HEARTGENETICS
GENETICS & BIOTECHNOLOGY

For use with iPLEX® MassARRAY® Systems from Agena BIOSCIENCE

Simplifying Genetic Testing

And Clinical Diagnostics

CE IVD

CE IVD

SECURE

A scalable and complete solution for molecular diagnostic professionals

bsi. ISO 13485 Medical Devices Quality Management

ISO 9001 BUREAU VERITAS Certification

About HEARTDECODE®

A powerful genetic reporting tool | Accurate | Hands-free

✓ Fully optimised and integrated with iPLEX MassARRAY® system from Agena BIOSCIENCE

SECURE

Multilanguage Platform

SOON AVAILABLE IN THE CLOUD WITH ISO 27001:2012

HEARTDECODE® is a CE-IVD medical device that uses machine learning algorithms to generate automated **clinically actionable** reports for **HeartGenetics'** genetic testing kits

Reduce turnaround times, improve patient monitoring today.

- ✓ **Automatic** complete report generation
- ✓ **Intuitive** interfaces for non-experts
- ✓ **Fully Scalable**
- ✓ **Customisable** to your lab and sample information
- ✓ **Comprehensive** information about genetic risk and pharmacogenetics*
- ✓ **Browser-based** platform
- ✓ **Reproducible** and highly robust
- ✓ **Validated** by medical doctors and geneticists

* Dependent of the genetic testing kit.

CE IVD

Effortless CE-IVD Genetic Testing

Primers & DNA controls manufactured according to GMPs

1.

Choose from 100% validated and ready-to-use **HEART**GENETICS' CE-IVD Genetic Testing Kits, fully optimised to detect specific diseases

2.

Follow the usual genotyping **iPLEX MassARRAY®** protocol from Agena BIOSCIENCE

3.

Get real-time and easy-to-read genetic reports with the **HEART**DECODE® Genetic Reporting Software from **HEART**GENETICS

Update your genetic testing portfolio with accurate and expert-defined genetic kits

CE IVD

Genetic Kit	Description	Genetic Variants
TromboGene Kit™ | 2016	Genetic study of Hereditary Thrombophilia	14
DNArterial® Kit | 2016	Study of Molecular Markers of Essential Hypertension and Associated Cardiovascular Events	57
Clopidogrel PGX Kit™ | 2016	Genetic Study of Clopidogrel Pharmacogenetics	3
Warfarin PGX Kit™ | 2016	Genetic Study of Warfarin Pharmacogenetics	3
Simvastatin PGX Kit™ | 2016	Genetic Study of Simvastatin Pharmacogenetics	3

To be launched soon

SportGene Kit™ | 2016	Genetic Study of Hypertrophic Cardiomyopathy	To be determined
LipoGene™ | 2016	Genetic Study of Familial Hypercholesterolemia	To be determined

Kit contents

Genetic Kits contain ready-to-use and fully optimised amplification and extension primer mixes for each targeted and clinical relevant genetic variant. Artificial DNA templates are also included to be used as an external control, ensuring that reagents were assembled correctly and performed according to the correct genotyping specifications. All kits are adapted to iPLEX® MassARRAY® system technology from Agena Bioscience.

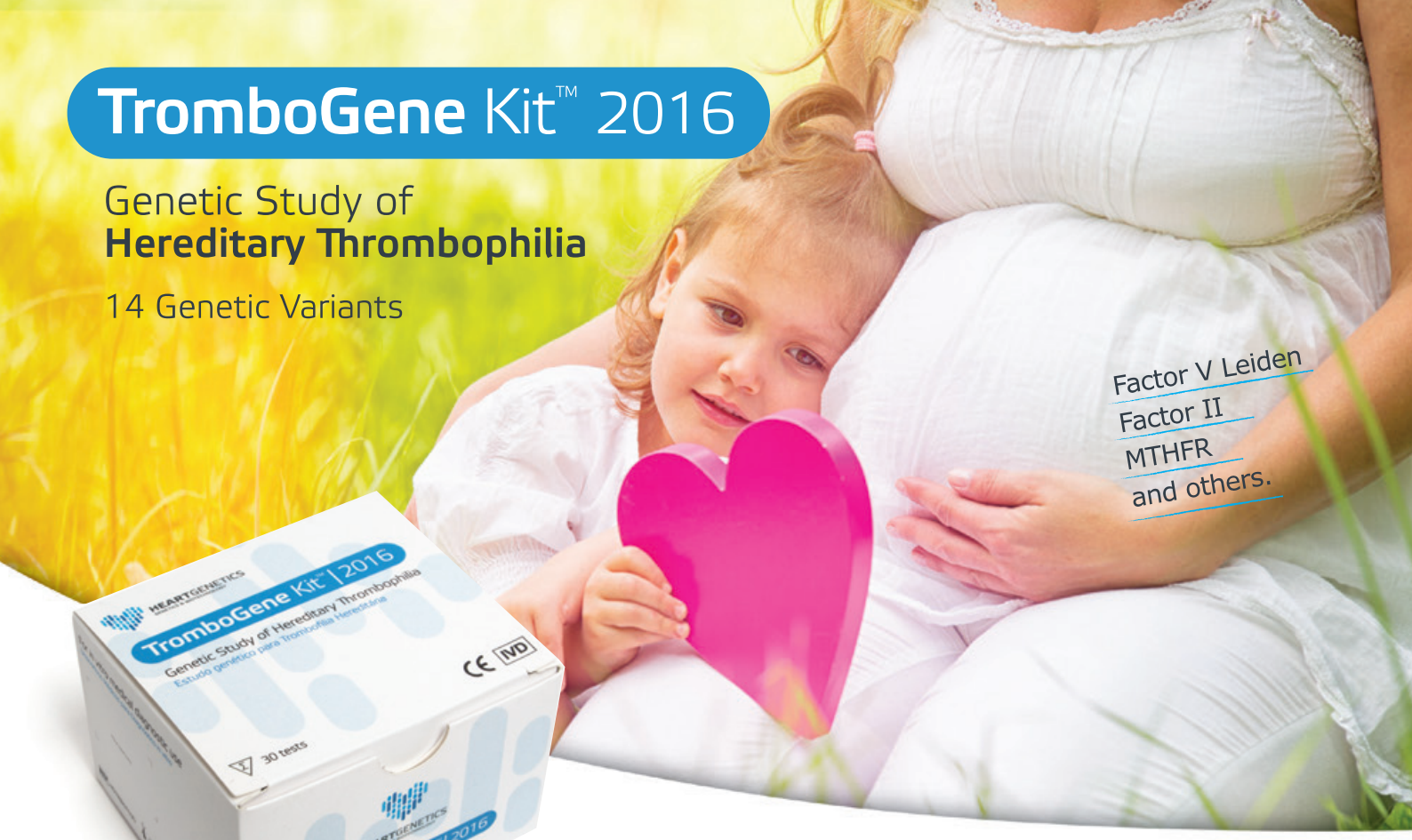
All genetic variants were carefully selected and curated from reference databases (HGMDP, NCBI-OMIM, NCBI- ClinVar, NCBI-Variation Reporter and Ensembl) and clinically validated by internationally recognized medical doctors and geneticists.

Personal and family history of cardiovascular diseases, blood pressure and cholesterol levels and lifestyle contribute to the risk of developing cardiovascular diseases. Screening for genetic risk is important for disease prognosis, diagnosis and both lifestyle and therapeutic adjustments.

TromboGene Kit™ 2016

Genetic Study of **Hereditary Thrombophilia**

14 Genetic Variants



REF 5039 Σ 30 tests

F2	Coagulation factor **II** (prothrombin)
FV	Coagulation factor V (proaccelerin, labile factor)
PROCR	Protein C receptor, endothelial
PROS1	Protein S (alpha)
MTHFR	Methylenetetrahydrofolate reductase (NAD(P)H)
PAI-1	Serpin Peptidase **I**nhibitor, Clade E (Nexin, Plasminogen Activator **I**nhibitor Type 1)
F13A1	Coagulation factor X**III**, A1 polypeptide
FGB	Fibrinogen beta chain
GP1BA	Glycoprotein **I**b (platelet), alpha polypeptide
SERPINC1	Serpin Peptidase **I**nhibitor, Clade C (Antithrombin), Member 1

CE IVD

Includes reproducible and automated genetic reports generated by HEARTDECODE® 2016

The Disease Problem

- ✓ 10% prevalence worldwide
- ✓ 50% risk for thromboembolic diseases for individuals with family history
- ✓ One of the major causes of fetal loss
- ✓ Causal risk factor for ischemic stroke
- ✓ Increased thrombotic risk during oral contraceptive or hormone therapy use

TromboGene Kit™

- ✓ Personal and family risk stratification for the disease
- ✓ Genetic analysis of well established F2, FV Leiden and MTHFR genetic risk variants
- ✓ Family Planning decisions
- ✓ Adequate therapy

DNArterial Kit® 2016

Study of Molecular Markers of **Essential Hypertension and Associated Cardiovascular Events**

57 Genetic Variants

NEW
WITH RISK EVALUATION
PATENT PENDING

REF 5015 Σ 25 tests

ACE	Angiotensin I converting enzyme
ADD1	Adducin 1 (alpha)
ADRA1A	Adrenoceptor Alpha 1A
ADRB1	Adrenoceptor Beta 1
ADRB2	Adrenoceptor Beta 2
AGT	Angiotensinogen
AGTR1	Angiotensin II Receptor, Type 1
AGTR2	Angiotensin II Receptor, Type 2
BDKRB2	Bradykinin Receptor B2
CACNA1C	Calcium Channel, Voltage-Dependent, L Type, Alpha 1C Subunit
CACNB2	Calcium Channel, Voltage-Dependent, Beta 2 Subunit
CALCA	Calcitonin-Related Polypeptide Alpha
CLCNKA	Chloride Channel, Voltage-Sensitive Ka
CLCNKB	Chloride Channel, Voltage-Sensitive Kb
CORIN	Corin, Serine Peptidase
CYBA	Cytochrome B-245, Alpha Polypeptide
CYP4A11	Cytochrome P450, Family 4, Subfamily A, Polypeptide 11
CYP17A1	Cytochrome P450, Family 17, Subfamily A, Polypeptide 1
DRD3	Dopamine Receptor D3
ECE1	Endothelin Converting Enzyme 1
EDN1	Endothelin 1
EDNRA	Endothelin Receptor Type A
FGF5	Fibroblast Growth Factor 5
GCH1	GTP Cyclohydrolase 1
GRK4	G Protein-Coupled Receptor Kinase 4
KCNMB1	Potassium Channel Subfamily M Regulatory Beta Subunit 1
NOS2	Nitric Oxide Synthase 2, Inducible
NOS3	Nitric Oxide Synthase 3 (Endothelial Cell)
NPPA	Natriuretic Peptide A
NPPC	Natriuretic Peptide C
NR3C2	Nuclear Receptor Subfamily 3, Group C, Member 2
REN	Renin
RETN	Resistin
SLC12A3	Solute Carrier Family 12 (Sodium/Chloride Transporter), Member 3
SCNN1At	Sodium Channel, Non Voltage Gated 1 Alpha Subunit
STK39	Serine Threonine Kinase 39
WNK1	WNK Lysine Deficient Protein Kinase 1

Includes reproducible and automated genetic reports generated by HEARTDECODE® 2016

CE IVD

The Disease Problem

- ✓ High blood pressure is a leading cause of death worldwide
- ✓ Genetics is a risk factor that could contribute to 30-50% of cases
- ✓ Family history suggests a genetic predisposition
- ✓ Treatment of patients with mild and moderate arterial hypertension is difficult to define

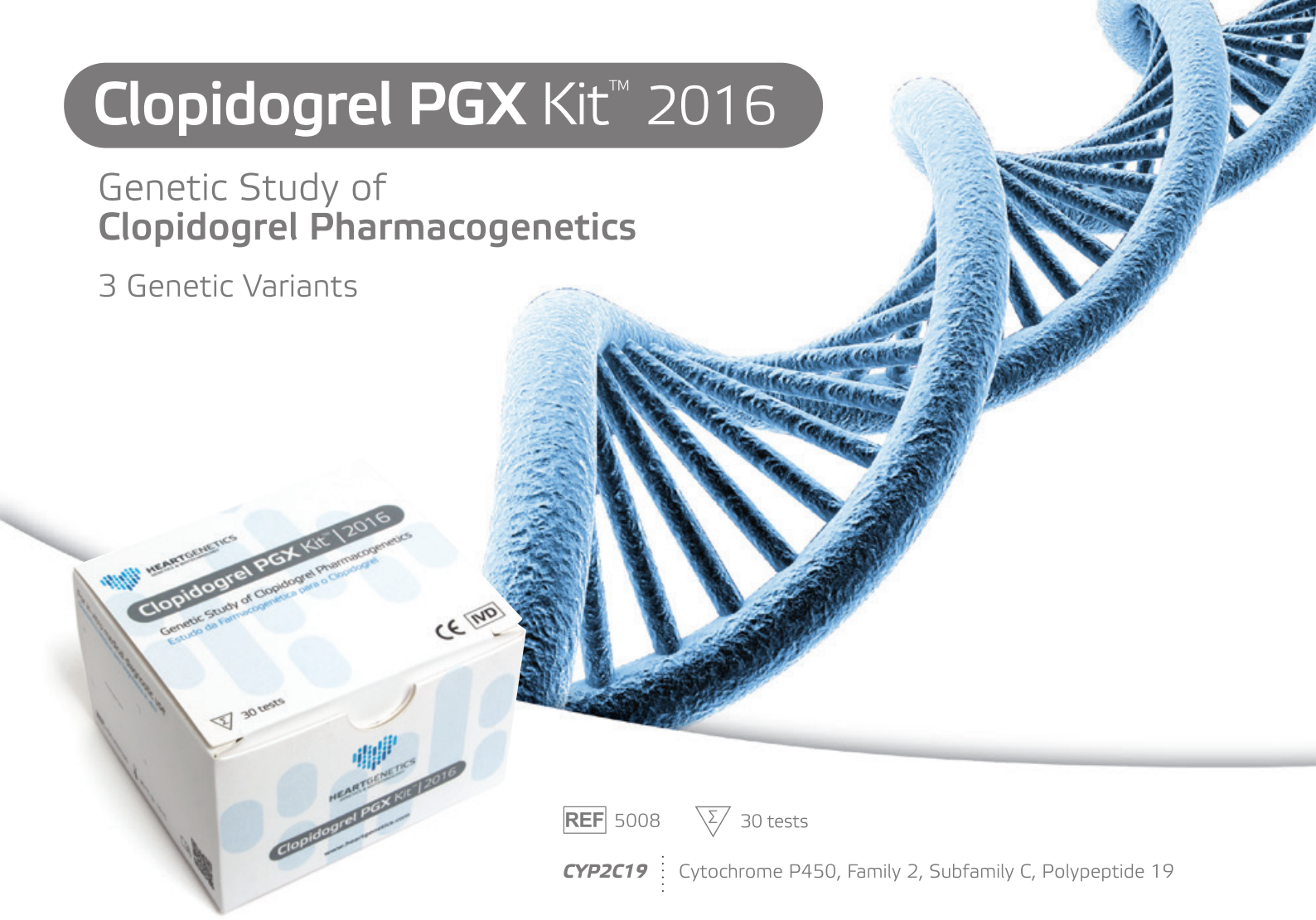
DNArterial® Kit

- ✓ Unique test worldwide
- ✓ 82% accuracy on the disease risk score classification
- ✓ Supports the diagnosis and treatment definition for mild to moderate arterial hypertension patients
- ✓ Evaluation of antihypertensive drugs efficacy according to the genetic profile
- ✓ Clinical trial with more than 600 patients

Clopidogrel PGX Kit™ 2016

Genetic Study of **Clopidogrel Pharmacogenetics**

3 Genetic Variants



REF 5008 Σ 30 tests

CYP2C19 Cytochrome P450, Family 2, Subfamily C, Polypeptide 19

As recommended by the Food and Drug Administration (FDA) and the Clinical Pharmacogenetics Implementation Consortium (CPIC)

CE IVD

Includes reproducible and automated genetic reports generated by HEARTDECODE® 2016

The Problem

- ✓ Highly variable patient response to Clopidogrel
- ✓ Adverse side-effects of non-optimal Clopidogrel drug usage

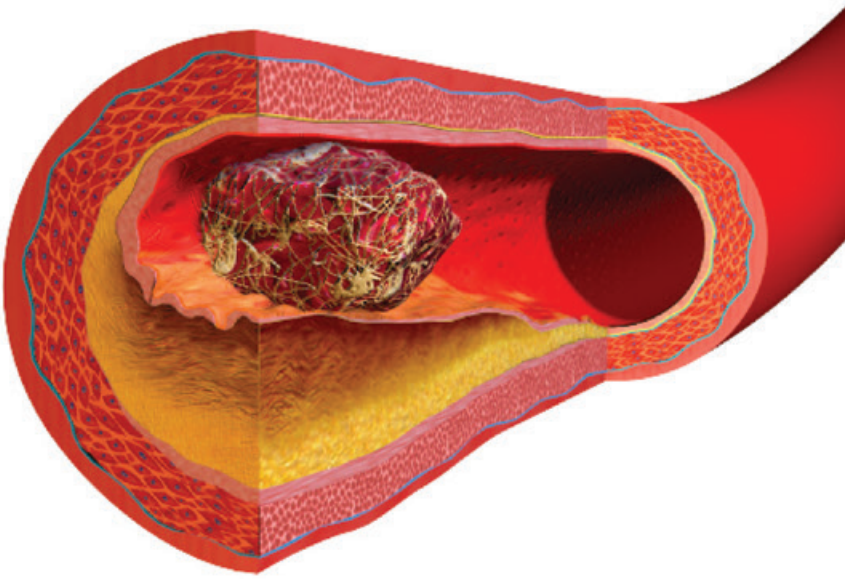
Clopidogrel PGX Kit™

- ✓ Defines the risk of adverse cardiovascular events and platelet aggregation
- ✓ Defines optimal dose therapy
- ✓ Recommends for alternative anti-platelet therapy
- ✓ Distinguishes non-responsive or drug resistant patients

Warfarin PGX Kit™ 2016

Genetic Study of **Warfarin Pharmacogenetics**

3 Genetic Variants



REF 5046 | 30 tests

CYP2C9	Cytochrome P450, Family 2, Subfamily C, Polypeptide 9
VKORC1	Vitamin K Epoxide Reductase Complex, Subunit 1

As recommended by the Food and Drug Administration (FDA) and the Clinical Pharmacogenetics Implementation Consortium (CPIC)

Includes reproducible and automated genetic reports generated by HEARTDECODE® 2016

CE IVD

The Problem

- ✓ Highly variable patient response to Warfarin
- ✓ Adverse side-effects of non-optimal Warfarin drug dosage

Warfarin PGX Kit™

- ✓ Defines optimal dose therapy
- ✓ Reduces the time to achieve a therapeutic prothrombin time
- ✓ Recommends for alternative anti-platelet therapy
- ✓ Minimises the risk for bleeding and blood-clot formation

Simvastatin PGX Kit™ 2016

Genetic Study of **Simvastatin Pharmacogenetics**

3 Genetic Variants

REF 5022 | 30 tests

SLC01B1 | Solute Carrier Organic Anion Transporter Family, Member 1B1

As recommended by the Food and Drug Administration (FDA) and the Clinical Pharmacogenetics Implementation Consortium (CPIC)

CE IVD

Includes reproducible and automated genetic reports generated by HEARTDECODE® 2016

The Problem

- ✓ Highly variable patient response to Simvastatin
- ✓ Adverse side-effects of non-optimal Simvastatin drug dosage

Simvastatin PGX Kit™

- ✓ Defines optimal dose therapy
- ✓ Recommends for alternative statin
- ✓ Defines and minimises the risk of Simvastatin-induced myopathy
- ✓ Up-to-date genetic information

HeartGenetics
CE-IVD Genetic Reports

Managing cardiovascular health

- For genetic diagnosis use
- Clinically actionable information
- Accurate and rigorous
- Updated Information
- Fully automatic generation
- Customisable for each lab
- Appealing layouts
- Multilanguage

Contact us for sample reports.

All reports include:

- Customer and sample information
- Genotyping summary table
- Gene function and associated genetic risk
- Phenotype/clinical profile association
- Frequency of the genetic variant
- Methods and analytical section
- Trustful scientific references
- Gene panel analysed
- Your company information and details

Depending on the genetic test:

- Pharmacogenetics
- Genetic risk evaluation
- Genetic risk score
- Genetic risk predisposition
- Graphs and other visual representations

Genetic reports follow all recommendations from the **European Society of Human Genetics**

Order Information:

CE IVD

Kit Name	Genetic tests	Genetic variants	Reference
TromboGene Kit™ | 2016	30	14	5039
DNArterial® Kit | 2016	25	57	5015
Clopidogrel PGX Kit™ | 2016	30	3	5008
Warfarin PGX Kit™ | 2016	30	3	5046
Simvastatin PGX Kit™ | 2016	30	3	5022
HEARTDECODE® 2016 annual fee	-	-	5053

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Reach further today

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