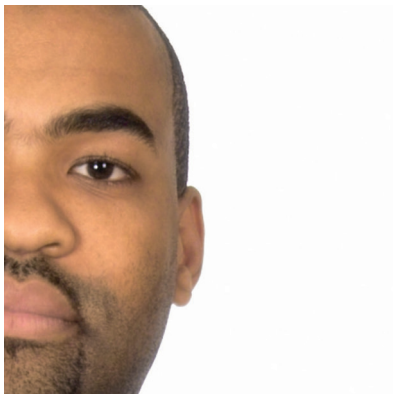
ViennaLab®






Product Catalog

Your partner for human molecular diagnostics

- Genetic Disorder
- Genetic Predisposition
- Cancer
- Pharmacogenetics
- Microbiology

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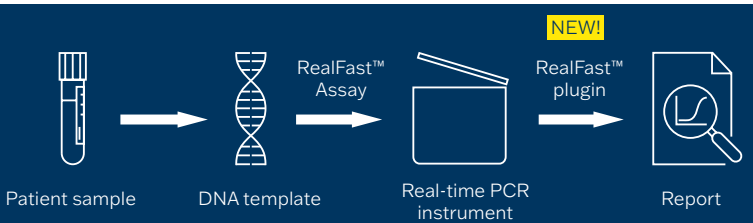
Sample Preparation Kits

Area	Product Name	REF	Reg. Status	Unit Size	Application
StripAssays® RealFast™ Assays	GEN^XTRACT™ 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
NEW!	Spinal Muscular Atrophy (SMA)	SMN1 RealFast™ Assay	7-700	prototype available	Detects *SMN1* c.840C which is used for SMA diagnostics
NEW!	Cystic Fibrosis (CF)	CF F508del RealFast™ Assay	7-260 / 7-263	CE/IVD	Detects the most common clinically relevant mutation (F508del) in the *CFTR* gene
	Carbamazepine Hypersensitivity	HLA-A3101 RealFast™ Assay	7-640 / 7-643	CE/IVD	Detects the human leukocyte antigen (HLA) *HLA-A*31:01* 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) *HLA-B*15:02* 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 *lactase (LCT)* 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 *fibrinogen beta-chain (FGB)* 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 *Factor V (F5)* gene
	CVD	FXII 46C>T RealFast™ Assay	7-240 / 7-243	CE/IVD	Identifies patients with the unfavorable TT genotype for *Factor XII (F12)*, 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 (F13A) among at-risk patients of hereditary thrombophilia
	CVD	MTHFR 677C>T RealFast™ Assay	7-160 / 7-163	CE/IVD	Detects common mutation in the *methylenetetrahydrofolate reductase (MTHFR)* 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 *methylenetetrahydrofolate reductase (MTHFR)* 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 *SERPINE1* gene, encoding plasminogen activator inhibitor-1 (PAI-1), and is associated with cardiovascular disease and pregnancy complications

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RealFast™ Assays

Category	Clinical Topic	Product Name	REF 100 / 32 Rxn	Reg. Status	Description
	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 *Factor II* 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 *CYP21A2* gene in patients with CAH. Recommended to be used in combination with CAH StripAssay® [REF 4-380]
	Genetic Predisposition	HLA-B27 RealFast™ Assay	7-620 / 7-623	IVDR CE_{0123}	Detects the human leukocyte antigen (HLA) *HLA-B*27* 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 *HFE* 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 *HFE* gene causing hereditary haemochromatosis (HH) type 1
	Pharmacogenetics	CYP2D6 RealFast™ CNV Assay	7-420 / ---	CE/IVD	Discriminates between deletions, duplications and normal copy number status of the *CYP2D6* 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) *HLA-B*57:01* allele, which is associated with hypersensitivity to the anti-HIV drug abacavir
	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
	Pharmacogenetics	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

Category	Clinical Topic	Product Name	REF 100 / 32 Rxn	Reg. Status	Description
NEW!	Severe Combined Immunodeficiency (SCID)	SCID-XLA mpx RealFast™ Assay	7-710	Assay in preparation	Allows for the simultaneous determination of the copy number of T-cell receptor excision circles (TRECs) and kappa-deleting recombination excision circles (KRECs)
NEW!	Sickle Cell Disease (SCD)	HbS-HbC mpx RealFast™ Assay	7-280	Assay in preparation	Allows for the simultaneous detection of c.20A>T (HbS) and c.19G>A (HbC) mutation in the β-globin (*HBB*) gene
	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 *Factor II* 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 *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 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

IVDR CE_{0123}: 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_{0123}.

CE/IVD: The light yellow marked products are already covered by the IVDR certificate - formal transition is currently in progress.

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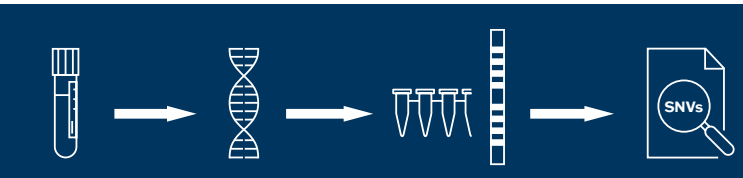
Workflow of StripAssays®



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 *BRAF* mutations in codons 600 and 601
	Cancer	EGFR XL StripAssay®	5-630	CE/IVD	20 tests	Ultra-sensitive detection of 30 *EGFR* mutations in exons 18/19/20/21
	Cancer	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
	Cancer	NRAS XL StripAssay®	5-620	CE/IVD	20 tests	Ultra-sensitive detection of 22 *NRAS* mutations in codons 12/13/59/60/61/146
	Carbohydrate Intolerance	Lactose Intolerance StripAssay®	4-300	CE/IVD	20 tests	Detection of two *lactase* gene polymorphisms -13910T>C and -22018A>G
	Carbohydrate Intolerance	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	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 *Factor V* Leiden and *Factor II*, encoding prothrombin (PTH), gene mutations
	CVD	FV-PTH-MTHFR StripAssay®	4-260	CE/IVD	20 tests	Detection of the *Factor V* Leiden, *Factor II*, encoding prothrombin (PTH), and *MTHFR* gene mutations
	Congenital Adrenal Hyperplasia (CAH)	CAH StripAssay®	4-380	IVDR CE_{0123}	20 tests	Testing for 11 most prevalent *CYP21A2* mutations. Recommended to be used in combination with CAH RealFast™ CNV Assay [REF 7-410]
	Cystic Fibrosis (CF)	CF StripAssay®	4-410	IVDR CE_{0123}	10 tests	Detection of 34 common *CFTR* mutations and the IVS8 variants 5T/7T/9T
	CF	CF StripAssay® GER	4-430	IVDR CE_{0123}	10 tests	Detection of 31 common *CFTR* mutations
	CF	CF StripAssay® TUR	4-420	IVDR CE_{0123}	10 tests	Detection of 24 common *CFTR* mutations and the IVS8 variants 5T/7T/9T
	CF	CF StripAssay® EXT	4-440	IVDR CE_{0123}	10 tests	Detection of 38 common *CFTR* mutations and the IVS8 variants 5T/7T/9T
	Familial Mediterranean Fever (FMF)	FMF StripAssay®	4-230	IVDR CE_{0123}	20 tests	Detection of 12 *MEFV* gene mutations
	FMF	FMF-SAA1 StripAssay®	4-390	IVDR CE_{0123}	20 tests	Detection of 12 *MEFV* gene mutations and *SAA1* genotypes 1.1, 1.3 and 1.5

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StripAssays®

Category	Clinical Topic	Product Name	REF	Reg. Status	Unit Size	Description
	Genetic Predisposition	HLA-B27 StripAssay®	4-320	CE/IVD	20 tests	Detection of all disease-relevant *HLA-B*27* 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	Haemochromatosis StripAssay® B	4-210	CE/IVD	20 tests	Detection of 3 *HFE* gene mutations: C282Y, H63D, S65C
	Pharmacogenetics	PGX-5FU XL StripAssay®	4-780	CE/IVD	20 tests	Detection of *DPYD* 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
	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-TPMT StripAssay®	4-740	CE/IVD	20 tests	Testing for *TPMT* variants *1, *2, *3A, *3B and *3C associated with response to thiopurine therapy
	Thalassemia	α-Globin StripAssay®	4-160	IVDR CE_{0123}	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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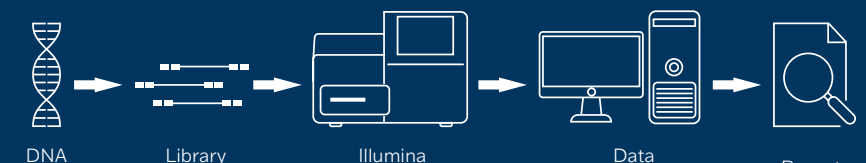
Workflow of NGS Assays



NGS Assays

Amplicon-based assays

Category	Clinical Topic	Product Name	REF	Reg. Status	Unit Size	Description
	Intestinal Microbiome	16S Microbiome + ITS NGS Assay [16 rxn]	9-131-16	RUO	16 Rxn	Targeted amplification of the bacterial V3-V4 variable regions of the 16S rRNA gene and the fungal ITS2 region. Includes bioinformatic analysis and report generation for species-level classification of the human gut microbiome.
	Intestinal Microbiome	16S Microbiome + ITS 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 + ITS 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 + ITS 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
	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.
	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. *BRCA1, BRCA2, CDH1,...*).
	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. *BRAF, EGFR, KRAS*, ...) and fusions in 3 genes (i.e. *ALK, RET, ROS1*).

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