



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.



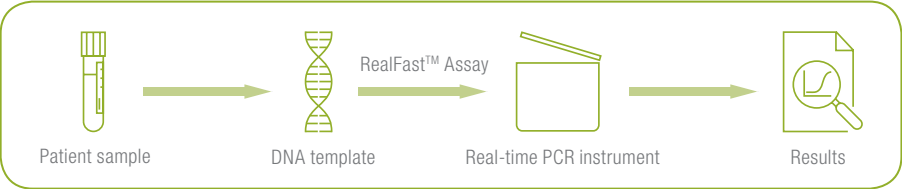
Platform Attributes

| | 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 |
| | SLC01B1c.521T>C RealFast™ Assay | 7-210 / 7-213 | CE/IVD | Detects a variant in human <i>solute carrier organic anion transporter family member 1B1 (SLC01B1)</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 (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 |
| 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 |



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