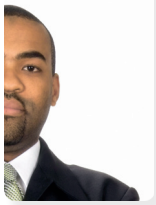
VIENNA LAB
ESTABLISHED INNOVATIONS IN DIAGNOSTICS



StripAssays® & RealFast™ Assays

In vitro diagnostic tests for inherited diseases, genetic predispositions, pharmacogenetics and oncology

ViennaLab is an Austrian company with a successful history of more than 20 years in developing, manufacturing and worldwide distributing genetic tests.

StripAssays® *based on reverse hybridization have up to 48 immobilized probes for wild-type and mutated alleles, are* ***accurate and reliable****.*

RealFast™ Assays *are based on* ***real-time PCR*** *and detect single nucleotide polymorphisms (SNPs) and copy number variations (CNVs)* ***fast and simply.***

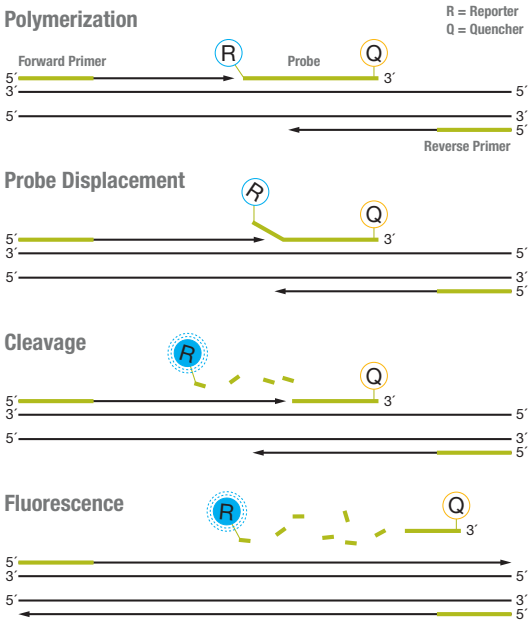
We offer

Tests for Cardiovascular Diseases, Thalassemia, Familial Mediterranean Fever, Haemochromatosis, Gaucher Disease, Alzheimer Disease, Sugar (Lactose, Fructuose) Intolerance, Congenital Adrenal Hyperplasia, Cystic Fibrosis, KRAS, BRAF, among others. Products of the **pharmacogenetics and oncology** portfolio help to achieve safer and more individualized anticoagulant and cancer therapies.

Quality Management System

All ViennaLab products are designed and manufactured according to the quality standards of **ISO 9001, ISO 13485**, and are **CE/IVD marked**. The tests are also used in many international research studies and quality assessment schemes, which allow scientific evidence of the quality employed.

Test Principle of RealFast™ Assays



RealFast™ Assays

Area	Product	REF	Label	Application
Carbohydrate Intolerance	LCT -13910C>T RealFast™ Assay	7-150	CE/IVD	Detects the most common polymorphism in the *lactase (LCT)* gene causing lactase non-persistence
Cardiovascular Diseases (CVD)	FGB -455G>A NEW! RealFast™ Assay	7-230	CE/IVD	Identifies homozygousity for the -455G>A *fibrinogen beta-chain (FGB)* allele which may increase susceptibility to atherothrombosis in at-risk patients
	FV Leiden RealFast™ Assay	7-110	CE/IVD	Detects the most common genetic risk factor associated with venous thromboembolism, the 1691G>A mutation in the *Factor V (FV)* gene
	FXII 46C>T NEW! RealFast™ Assay	7-240	CE/IVD	Identifies patients with the unfavorable TT genotype for *Factor XII (FXII)*, who may have an increased susceptibility to thrombotic disorders
	FXIII V34L NEW! RealFast™ Assay	7-250	CE/IVD	Identifies carriers of the 34L variant of Factor XIII (FXIII) and hence at-risk patients of hereditary thrombophilia
	MTHFR 677C>T RealFast™ Assay	7-160	CE/IVD	Detect common mutations in the *methylenetetrahydrofolate reductase (MTHFR)* gene causing hyperhomocysteinemia, which is a risk factor for cardiovascular disease
	MTHFR 1298A>C RealFast™ Assay	7-170	CE/IVD	
	PAI-1 4G/5G RealFast™ Assay	7-180	CE/IVD	Detects the 4G risk allele in the *plasminogen activator inhibitor-1 (PAI-1)* gene, associated with cardiovascular disease and pregnancy complications
	PTH 20210G>A RealFast™ Assay	7-120	CE/IVD	Detects the second most important genetic risk factor for venous thromboembolism in the *prothrombin (PTH)* gene
Congenital Adrenal Hyperplasia	CAH RealFast™ CNV Assay	7-410	CE/IVD	Discriminates between deletions, duplications and normal copy number status of the *CYP21A2* gene in patients with CAH
Genetic Predisposition	HLA-B27 RealFast™ Assay	7-620	CE/IVD	Detects the human leukocyte antigen-B (HLA-B) 27 allele, which is associated with ankylosing spondylitis
Haemochromatosis	HFE C282Y RealFast™ Assay	7-130	CE/IVD	Detect common mutations in the *high Fe (HFE)* gene causing hereditary haemochromatosis (HH) type 1
	HFE H63D RealFast™ Assay	7-140	CE/IVD	
Pharmacogenetics	HLA-B5701 RealFast™ Assay	7-610	CE/IVD	Detects human leukocyte antigen-B (HLA-B) 5701 allele, which is associated with hypersensitivity to the anti-HIV drug abacavir
	IL28B NEW! RealFast™ Assay	7-200	CE/IVD	Detects a dinucleotide frame-shift variant coding for interleukin 28B (IL28B) and helps to predict the therapeutic response in Hepatitis C Virus infected patients
	SLCO1B1c.521T>C NEW! RealFast™ Assay	7-210	CE/IVD	Detects a variant in human *solute carrier organic anion transporter family member 1B1 (SLCO1B1)* gene in patients who are at higher risk for developing statin-induced myopathy
	VKORC1 -1639G>A RealFast™ Assay	7-190	CE/IVD	Detects the most important polymorphism in the *Vitamin K Epoxide Reductase Complex 1 (VKORC1)* gene associated with interindividual dose requirements for oral anticoagulants
Service	RealFast™ Confirmation Service	CS-045	---	Service to assist in establishing RealFast™ Assays as well as for performance monitoring

The three steps of the StripAssays®

1. Amplification: Multiplex PCR. Simultaneous biotin-labelling
2. Hybridization: Directly on the StripAssay® teststrips
3. Identification: Labeled products detected by streptavidin-alkaline phosphatase

StripAssays®

Area	Product	REF	Label	Application
Alzheimer Disease	Apo E StripAssay®	4-280	CE/IVD	Detection of isoforms Apo E2, E3 and E4
Carbohydrate Intolerance	Lactose Intolerance StripAssay®	4-300	CE/IVD	Detection of two *lactase* gene polymorphisms -13910T>C and -22018A>G
	Sugar Intolerance StripAssay®	4-310	CE/IVD	Detection of two *lactase* gene polymorphisms and four *aldolase B* gene mutations
Cardiovascular Diseases	CVD StripAssay®	4-240	CE/IVD	Testing for 12 genetic variants associated with cardiovascular diseases
	CVD StripAssay® A	4-370	CE/IVD	Testing for 8 genetic variants predisposing to atherosclerosis
	CVD StripAssay® T	4-360	CE/IVD	Testing for 9 genetic variants predisposing to venous thromboembolism
	FV StripAssay®	4-330	CE/IVD	Detection of the *Factor V* gene mutation R506Q (FV Leiden)
	FV-PTH StripAssay®	4-290	CE/IVD	Detection of the *Factor V* Leiden and *prothrombin* gene mutations
	FV-PTH-MTHFR StripAssay®	4-260	CE/IVD	Detection of the *Factor V* Leiden, *prothrombin* and *MTHFR* gene mutations
	MTHFR StripAssay®	4-350	CE/IVD	Detection of the *MTHFR* gene mutation 677C>T
	PTH StripAssay®	4-340	CE/IVD	Detection of the *prothrombin* gene mutation 20210G>A
Congenital Adrenal Hyperplasia	CAH StripAssay®	4-380	CE/IVD	Testing for 11 *CYP21A2* mutations
Cystic Fibrosis	CF StripAssay®	4-410	CE/IVD	Detection of 34 common *CFTR* mutations and the IVS8 variants 5T/7T/9T
	CF StripAssay® GER	4-430	CE/IVD	Detection of 31 common *CFTR* mutations
	CF StripAssay® TUR	4-420	CE/IVD	Detection of 24 common *CFTR* mutations and the IVS8 variants 5T/7T/9T
Familial Mediterranean Fever	FMF StripAssay®	4-230	CE/IVD	Detection of 12 *MEFV* gene mutations
	FMF-SAA1 StripAssay®	4-390	CE/IVD	Detection of 12 *MEFV* gene mutations and *SAA1* genotypes 1.1, 1.3 and 1.5
Gaucher Disease	Gaucher Disease StripAssay®	4-250	CE/IVD	Detection of 8 mutations and two recombinant alleles in the *glucocerebrosidase (GBA)* gene
Genetic Predisposition	HLA-B27 StripAssay®	4-320	CE/IVD	Detection of all disease-relevant *HLA-B27* subtypes
Haemochromatosis	Haemochromatosis StripAssay® A	4-220	CE/IVD	Detection of 18 mutations: twelve *HFE* mutations, four *TFR2* mutations and two *FPN1* mutations
	Haemochromatosis StripAssay® B	4-210	CE/IVD	Detection of 3 *HFE* gene mutations: C282Y, H63D, S65C
Pharmacogenetics (PGX) & Oncology	BRAF StripAssay®	5-570	CE/IVD	Ultra-sensitive detection of *BRAF* V600E mutation
	BRAF 600/601 StripAssay®	5-560	CE/IVD	Ultra-sensitive detection of 9 *BRAF* mutations in codons 600 and 601
	EGFR XL StripAssay®	5-630	CE/IVD	Ultra-sensitive detection of 30 *EGFR* mutations in exons 18/19/20/21
	FCGR StripAssay®	5-670	CE/IVD	Detection of allelic variants of Fc gamma-Receptor 2A (H131R) and 3A (F158V) associated with response to IgG antibody therapy
	KRAS StripAssay®	5-590	CE/IVD	Ultra-sensitive detection of 10 *KRAS* mutations in codons 12 and 13
	KRAS-BRAF StripAssay®	5-580	CE/IVD	Ultra-sensitive detection of 10 *KRAS* mutations in codons 12/13 and *BRAF* V600E mutation
	KRAS XL StripAssay®	5-680	CE/IVD	Ultra-sensitive detection of 29 *KRAS* mutations in codons 12/13/59/60/61/117/146
	NRAS XL StripAssay®	5-620	CE/IVD	Ultra-sensitive detection of 22 *NRAS* mutations in codons 12/13/59/60/61/146
	PGX-5FU StripAssay®	4-720	CE/IVD	Detection of *DPYD* allelic variant IVS14+1 G>A associated with toxicity of 5-FU therapy
	PGX-CYP2C19 StripAssay®	4-750	CE/IVD	Testing for CYP2C19 variants *2, *3, *4, *5, *6, *7, *8 and *17
	PGX-CYP2D6 StripAssay®	4-760	CE/IVD	Testing for CYP2D6 variants *3, *4 and *6
	PGX-HIV StripAssay®	4-710	CE/IVD	Testing for genotypes associated with response to HIV highly active anti-retroviral therapy
	PGX-Thrombo StripAssay®	4-730	CE/IVD	Testing for *CYP2C9* and *VKORC1* variants associated with anticoagulant dose requirements (Coumadin®, Marcumar®, Sintrom®)
	PGX-TPMT StripAssay®	4-740	CE/IVD	Testing for TPMT variants *2, *3A, *3B and *3C associated with response to thiopurine therapy
Software	StripAssay® Evaluator	6-100	CE/IVD	Software for automated teststrip scanning and interpretation of results
Thalassemia	α-Globin StripAssay®	4-160	CE/IVD	Detection of 21 common α-Globin gene mutations
	β-Globin StripAssay® MED	4-130	CE/IVD	Detection of 22 mutations covering >90% of β-Globin defects found in Mediterranean countries
	β-Globin StripAssay® IME	4-140	CE/IVD	Detection of 22 mutations covering >90% of β-Globin defects found in the Middle East and India
	β-Globin StripAssay® SEA	4-150	CE/IVD	Detection of 22 mutations covering >90% of β-Globin defects found in Southeast Asia
	β-Thal Modifier StripAssay®	4-170	CE/IVD	Testing for 5 polymorphisms associated with severity of β-Thalassemia
Service	StripAssay® Confirmation Service	CS-042	---	Service to assist in establishing StripAssays® as well as for performance monitoring

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Platform Attributes

	StripAssay®	RealFast™ Assay
• **Simplicity**	Simple and straightforward protocols	Fast and easy handling
• **Efficiency**	Manual or automated	Compatible with many real-time PCR instruments
• **Speed**	Less than 6 hours from DNA to result	Less than 90 min from DNA to result
• **Reliability**	Easy and clear interpretation of results	Include controls for wild type and mutant genotypes
• **Flexibility**	Additional mutations readily integrated	Same protocol for all genotyping assays
• **Convenience**	Ready-to-use reagents; inexpensive equipment; CE/IVD labeled kits; sensitive and affordable	

StripAssay® Evaluator Software

For scanning and analyzing teststrips that have been processed according to StripAssay® instructions. In combination with a flatbed office scanner the Evaluator software permits one-step, automated analysis of up to 20 teststrips.

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