

## Product Catalog

**Your partner for human molecular diagnostics**



**Genetic Disorder**



**Genetic Predisposition**



**Cancer**



**Pharmacogenetics**

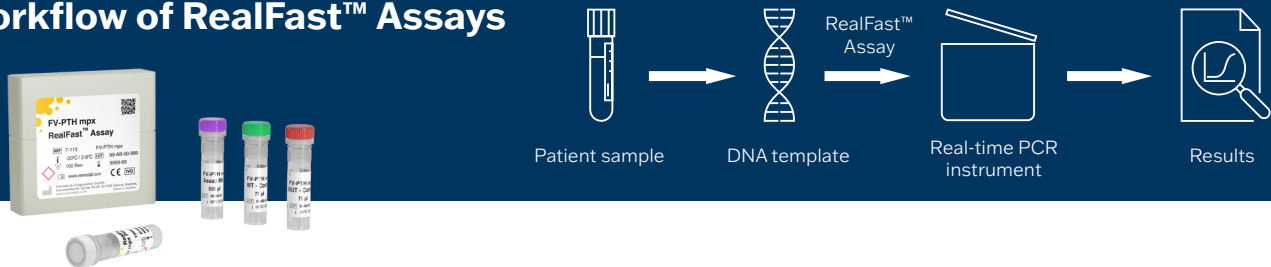


**Microbiology**

# Sample Preparation Kits













Area	Product Name	REF	Reg. Status	Unit Size	Application
StripAssays® RealFast™ Assays	GENxTRACT™ 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

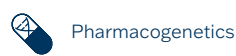
## Workflow of RealFast™ Assays









## RealFast™ Assays

### Single marker detection






Category	Clinical Topic	Product Name	REF 100 / 32 Rxn	Reg. Status	Description
	Carbamazepine Hypersensitivity	HLA-A3101 RealFast™ Assay	7-640 / 7-643	CE/IVD	Detects the human leukocyte antigen (HLA) <i>HLA-A*31:01</i> allele, which is strongly associated with carbamazepine hypersensitivity reactions in Europeans and Japanese
	Carbamazepine Hypersensitivity	HLA-B1502 RealFast™ Assay	7-630 / 7-633	CE/IVD	Detects the human leukocyte antigen (HLA) <i>HLA-B*15:02</i> 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
	CVD	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
	CVD	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
	CVD	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
	CVD	MTHFR 677C>T RealFast™ Assay	7-160 / 7-163	CE/IVD	Detects common mutation in the <i>methylenetetrahydrofolate reductase (MTHFR)</i> gene causing hyperhomocysteinemia, which is a risk factor for cardiovascular disease
	CVD	MTHFR 1298A>C RealFast™ Assay	7-170 / 7-173	CE/IVD	Detects common mutation in the <i>methylenetetrahydrofolate reductase (MTHFR)</i> gene causing hyperhomocysteinemia, which is a risk factor for cardiovascular disease
	CVD	PAI-1 4G/5G RealFast™ Assay	7-180 / 7-183	CE/IVD	Detects the 4G risk allele in the <i>SERPINE1</i> gene, encoding plasminogen activator inhibitor-1 (PAI-1), and is associated with cardiovascular disease and pregnancy complications
	CVD	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>Factor II</i> gene, encoding prothrombin (PTH)
	Congenital Adrenal Hyperplasia (CAH)	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® [REF 4-380]



# RealFast™ Assays

Category	Clinical Topic	Product Name	REF 100 / 32 Rxn	Reg. Status	Description
	Genetic Predisposition	HLA-B27 RealFast™ Assay	7-620 / 7-23	IVDR CE <sub>0123</sub>	Detects the human leukocyte antigen (HLA) <i>HLA-B*27</i> allele, which is associated with ankylosing spondylitis
	Haemochromatosis	HFE C282Y RealFast™ Assay	7-130 / 7-133	CE/IVD	Detects the common C282Y variant in the <i>HFE</i> gene causing hereditary haemochromatosis (HH) type 1
	Haemochromatosis	HFE H63D RealFast™ Assay	7-140 / 7-143	CE/IVD	Detects the common H63D variant in the <i>HFE</i> gene causing hereditary haemochromatosis (HH) type 1
NEW! 	Pharmacogenetics	CYP2D6 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®[REF 4-770]
	Pharmacogenetics	HLA-B5701 RealFast™ Assay	7-610 / 7-613	CE/IVD	Detects the human leukocyte antigen (HLA) <i>HLA-B*57:01</i> allele, which is associated with hypersensitivity to the anti-HIV drug abacavir
	Pharmacogenetics	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
	Pharmacogenetics	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 (SLCO1B1)</i> gene in patients who are at higher risk for developing statin-induced myopathy
	Pharmacogenetics	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

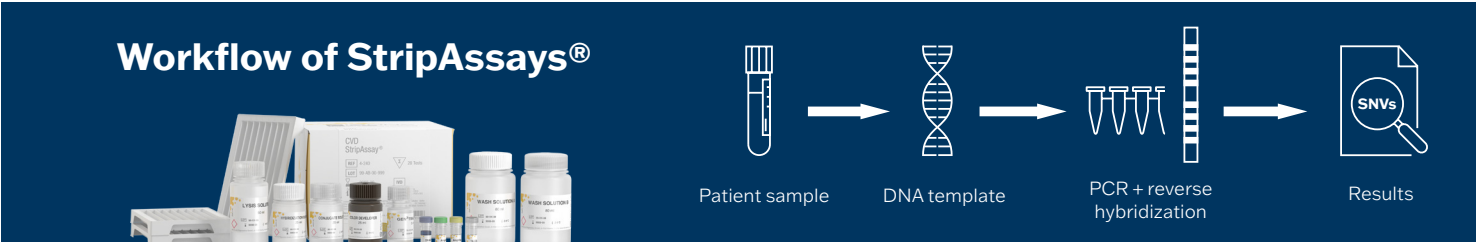
## Multiplex testing - save costs and sample material

Category	Clinical Topic	Product Name	REF 100 / 32 Rxn	Reg. Status	Description
	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>Factor II</i> gene, encoding prothrombin (PTH)
	CVD	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




















## COVID-19
















Category	Clinical Topic	Product Name	REF 100 / 500 Rxn	Reg. Status	Description
	Respiratory Infections	SARS-CoV-2 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

IVDR CE<sub>0123</sub>: Products marked with this symbol comply to the Regulation (EU) 2017/746 on *in vitro diagnostic* devices (IVDR) and have been approved by the Notified Body, TÜV Süd, indicated by CE<sub>0123</sub>.



## StripAssays®

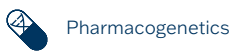
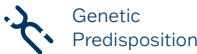
Category	Clinical Topic	Product Name	REF	Reg. Status	Unit Size	Description
	Alzheimer Disease	Apo E StripAssay®	4-280	CE/IVD	20 tests	Detection of isoforms Apo E2, E3 and E4
	Cancer	BRAF 600/601 StripAssay®	5-560	CE/IVD	20 tests	Ultra-sensitive detection of 9 <i>BRAF</i> mutations in codons 600 and 601
	Cancer	EGFR XL StripAssay®	5-630	CE/IVD	20 tests	Ultra-sensitive detection of 30 <i>EGFR</i> mutations in exons 18/19/20/21
	Cancer	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
	Cancer	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
	Cancer	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
	Carbohydrate Intolerance	Lactose Intolerance StripAssay®	4-300	CE/IVD	20 tests	Detection of two <i>lactase</i> gene polymorphisms -13910T>C and -22018A>G
	Carbohydrate Intolerance	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	CVD StripAssay® A	4-370	CE/IVD	20 tests	Testing for 8 genetic variants predisposing to atherosclerosis
	CVD	CVD StripAssay® T	4-360	CE/IVD	20 tests	Testing for 9 genetic variants predisposing to venous thromboembolism
	CVD	FV-PTH StripAssay®	4-290	CE/IVD	20 tests	Detection of the <i>Factor V</i> Leiden and <i>Factor II</i> , encoding prothrombin (PTH), gene mutations
	CVD	FV-PTH-MTHFR StripAssay®	4-260	CE/IVD	20 tests	Detection of the <i>Factor V</i> Leiden, <i>Factor II</i> , encoding prothrombin (PTH), and <i>MTHFR</i> gene mutations
	Congenital Adrenal Hyperplasia (CAH)	CAH StripAssay®	4-380	IVDR CE <sub>0123</sub>	20 tests	Testing for 11 most prevalent <i>CYP21A2</i> mutations. Recommended to be used in combination with CAH RealFast™ CNV Assay [REF 7-410]
	Cystic Fibrosis (CF)	CF StripAssay®	4-410	IVDR CE <sub>0123</sub>	10 tests	Detection of 34 common <i>CFTR</i> mutations and the IVS8 variants 5T/7T/9T
	CF	CF StripAssay® GER	4-430	IVDR CE <sub>0123</sub>	10 tests	Detection of 31 common <i>CFTR</i> mutations
	CF	CF StripAssay® TUR	4-420	IVDR CE <sub>0123</sub>	10 tests	Detection of 24 common <i>CFTR</i> mutations and the IVS8 variants 5T/7T/9T
	CF	CF StripAssay® EXT	4-440	IVDR CE <sub>0123</sub>	10 tests	Detection of 38 common <i>CFTR</i> mutations and the IVS8 variants 5T/7T/9T
	Familial Mediterranean Fever (FMF)	FMF StripAssay®	4-230	IVDR CE <sub>0123</sub>	20 tests	Detection of 12 <i>MEFV</i> gene mutations

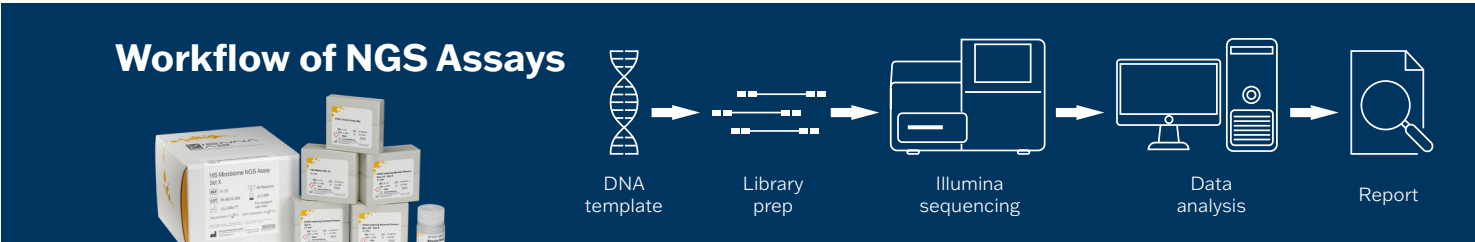
Category	Clinical Topic	Product Name	REF	Reg. Status	Unit Size	Description
	FMF	FMF-SAA1 StripAssay®	4-390	IVDR CE <sub>0123</sub>	20 tests	Detection of 12 <i>MEFV</i> gene mutations and <i>SAA1</i> genotypes 1.1, 1.3 and 1.5
	Genetic Predisposition	HLA-B27 StripAssay®	4-320	CE/IVD	20 tests	Detection of all disease-relevant <i>HLA-B*27</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	Haemochromatosis StripAssay® B	4-210	CE/IVD	20 tests	Detection of 3 <i>HFE</i> gene mutations: C282Y, H63D, S65C
NEW! 	Pharmacogenetics	PGX-5FU XL StripAssay®	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
	Pharmacogenetics	PGX-CYP2C19 StripAssay®	4-750	CE/IVD	20 tests	Testing for CYP2C19 variants *1, *2, *3, *4, *5, *6, *7, *8 and *17
NEW! 	Pharmacogenetics	PGX-CYP2D6 XL StripAssay®	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 [REF 7-420].
	Pharmacogenetics	PGX-HIV StripAssay®	4-710	CE/IVD	20 tests	Testing for genotypes associated with response to HIV highly active anti-retroviral therapy
	Pharmacogenetics	PGX-Thrombo StripAssay®	4-730	CE/IVD	20 tests	Testing for <i>CYP2C9</i> and <i>VKORC1</i> variants associated with anticoagulant dose requirements
	Pharmacogenetics	PGX-TPMT StripAssay®	4-740	CE/IVD	20 tests	Testing for <i>TPMT</i> variants *1, *2, *3A, *3B and *3C associated with response to thiopurine therapy
	Thalassemia	α-Globin StripAssay®	4-160	IVDR CE <sub>0123</sub>	10 tests	Detection of 21 common α-Globin gene mutations
	Thalassemia	β-Globin StripAssay® MED	4-130	CE/IVD	20 tests	Detection of 22 mutations covering >90% of β-Globin defects found in Mediterranean countries
	Thalassemia	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
	Thalassemia	β-Globin StripAssay® SEA	4-150	CE/IVD	20 tests	Detection of 22 mutations covering >90% of β-Globin defects found in Southeast Asia
	Thalassemia	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 Name	REF	Reg. Status	Unit Size	Application
StripAssays®	StripAssay® Evaluator	6-100	RUO	---	Software for automated scanning of teststrips, interpretation, and archiving of results





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




## NGS Assays

### Amplicon-based Assays

Category	Clinical Topic	Product Name	REF	Reg. Status	Unit Size	Description
W! 	Intestinal Microbiome	16S Microbiome NGS Assay [16 rxn]	9-131-16	RUO	16 Rxn	Targeted amplification of V3-V4 variable regions of the 16S rRNA gene incl. bioinformatic analysis and report generation for species-level classification of the human gut microbiome.
	Intestinal Microbiome	16S Microbiome NGS Assay [Set A]	9-131	RUO	96 Rxn	Differs from [Set B] and [Set C] in indexing primers only. Multiplexing up to 288 samples.
	Intestinal Microbiome	16S Microbiome NGS Assay [Set B]	9-132	RUO	96 Rxn	Differs from [Set A] and [Set C] in indexing primers only. Multiplexing up to 288 samples.
	Intestinal Microbiome	16S Microbiome NGS Assay [Set C]	9-133	RUO	96 Rxn	Differs from [Set A] and [Set B] in indexing primers only. Multiplexing up to 288 samples.

### Hybridization capture-based Assays

Category	Clinical Topic	Product Name	REF	Reg. Status	Unit Size	Description	
NEW!		Genetic Disorders	Clinical Exome Sequencing (CES) NGS Assay	9-241	RUO	(4x4) Rxn	All-in-one solution (library preparation, GENOVESA bioinformatic solution, genetic report generation) for detection of SNVs and InDels in 7500+ clinically relevant genes. Covers the whole coding sequence (CDS) of targeted genes.
NEW!		Cancer	Hereditary Cancer NGS Assay	9-221	RUO	16 Rxn	All-in-one solution (library preparation, GENOVESA bioinformatic solution, genetic report generation) targeting the whole CDS of 31 genes. Allows detection of SNVs, InDels, and CNVs of the covered genes (e.g. <i>BRCA1</i> , <i>BRCA2</i> , <i>CDH1</i> ,...).
NEW!		Cancer	Somatic Mutations NGS Assay	9-231	RUO	16 Rxn	All-in-one solution (library preparation, GENOVESA bioinformatic solution, genetic report generation) targeting the whole CDS of genes covered. Detects SNVs and InDels in 10 genes (e.g. <i>BRAF</i> , <i>EGFR</i> , <i>KRAS</i> , ...) and fusions in 3 genes (i.e. <i>ALK</i> , <i>RET</i> , <i>ROS1</i> ).

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