

CVD StripAssays®

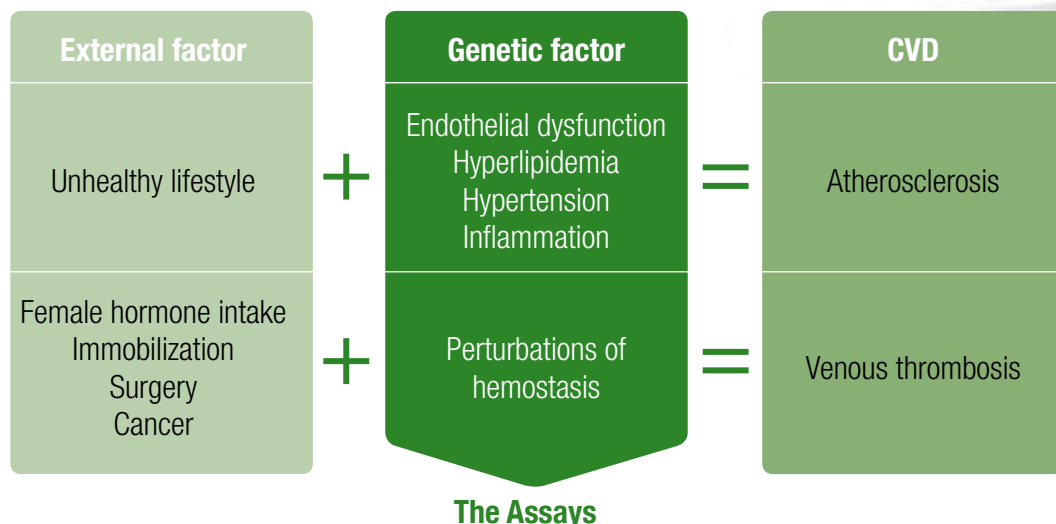
The easy way to test for Cardiovascular Disease risk factors using established innovations in diagnostics

Cardiovascular Disease Assays. Key to efficient testing.

Cardiovascular Diseases (CVD) are common, but in many cases they can be avoided. The best way for avoidance is a lifestyle that is in accordance with an individual's genetic predisposition.

Atherosclerosis and venous thrombosis are the two major manifestations of CVD. Both are caused by complex interactions of environmental and genetic parameters. An unhealthy lifestyle in combination with certain genetic variants can contribute to atherosclerosis. Relevant genes include those involved in endothelial dysfunction, hyperlipidemia, hypertension, and inflammation. Similarly, a combination of adverse influences (female hormone intake, immobilization, surgery or cancer) and variations in genes responsible for the coagulation system can lead to thrombosis. Testing for the genetic variations can greatly contribute to lowering the individual CVD risks.

The CVD StripAssays® offer an easy way to identify variations in genes that are relevant for atherosclerosis and venous thrombosis. ViennaLab offers eight different StripAssays® that detect various combinations of genetic CVD risk factors.





The ViennaLab CVD StripAssays® detect genetic variants that are associated with Cardiovascular Diseases:

Factor V (FV):

FV Leiden (G1691A; R506Q): represents one of the most important genetic risk factors for inherited thrombophilia; leads to activated protein C resistance; occurs in 20-50% of patients with VTE.

FV R2 haplotype (H1299R): mild risk factor for thrombosis; increases CVD risk for carriers of FV Leiden.

Prothrombin (PTH; Factor II) G20210A:

carriers have about 3-fold elevated risk for cerebral and deep vein thrombosis; risk significantly increases in combination with FV Leiden; the A allele is associated with increased prothrombin levels.

5,10-Methylenetetrahydrofolate Reductase (MTHFR):

MTHFR C677T: homozygosity predisposes to arterial and venous thrombosis in the presence of additional risk factors; the thermolabile variant (T allele) is associated with reduced enzyme activity and elevated plasma homocysteine levels in conjunction with folate deficiency.

MTHFR A1298C: compound heterozygosity for C677T and A1298C is considered as CVD risk factor; the C allele is also associated with reduced MTHFR enzyme activity.

Factor XIII (FXIII) V34L:

the L variant offers a protective effect against VTE.

Plasminogen Activator Inhibitor 1 (PAI-1, Serpin E1) 4G/5G:

is considered to be a mild risk factor for VTE and MI; the 4G allele is associated with higher PAI-1 transcription rates.

Endothelial Protein C Receptor (EPCR):

EPCR 4600 A>G (A3 haplotype): carriers of A3 are predisposed to VTE and fetal loss due to higher soluble EPCR plasma levels.

EPCR 4678 G>C (A1 haplotype): homozygous A1 exerts a protective effect in carriers of FV Leiden.

Apolipoprotein B (Apo B) R3500Q:

severe hypercholesterolemia and elevated risk for atherosclerosis; is a dominant but rare mutation.

Apolipoprotein E (Apo E) E2/E3/E4:

the E4 allele is associated with increased susceptibility to early-onset MI, particularly in smokers; important predictors of the plasma lipid profile with E2 showing lowest and E4 showing highest LDL and total cholesterol levels.

Beta-Fibrinogen (FGB) -455 G>A:

increases the risk for premature MI and ischemic stroke; confers elevated beta-fibrinogen plasma levels.

Human Platelet Antigen 1 (HPA1; Gp IIIa; integrin beta 3) L33P (1a/b):

HPA1b is a risk factor for early-onset MI and stroke, particularly in smokers.

Angiotensin-Converting Enzyme (ACE) 287 bp insertion/deletion (I/D):

represents a risk factor for MI in elder patients and in smokers; the D allele is associated with elevated ACE activity and plasma levels.

Endothelial Nitric Oxide Synthase (eNOS; NOS3):

eNOS -786 T>C: the C allele causes a higher susceptibility to coronary heart disease.

eNOS 894 G>T (Glu298Asp): the T allele confers an increased risk for premature MI.

Lymphotoxin Alpha (LTA) 804 C>A (Thr26Asn):

is in almost complete linkage with LTA 252 A>G; both variants act strongly proinflammatory and are associated with coronary artery disease.

MI: myocardial infarction, VTE: venous thromboembolism

ViennaLab offers customers great flexibility to choose the optimal CVD StripAssay®. Several genetic variants can be detected on a single teststrip.

| Gene | Genetic variant | FV StripAssay® 4-330 | PTH StripAssay® 4-340 | MTHFR StripAssay® 4-350 | FV-PTH StripAssay® 4-290 | FV-PTH-MTHFR StripAssay® 4-260 | CVD StripAssay® T 4-360 | CVD StripAssay® A 4-370 | Apo E StripAssay® 4-280 |
|-------|-----------------|----------------------|-----------------------|-------------------------|--------------------------|--------------------------------|-------------------------|-------------------------|-------------------------|
| FV | G1691A (Leiden) | ■ | | | ■ | ■ | ■ | | |
| | H1299R (R2) | | | | | | ■ | | |
| PTH | G20210A | | ■ | | ■ | ■ | | | |
| MTHFR | C677T | | | ■ | | ■ | | | |
| | A1298C | | | | | | ■ | | |
| FXIII | V34L | | | | | | ■ | | |
| PAI-1 | 4G / 5G | | | | | | ■ | | |
| EPCR | A4600G (A3) | | | | | | ■ | | |
| | G4678C (A1) | | | | | | ■ | | |
| ApoB | R3500Q | | | | | | | ■ | |
| ApoE | E2 / E3 / E4 | | | | | | | ■ | ■ |
| FGB | -455 G>A | | | | | | | ■ | |
| HPA1 | a / b | | | | | | | ■ | |
| ACE | I / D | | | | | | | ■ | |
| eNOS | -786 T>C | | | | | | | ■ | |
| | G894T | | | | | | | ■ | |
| LTA | C804A | | | | | | | ■ | |

ViennaLab offers or currently develops StripAssays® for a wide range of diagnostic applications. These include Cancer, Familial Mediterranean Fever, Gaucher Disease, Haemochromatosis, Pharmacogenetics, Sugar Intolerance, and Thalassemia.

See the full and most recent range at www.viennalab.com

The ViennaLab CVD StripAssays® meet customer requirements

| Requirement | ViennaLab's offer |
|-------------|---|
| Easy | Three simple steps. 6 h. Done. |
| Reliable | Can be done automated. Probes for variants and controls combined on one teststrip. |
| Versatile | Effective genotyping of DNA from various sample types. |
| Affordable | Reagents. Thermocycler. Incubator. That is all you need. A software is optional. |

The ViennaLab CVD StripAssays® combine all these requirements. Better than any other assay currently on the market.

The ViennaLab CVD StripAssays®

- are based on reverse-hybridization of biotinylated PCR products
- combine probes for variants and controls in a parallel array of allele-specific oligonucleotides
- work with immobilized oligos on a teststrip
- generate test results by enzymatic color reaction easily visible to the naked eye

Genetic variants detected

Thrombosis: Factor V, Prothrombin, Methylene-tetrahydrofolate Reductase, Factor XIII, Plasminogen Activator Inhibitor 1, Endothelial Protein C Receptor
Atherosclerosis: Apolipoprotein B, Apolipoprotein E, Beta-Fibrinogen, Human Platelet Antigen 1, Angiotensin-Converting Enzyme, Endothelial Nitric Oxide Synthase, Lymphotoxin Alpha

The three steps of the ViennaLab CVD StripAssays®

| Step | Requirement |
|--|---------------------------------|
| 1. Amplification: Multiplex PCR-amplification. Simultaneous biotin-labeling | Thermocycler |
| 2. Hybridization: Directly on the StripAssay® teststrips | Incubator |
| 3. Identification: Labeled products detected by streptavidine alkaline phosphatase | Naked eye or scanner & software |

Cat.no.:

FV StripAssay®: 4-330 (20 tests/kit)
 PTH StripAssay®: 4-340 (20 tests/kit)
 MTHFR StripAssay®: 4-350 (20 tests/kit)
 FV-PTH StripAssay®: 4-290 (20 tests/kit)
 FV-PTH-MTHFR StripAssay®: 4-260 (20 tests/kit)

CVD StripAssay® T: 4-360 (20 tests/kit)
 CVD StripAssay® A: 4-370 (20 tests/kit)
 Apo E StripAssay®: 4-280 (20 tests/kit)

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