



Product Catalog

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 13485** and are **CE/IVD** marked where indicated. The tests are also used in many international research studies and quality assessment schemes, which allow scientific evidence of the quality employed.



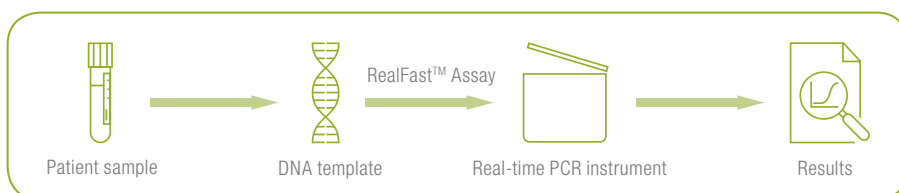
Platform Attributes

	StripAssay®	RealFast™ Assay
• Simplicity	Simple and straightforward protocols	Fast and easy handling
• Efficiency	Manual or automated	Same protocol for all genotyping assays
• 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	Compatible with many real-time PCR instruments
• Convenience	Ready-to-use reagents; low complexity instrumentation; 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	RUO	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	2-040	RUO	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	
Carbamazepine Hypersensitivity	HLA-A3101 RealFast™ Assay	7-640 / 7-643	CE/IVD	Detects the human leukocyte antigen-A (HLA-A) 3101 allele, which is strongly associated with carbamazepine hypersensitivity reactions in Europeans and Japanese	
	HLA-B1502 RealFast™ Assay	7-630 / 7-633	CE/IVD	Detects the human leukocyte antigen-B (HLA-B) 1502 allele, which is strongly associated with carbamazepine hypersensitivity reactions in Asian populations	
Carbohydrate Intolerance	LCT -13910C>T RealFast™ Assay	7-150 / 7-153	CE/IVD	Detects the most common polymorphism in the <i>lactase (LCT)</i> gene causing lactase non-persistence	
Cardiovascular Diseases (CVD)	FGB -455G>A RealFast™ Assay	7-230 / 7-233	CE/IVD	Identifies homozygosity for the -455G>A <i>fibrinogen beta-chain (FGB)</i> 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 <i>Factor V (FV)</i> gene	
	FXII 46C>T RealFast™ Assay	7-240 / 7-243	CE/IVD	Identifies patients with the unfavorable TT genotype for <i>Factor XII (FXII)</i> , 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 <i>methylenetetrahydrofolate reductase (MTHFR)</i> 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 <i>plasminogen activator inhibitor-1 (PAI-1)</i> 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 <i>prothrombin (PTH)</i> gene	
Congenital Adrenal Hyperplasia	CAH RealFast™ CNV Assay	7-410 / ---	CE/IVD	Discriminates between deletions, duplications and normal copy number status of the <i>CYP21A2</i> gene in patients with CAH. Recommended to be used in combination with CAH StripAssay®	
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 <i>HFE</i> gene causing hereditary haemochromatosis (HH) type 1	
	HFE H63D RealFast™ Assay	7-140 / 7-143	CE/IVD		

RealFast™ Assays

Area	Product	REF 100 / 32 Rxn	Label	Application
Pharmacogenetics	CYP2D6 ^{NEW!} RealFast™ CNV Assay	7-420 / ---	CE/IVD	Discriminates between deletions, duplications and normal copy number status of the <i>CYP2D6</i> gene. Recommended to be used in combination with PGX-CYP2D6 XL StripAssay®
	HLA-B5701 RealFast™ Assay	7-610 / 7-613	CE/IVD	Detects the 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
	SLCO1B1c.521T>C RealFast™ Assay	7-210 / 7-213	CE/IVD	Detects a variant in human <i>solute carrier organic anion transporter family member 1B1</i> (<i>SLCO1B1</i>) 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 <i>Vitamin K Epoxide Reductase Complex 1</i> (<i>VKORC1</i>) gene associated with interindividual dose requirements for oral anticoagulants

Multiplex testing - save costs and sample material

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 <i>Factor V</i> gene and 20210G>A in the <i>prothrombin</i> gene
	MTHFR mpX RealFast™ Assay	7-165 / 7-168	CE/IVD	Simultaneous detection of the most common two mutations in the <i>MTHFR</i> 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 <i>SERPINA1</i> 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 <i>HFE</i> gene: H63D and C282Y
Pharmacogenetics	CYP2C9 mpX RealFast™ Assay	7-225 / 7-228	CE/IVD	Simultaneous detection of <i>CYP2C9</i> *2 (c.430C>T) and <i>CYP2C9</i> *3 (c.1075A>C) polymorphisms to determine the drug response of known targets, like S-warfarin or phenytoin
Service	RealFast™ Confirmation Service	CS-045	---	Service to assist in establishing RealFast™ Assays as well as for performance monitoring

Liquid Profiling

Oncology	EGFR T790M RealFast™ Assay	8-110 / 8-113	CE/IVD	Detects the T790M mutation in the <i>EGFR</i> gene in cell-free DNA. For monitoring of lung cancer patients who undergo treatment with EGFR tyrosine kinase inhibitors
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COVID-19 ^{NEW!}

Area	Product	REF 100 / 500 Rxn	Label	Application
Respiratory Infections	SARS-CoV-2 ^{NEW!} RealFast™ Assay	8-410 / 8-412	CE/IVD	Detects the viral <i>N</i> and <i>RdRP/ORF1ab</i> genes and the human <i>ACTB</i> gene as internal control in a multiplex one-step RT-PCR



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 <i>lactase</i> gene polymorphisms -13910T>C and -22018A>G
	Sugar Intolerance StripAssay®	4-310	CE/IVD	20 Tests	Detection of two <i>lactase</i> gene polymorphisms and four <i>aldolase B</i> 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

StripAssays®

Area	Product	REF	Label	Tests	Application
Cardiovascular Diseases (CVD)	FV-PTH StripAssay®	4-290	CE/IVD	20 Tests	Detection of the <i>Factor V</i> Leiden and <i>prothrombin</i> gene mutations
	FV-PTH-MTHFR StripAssay®	4-260	CE/IVD	20 Tests	Detection of the <i>Factor V</i> Leiden, <i>prothrombin</i> and <i>MTHFR</i> gene mutations
Congenital Adrenal Hyperplasia	CAH StripAssay®	4-380	CE/IVD	20 Tests	Testing for 11 most prevalent <i>CYP21A2</i> mutations. Recommended to be used in combination with CAH RealFast™ CNV Assay
Cystic Fibrosis	CF StripAssay®	4-410	CE/IVD	10 Tests	Detection of 34 common <i>CFTR</i> mutations and the IVS8 variants 5T/7T/9T
	CF StripAssay® GER	4-430	CE/IVD	10 Tests	Detection of 31 common <i>CFTR</i> mutations
	CF StripAssay® TUR	4-420	CE/IVD	10 Tests	Detection of 24 common <i>CFTR</i> mutations and the IVS8 variants 5T/7T/9T
Familial Mediterranean Fever	FMF StripAssay®	4-230	CE/IVD	20 Tests	Detection of 12 <i>MEFV</i> gene mutations
	FMF-SAA1 StripAssay®	4-390	CE/IVD	20 Tests	Detection of 12 <i>MEFV</i> gene mutations and <i>SAA1</i> 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 <i>glucocerebrosidase (GBA)</i> gene
Genetic Predisposition	HLA-B27 StripAssay®	4-320	CE/IVD	20 Tests	Detection of all disease-relevant <i>HLA-B27</i> subtypes
Haemochromatosis	Haemochromatosis StripAssay® A	4-220	CE/IVD	20 Tests	Detection of 18 mutations: twelve <i>HFE</i> mutations, four <i>TFR2</i> mutations and two <i>FPN1</i> mutations
	Haemochromatosis StripAssay® B	4-210	CE/IVD	20 Tests	Detection of 3 <i>HFE</i> gene mutations: C282Y, H63D, S65C
Pharmacogenetics (PGX) & Oncology	BRAF 600/601 StripAssay®	5-560	CE/IVD	20 Tests	Ultra-sensitive detection of 9 <i>BRAF</i> mutations in codons 600 and 601
	EGFR XL StripAssay®	5-630	CE/IVD	20 Tests	Ultra-sensitive detection of 30 <i>EGFR</i> mutations in exons 18/19/20/21
	FCGR StripAssay®	5-670	RUO	20 Tests	Detection of allelic variants of Fc gamma-Receptor 2A (H131R) and 3A (F158V) associated with response to IgG antibody therapy
	KRAS XL StripAssay®	5-680	CE/IVD	20 Tests	Ultra-sensitive detection of 29 <i>KRAS</i> mutations in codons 12/13/59/60/61/117/146
	NRAS XL StripAssay®	5-620	CE/IVD	20 Tests	Ultra-sensitive detection of 22 <i>NRAS</i> mutations in codons 12/13/59/60/61/146
	PGX-5FU StripAssay®	4-720	CE/IVD	20 Tests	Detection of <i>DPYD</i> genetic variant DPYD*2A associated with toxicity of 5-fluorouracil therapy
	PGX-5FU XL StripAssay® NEW!	4-780	CE/IVD	20 Tests	Detection of <i>DPYD</i> genetic variants HapB3, DPYD*13, DPYD*2A, p.D949V associated with toxicity of 5-fluorouracil 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 XL StripAssay® NEW!	4-770	CE/IVD	20 Tests	Testing for CYP2D6 variants *1-*12, *14, *15*, *17, *29, *35, *39, *40, *41, *58, *114. Recommended to be used in combination with CYP2D6 RealFast™ CNV Assay.
	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 <i>CYP2C9</i> and <i>VKORC1</i> 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	RUO	Software for automated scanning of teststrips and interpretation of results



Manufacturer:

ViennaLab Diagnostics GmbH

Gaudenzdorfer Guertel 43-45

A-1120 Vienna, Austria

www.viennalab.com

t: (+43-1) 8120156-0

e: info@viennalab.com

Distributor: