VIENNA LAB
ESTABLISHED INNOVATIONS IN DIAGNOSTICS

StripAssays® & RealFast™ Assays

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

ViennaLab Diagnostics

ViennaLab Diagnostics is an Austrian company with a successful history of more than 25 years in developing, manufacturing and worldwide distributing genetic tests.

StripAssays® based on **PCR** followed by **reverse hybridization** have up to 48 immobilized probes for wild type and mutated alleles, and are easy to use.

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

We offer

Tests for Cardiovascular Diseases (CVD), Thalassemia, Familial Mediterranean Fever (FMF), Haemochromatosis, Gaucher Disease, Alzheimer Disease, Sugar (Lactose, Fructose) Intolerance, Congenital Adrenal Hyperplasia (CAH), Cystic Fibrosis (CF), 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.

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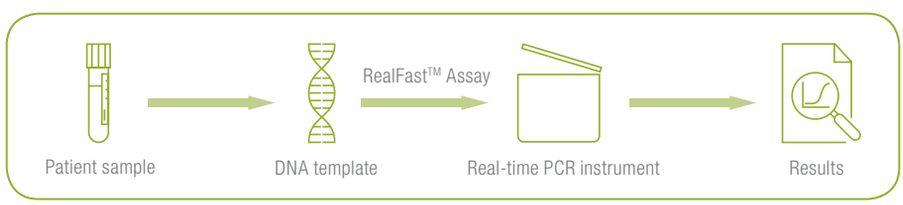
Platform Attributes

	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	Controls for wild type and mutant genotypes included
• **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	

Sample Preparation Kits

Area	Product	REF	Label	Rxn	Application
StripAssays® RealFast™ Assays	**GEN^{X}TRACT™** Blood DNA Extraction System	2-014	CE/IVD	100 Rxn	DNA extraction from fresh, frozen and dried blood
StripAssays® RealFast™ Assays	**Spin Micro DNA Extraction Kit**	2-020	CE/IVD	20 Rxn	DNA extraction and purification from whole blood and buccal swabs
RealFast™ Assays	**D2PCR™ Buffer**	2-030	CE/IVD	100 Rxn	For direct-to-PCR applications
Liquid Profiling EGFR T790M	**Plasma cfDNA Extraction Kit** NEW!	2-040	---	50 Rxn	Sample preparation kit for extraction of circulating cell-free DNA (cfDNA) from up to 4 mL plasma; For use with the EGFR T790M RealFast™ Assay

Workflow of RealFast™ Assays



RealFast™ Assays

Single marker detection				
Area	**Product**	**REF 100 / 32 Rxn**	**Label**	**Application**
Carbohydrate Intolerance	**LCT -13910C>T** RealFast™ Assay	7-150 / 7-153	CE/IVD	Detects the most common polymorphism in the *lactase (LCT)* gene causing lactase non-persistence
Cardiovascular Diseases (CVD)	**FGB -455G>A** RealFast™ Assay	7-230 / 7-233	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 / 7-113	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 RealFast™ Assay	7-240 / 7-243	CE/IVD	Identifies patients with the unfavorable TT genotype for *Factor XII (FXII)*, who may have an increased susceptibility to thrombotic disorders
	FXIII V34L RealFast™ Assay	7-250 / 7-253	CE/IVD	Identifies carriers of the protective 34L variant of Factor XIII (FXIII) among at-risk patients of hereditary thrombophilia
	MTHFR 677C>T RealFast™ Assay	7-160 / 7-163	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 / 7-173	CE/IVD	
	PAI-1 4G/5G RealFast™ Assay	7-180 / 7-183	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 / 7-123	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 / 7-623	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 / 7-133	CE/IVD	Detect common mutations in the *HFE* gene causing hereditary haemochromatosis (HH) type 1
	HFE H63D RealFast™ Assay	7-140 / 7-143	CE/IVD	
Pharmacogenetics	**HLA-B5701** RealFast™ Assay	7-610 / 7-613	CE/IVD	Detects human leukocyte antigen-B (HLA-B) 5701 allele, which is associated with hypersensitivity to the anti-HIV drug abacavir
	IL28B RealFast™ Assay	7-200 / 7-203	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

RealFast™ Assays

Pharmacogenetics	**SLCO1B1c.521T>C** RealFast™ Assay	7-210 / 7-213	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 / 7-193	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

Multiplex testing - save costs and sample material

Area	Product	REF 100 / 32 Rxn	Label	Application
Cardiovascular Diseases (CVD)	**FV-PTH mpx** RealFast™ Assay	7-115 / 7-118	CE/IVD	Simultaneous detection of the most important thrombophilic mutations 1691G>A in the *Factor V* gene and 20210G>A in the *prothrombin* gene
	MTHFR mpx RealFast™ Assay	7-165 / 7-168	CE/IVD	Simultaneous detection of the most common two mutations in the *MTHFR* gene: 677C>T and 1298A>C
AAT deficiency/ COPD	**AAT mpx** RealFast™ Assay	7-265 / 7-268	CE/IVD	Detects *S and *Z variants of the *SERPINA1* gene predisposing individuals to chronic obstructive pulmonary disease (COPD) and liver disease due to deficiency of alpha-1 antitrypsin (AAT)
Haemochromatosis	**HFE mpx** RealFast™ Assay	7-135 / 7-138	CE/IVD	Simultaneous detection of the two most common mutations in the *HFE* gene: H63D and C282Y
Pharmacogenetics	**CYP2C9 mpx** RealFast™ Assay	7-225 / 7-228	CE/IVD	Simultaneous detection of *CYP2C9*2* (c.430C>T) and *CYP2C9*3* (c.1075A>C) polymorphisms to determine the drug response of coumarin-based anticoagulation therapy
Service	**RealFast™ Confirmation Service**	CS-045	---	Service to assist in establishing RealFast™ Assays as well as for performance monitoring

Liquid Profiling

Oncology	**EGFR T790M** NEW! RealFast™ Assay	8-110 / 8-113	CE/IVD	Detects the T790M mutation in the *EGFR* gene from cell-free DNA. For monitoring of lung cancer patients who undergo treatment with EGFR tyrosine kinase inhibitors.

The three steps of 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	Tests	Application
Alzheimer Disease	**Apo E** StripAssay®	4-280	CE/IVD	20 Tests	Detection of isoforms Apo E2, E3 and E4
Carbohydrate Intolerance	**Lactose Intolerance** StripAssay®	4-300	CE/IVD	20 Tests	Detection of two *lactase* gene polymorphisms -13910T>C and -22018A>G
	Sugar Intolerance StripAssay®	4-310	CE/IVD	20 Tests	Detection of two *lactase* gene polymorphisms and four *aldolase B* gene mutations
Cardiovascular Diseases (CVD)	**CVD** StripAssay®	4-240	CE/IVD	20 Tests	Testing for 12 genetic variants associated with cardiovascular diseases
	CVD StripAssay® **A**	4-370	CE/IVD	20 Tests	Testing for 8 genetic variants predisposing to atherosclerosis
	CVD StripAssay® **T**	4-360	CE/IVD	20 Tests	Testing for 9 genetic variants predisposing to venous thromboembolism
	FV StripAssay®	4-330	CE/IVD	20 Tests	Detection of the *Factor V* gene mutation R506Q (FV Leiden)
	FV-PTH StripAssay®	4-290	CE/IVD	20 Tests	Detection of the *Factor V* Leiden and *prothrombin* gene mutations
	FV-PTH-MTHFR StripAssay®	4-260	CE/IVD	20 Tests	Detection of the *Factor V* Leiden, *prothrombin* and *MTHFR* gene mutations
	MTHFR StripAssay®	4-350	CE/IVD	20 Tests	Detection of the *MTHFR* gene mutation 677C>T
	PTH StripAssay®	4-340	CE/IVD	20 Tests	Detection of the *prothrombin* gene mutation 20210G>A

StripAssays®

Area	Product	REF	Label	Tests	Application
Congenital Adrenal Hyperplasia	**CAH** StripAssay®	4-380	CE/IVD	20 Tests	Testing for 11 *CYP21A2* mutations
Cystic Fibrosis	**CF** StripAssay®	4-410	CE/IVD	10 Tests	Detection of 34 common *CFTR* mutations and the IVS8 variants 5T/7T/9T
	CF StripAssay® **GER**	4-430	CE/IVD	10 Tests	Detection of 31 common *CFTR* mutations
	CF StripAssay® **TUR**	4-420	CE/IVD	10 Tests	Detection of 24 common *CFTR* mutations and the IVS8 variants 5T/7T/9T
Familial Mediterranean Fever	**FMF** StripAssay®	4-230	CE/IVD	20 Tests	Detection of 12 *MEFV* gene mutations
	FMF-SAA1 StripAssay®	4-390	CE/IVD	20 Tests	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	20 Tests	Detection of 8 mutations and two recombinant alleles in the *glucocerebrosidase (GBA)* gene
Genetic Predisposition	**HLA-B27** StripAssay®	4-320	CE/IVD	20 Tests	Detection of all disease-relevant *HLA-B27* subtypes
Haemochromatosis	**Haemochromatosis** StripAssay® **A**	4-220	CE/IVD	20 Tests	Detection of 18 mutations: twelve *HFE* mutations, four *TFR2* mutations and two *FPN1* mutations
	Haemochromatosis StripAssay® **B**	4-210	CE/IVD	20 Tests	Detection of 3 *HFE* gene mutations: C282Y, H63D, S65C
Pharmacogenetics (PGX) & Oncology	**BRAF** StripAssay®	5-570	CE/IVD	20 Tests	Ultra-sensitive detection of *BRAF* V600E mutation
	BRAF 600/601 StripAssay®	5-560	CE/IVD	20 Tests	Ultra-sensitive detection of 9 *BRAF* mutations in codons 600 and 601
	EGFR XL StripAssay®	5-630	CE/IVD	20 Tests	Ultra-sensitive detection of 30 *EGFR* mutations in exons 18/19/20/21
	FCGR StripAssay®	5-670	CE/IVD	20 Tests	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	20 Tests	Ultra-sensitive detection of 10 *KRAS* mutations in codons 12 and 13
	KRAS-BRAF StripAssay®	5-580	CE/IVD	20 Tests	Ultra-sensitive detection of 10 *KRAS* mutations in codons 12/13 and *BRAF* V600E mutation
	KRAS XL StripAssay®	5-680	CE/IVD	20 Tests	Ultra-sensitive detection of 29 *KRAS* mutations in codons 12/13/59/60/61/117/146
	NRAS XL StripAssay®	5-620	CE/IVD	20 Tests	Ultra-sensitive detection of 22 *NRAS* mutations in codons 12/13/59/60/61/146
	PGX-5FU StripAssay®	4-720	CE/IVD	20 Tests	Detection of *DPYD* allelic variant IVS14+1 G>A associated with toxicity of 5-FU therapy
	PGX-CYP2C19 StripAssay®	4-750	CE/IVD	20 Tests	Testing for CYP2C19 variants *2, *3, *4, *5, *6, *7, *8 and *17
	PGX-CYP2D6 StripAssay®	4-760	CE/IVD	20 Tests	Testing for CYP2D6 variants *3, *4 and *6
	PGX-HIV StripAssay®	4-710	CE/IVD	20 Tests	Testing for genotypes associated with response to HIV highly active anti-retroviral therapy
	PGX-Thrombo StripAssay®	4-730	CE/IVD	20 Tests	Testing for *CYP2C9* and *VKORC1* variants associated with anticoagulant dose requirements (Coumadin®, Marcumar®, Sintrom®)
	PGX-TPMT StripAssay®	4-740	CE/IVD	20 Tests	Testing for TPMT variants *2, *3A, *3B and *3C associated with response to thiopurine therapy
Thalassemia	**α-Globin** StripAssay®	4-160	CE/IVD	10 Tests	Detection of 21 common α-Globin gene mutations
	β-Globin StripAssay® **MED**	4-130	CE/IVD	20 Tests	Detection of 22 mutations covering >90% of β-Globin defects found in Mediterranean countries
	β-Globin StripAssay® **IME**	4-140	CE/IVD	20 Tests	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	20 Tests	Detection of 22 mutations covering >90% of β-Globin defects found in Southeast Asia
	β-Thal Modifier StripAssay®	4-170	CE/IVD	20 Tests	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

Software

Area	Product	REF	Label	Application
StripAssays®	**StripAssay® Evaluator**	6-100	CE/IVD	Software for automated scanning of teststrips and interpretation of results

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February 2019 • ISO 9001 • ISO 13485