
- Easy to use: no laboratory training required.
- Patient-friendly: non-invasive test using a buccal swab.
- Doctors may choose to prescribe alternative anti-platelet therapy to CYP2C19*2 carriers.
- CE IVD Mark regulatory approval.

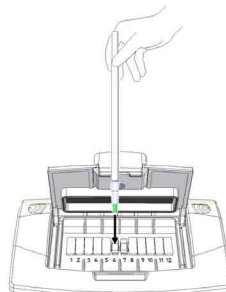
Sample to Result in 4 Easy Steps



1. Collect buccal sample.



2. Add sample to tube.



3. Insert tube into Spartan RX.

Press “Go”

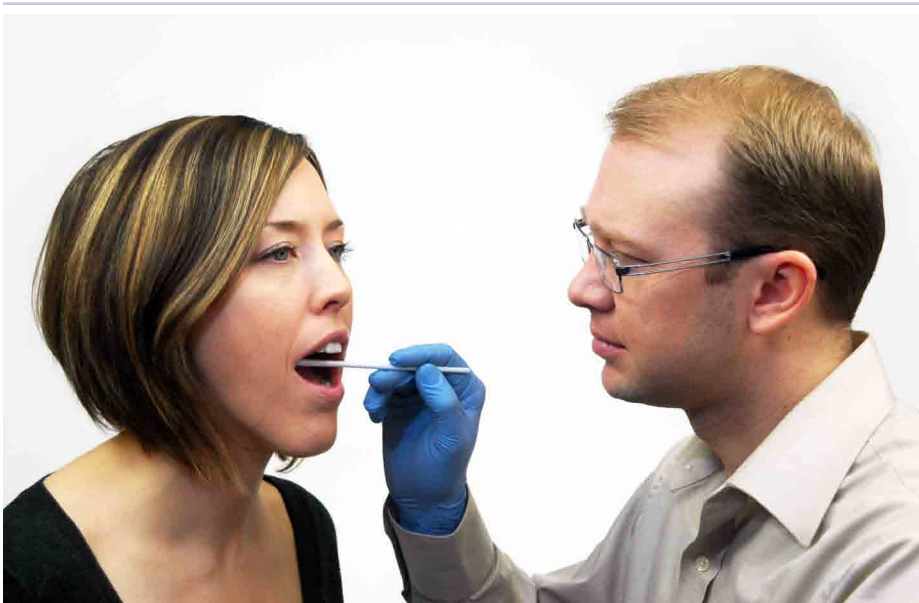
4. DNA results in 1 hour.

↘ DNA Results on Demand

“As a one-hour point-of-care test, the Spartan RX CYP2C19 has the potential to significantly reduce major cardiac events in heart attack patients.”

Dr. Derek So, M.D.

Staff cardiologist, University of Ottawa Heart Institute



Pre-clinical Data

- ↘ Spartan RX CYP2C19 genotypes showed 100% concordance with DNA sequencing (n=107).
- ↘ Performance is equivalent to lab-based DNA tests (n=970)
 - ↘ 99.5% reliability
 - ↘ 100% sensitivity and specificity

Clinical Data

- ↘ RAPID GENE (ClinicalTrials.gov: NCT01184300)
 - ↘ Results presented at TCT 2011 Conference.
 - ↘ Point-of-care genotyping and prasugrel for CYP2C19*2 carriers completely eliminated high on-treatment platelet reactivity (HPR).
 - ↘ In contrast, 30.4% of carriers had HPR at 1 week on standard clopidogrel therapy.

Additional Products

- ↘ The Spartan RX CYP2C19 test currently identifies the *2 loss-of-function allele. This accounts for 95% of all carriers.²
- ↘ *3, *17, and ABCB1 are available for Research Use Only. Please contact Spartan for additional information.



Developed and manufactured by

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References

1. Damani SB, Topol EJ. (2010). *J Am Coll Cardiol.* 56:109–111.
2. Mega JL et al. (2009). *N Engl J Med.* 360:354–62.
3. Wiviott SD et al. (2007). *N Engl J Med.* 357:2001–2015.

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Not available for sale in the United States.